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ABSTRACTS

Camera Movement during Telementoring and Laparoscopic Surgery: Challenges and Innovative Solutions

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Abstract

Advances in surgical telementoring systems open new grounds for enhancing the remote supervision and training of the surgeons. Verbal communication links between the mentor and mentee are being upgraded with graphical annotation, medical image and 3D model overlay capacities. While the advancing setups are regulated as verbal communication systems, the potential patient safety risks introduced by the extra features are rarely evaluated. In this paper surgical camera movement is researched in the context of the advanced telementoring systems. The analysis of potential computational techniques to eliminate its impact on the quality of remote supervision is presented. Focusing on the mobile platforms as common remote side telementoring hardware, an architecture for distributed telementoring system is proposed that eliminates the resources bottleneck for highly computationally intensive live video processing tasks.

Keywords:
telementoring, telestration, laparoscopic, endo-scopic, annotation, camera movement, tracking, distributed architecture

Introduction

Medical services, delivered via an interactive audio-video communication channel without direct physician-patient interaction (telemedicine) have become a common research area [1]. The advances in Information Communication Technologies (ICT) provide a solid basis for supporting a variety of telemedical tools. The forecasted shortage of surgical workforce is an important motivator for the rapid spread of the online practices. Given the constantly growing population, the increasing demand of surgical workload and the time required to train a surgeon, we are facing a rising demand of surgical personnel with a limited supply [2]. The ongoing development of new surgical techniques also requires tools for disseminating knowledge and providing a medium for the practical training of surgeons. Telementoring is an important tool to facilitate collaboration among surgeons and provide better quality of healthcare service to the patient [3].

The paper explores remote supervision of novice surgeons via video conferencing (VC), while the expert is not available onsite (telementoring) [1]. VC in combination with live free-hand annotations of the video from laparoscopic camera (telestration) offers valuable benefits concerning improved clinical and educational outcomes, increased speed of procedures and reduced relocation costs of the expert [4]. Telementoring is a platform for surgical education, where the remote expert acts as a personal tutor for the surgeon performing the operation. ICT provide a medium for widening the scope of education from a typical mentor-mentee interaction onsite to an n-way mentoring-education process (multiple mentors, additional participants following the session for interactive training) [5]. The overall benefits are not limited to the potentially improved patient outcomes, but they also contribute to increasing the availability of the experts and improving surgical education by using live content based on actual cases instead of imitations.

Telementoring for minimally invasive (laparoscopic) procedures has attracted major focus lately. One of the main characteristics of laparoscopic surgeries is the importance of the visual component: the progress of the procedure in the OR is presented on a monitor in front of the surgeon, sharing this information with a remote mentor without losing much is highly feasible.

Camera movement is an important factor, potentially leading to the decreased accuracy in the actions of the surgeon. Moreover, if the telestration feature is introduced, it might result in even more challenges. Graphical guidance (annotations) are produced over a particular location, for example, a mentor draws a line marking the location of the incision. In the case of camera movement, the line will shift to a different location and result in inaccurate advice, which may then lead to critical failures. After analyzing a set of laparoscopic videos (N = 10 laparoscopic sigmoidectomy procedures), we came to the conclusion that camera movement is an integral part of the procedure that cannot be omitted [6]. The movement can be minimized when dealing with less complicated cases or when the assisting surgeon is highly experienced. However, even with the simplest case and the most experienced surgeon, it is not possible to avoid camera movement while telestrating on a live video stream. Moreover, the moving camera is not the only factor resulting in the repositioning of annotations. The movement and poor color distinction of intra-abdominal soft tissues also contributes to the complexity of the situation (Figure 1).

The use of telestration while mentoring is the first step towards surgical navigation systems: verbal interaction between the mentor and mentee becomes guidance by graphical artifacts, produced over laparoscopic video. It introduces additional risks for the patient safety. The intended influence on the flow of the surgery makes such systems medical devices, with regulations for development and application [7]. However, in practice they are often treated as communication modules, denying the potential patient safety threats to avoid the additional complexity in complying with the regulations.

The paper looks into the specifics of surgical telementoring. Although the actual impact of telestration is unknown, the earlier mentioned assumptions call for solution anchoring the annotations to their initial locations. A review of the potential solutions is presented in later sections followed by an architecture for a distributed telementoring system able to handle resource intensive computations on relatively low-powered hardware.

Materials and Methods

To maintain constant position of annotations, they need to be anchored to continuously identifiable features in the video. Two potential approaches for solving the camera movement problem (CMP) were identified in the literature: anatomical landmark tracking and 3D modeling for laparoscopic surgery. Additional method to avoid the problem - combination of laparoscopic video and still images for telestration was presented. A systematic literature search to support the approaches was performed in the PubMed, the Association of Computing Machinery (ACM) and the Institute of Electrical and Electronics Engineers (IEEE) online research databases using a predefined set of keywords (vessel tracking, vessel identification, vessel detection, tissue tracking, track tissue deformations, 3d laparoscopic, 3d mentoring, 3d laparoscopic models) on the 22nd of November, 2014. Publication period between 01/01/2000 and 22/11/2014 was covered. Eight papers were included in the full text analysis.

The results formed a sufficient body of literature to support the initial claims. Challenges to adopt the techniques for the use on mobile devices were reported. To identify the feasible methods for solving the CMP in a mobile medium, guidelines to overcome the challenges were defined and summarized in a proposal for a distributed telementoring system architecture.

Results: Can Computational Techniques Solve the CMP?

In the previous section we mentioned the external factors (level of complexity, experience of a surgeon) that can improve the accuracy of mentoring advices presented in the form of annotations. However, the camera movement problem remains. Therefore, we suggest a set of computational solutions. To simplify the description, the area observed by the surgeon in the screen is defined and referred to as the operative field.

Combining Video and Still Images

The operative field is in continuous motion. Regardless the instable human-held camera, the surrounding environment (soft tissues) is also moving, either responding to the changing pressure inside the cavity or to the tools controlled by the surgeon (Figure 1). These factors prevent having stable landmarks to ensure the accurate positioning of telestrations. From the mentor's perspective, it may be difficult to provide an accurate graphical advice (annotation) under such conditions. To ensure the necessary accuracy, the best solution may be to pause for a moment, stabilize the movement of the internal tissues as much as possible (for example, keeping the pressure constant) and observe the scene. This representation makes it easier for the mentor to analyze the situation, as it becomes less ambiguous due to the minimized influence of changes. The stability of the operative field enables accurate telestration as the reference points maintain a constant position. If we look at this situation from another perspective, it is a shift from a video stream to a still image. Due to the minimized influence of the motion, the laparoscopic video, observed on a monitor by the local surgeon and the remote mentor, becomes a still image for the purpose of accurate telestration.

The schematic view of the proposed solution is depicted in Figure 1. The main idea is to add extra functionality to the video conferencing software that enables the video to be stopped at any moment, converts the frame to a still image that supports a discussion between the mentor and mentee (including the telestration capacity if it is necessary). After the discussion is completed by a corporate decision, the procedure, as well as the video-based mentoring session, is resumed until another critical moment, requiring a discussion to find the best solution, occurs.

Regardless the simplistic implementation, maintaining the accuracy in transition from the still image to the dynamic representation of the operative field may be challenging for the surgeon. An overlay of the scene used in the discussion over the actual video could offer an improvement, assuming no major changes occurred in the operating field after the screenshot was taken. However, to avoid the ambiguities between the representations used for mentoring and the surgery, employing the live video feed is discussed in later sections.

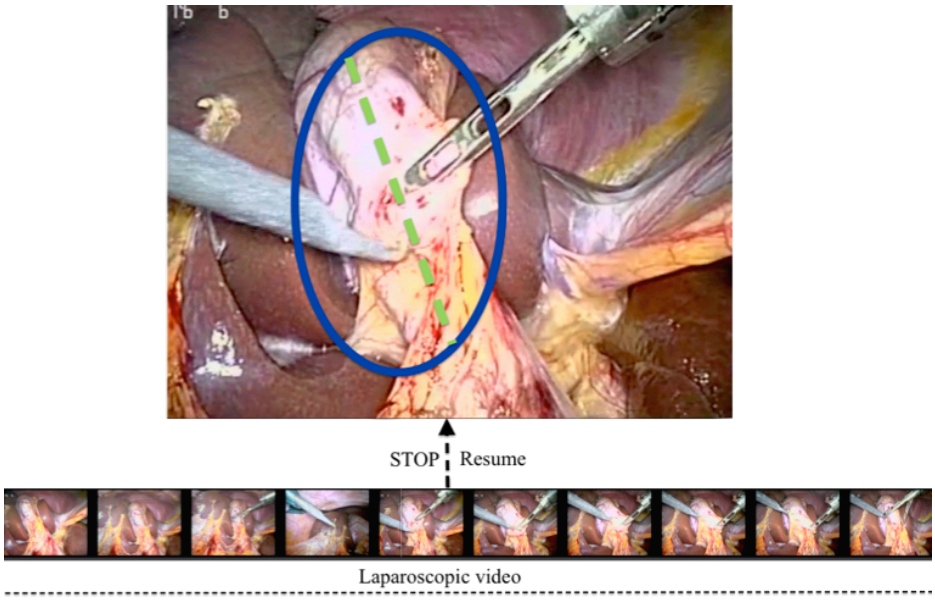

Figure 1- Combination of video and still images for telestration

Anatomical Landmark Tracking

To attach telestrations to anatomical landmarks, a set of stable reference points is required. The higher the number of references, the more reliable and robust the anchoring is. Research on blood vessel identification and tracking has revealed the growing potential of applications [8–10]. Computer vision techniques implement the idea of comparing the intensiveness of the pixels in the image with respect to the background. A blood vessel is identified when the result of the comparison exceeds a threshold value [9]. Although all the attempts have dealt with tracking blood vessels in still images, we propose extending this functionality to video content analysis. As the tracking of all full-length blood vessels (including forking and crossing) in the environment is not necessary in the telementoring case, the computations could be simplified and accelerated. The continuous detection of reference points attaches the annotations and stabilizes their position despite the camera movement. However, the approach is not representative due to the deformation of the soft tissues: the annotation may be stable, but reacting to the surface changes in the close vicinity is required (for example, inside the blue circle in Figure 1).

Tracking a high number of reference points on the surfaces appearing in the operative field extends the approach to the soft tissue deformation tacking. The core idea is to build an artificial representation of the deforming surfaces, observable in an operative field and represent their motion based on the tracked reference points. Attempts to use the captured reference points as anchors for annotations were also reported. Although the algorithms are computationally intensive, positive results in applying the techniques to process live video streams were presented [11,12].

The solution encounters a number of challenges to be dealt with. In some cases, the problem of identifying the landmarks becomes complicated due to limited visibility or reappearing artifacts (for instance, surgical tools). The homogenous structures in the operating field influence the detection process. For example, the more fat the tissue contains, the more complicated it is to find a blood vessel or another distinct object. Moreover, big camera movements call for reidentifying the same points, which were out of the operative field for a while. Fiducial markers could be of help as suggested by Mountney et al. to create a traceable landmark [13].

3D Models for Laparoscopic Surgery

Research dealing with the 3D modeling of the operative field encompasses the achievements of the tracking techniques. Su et al. presented an approach of combining Computed Tomography (CT) or magnetic resonance (MR) images and laparoscopic video. A markerless tracing system for real-time visualizations was investigated, enabling the modeling of the surfaces of the tissues in the operative field. The internal structure of a particular organ, based on CT or MR images, was designed and overlaid on a laparoscopic video, creating a three-dimensional representation of the operative field. The consolidation of two modalities (CT/MR images and live video) enables an augmented perception of the operative field. It allows internal and external observation before performing the incisions [14].

The described approach lays a fertile ground for solving the CMP. The CT/MR based model is a perfect artifact for attaching the annotations. Moreover, the internal model is aligned according to the reference points tracked on the surface of the tissue [14], making it responsive to the deformations.

The objective of this paper is to analyze the solutions to the CMP and adapt them for use in mobile environments. Although 3D modeling looks like the most promising approach, it has high demand for computational and representational power. The application of the discussed methods to mobile platforms would be feasible only after the complexity of computations is decreased or distributed among the components of the system. Therefore, we propose an architecture for a distributed telementoring system, capable of providing the required computational power.

A Distributed Telementoring System

The main drawback of tissue tracking and modeling approaches is the high demand for computational resources. Mobile deployment platforms increase this limitation and prevent straightforward development. However, the distribution of the computations among the components of the system looks promising. This section presents the architecture for a distributed telementoring system, aligned with the achievements of Zhou and Liu in developing an n-way visual content sharing

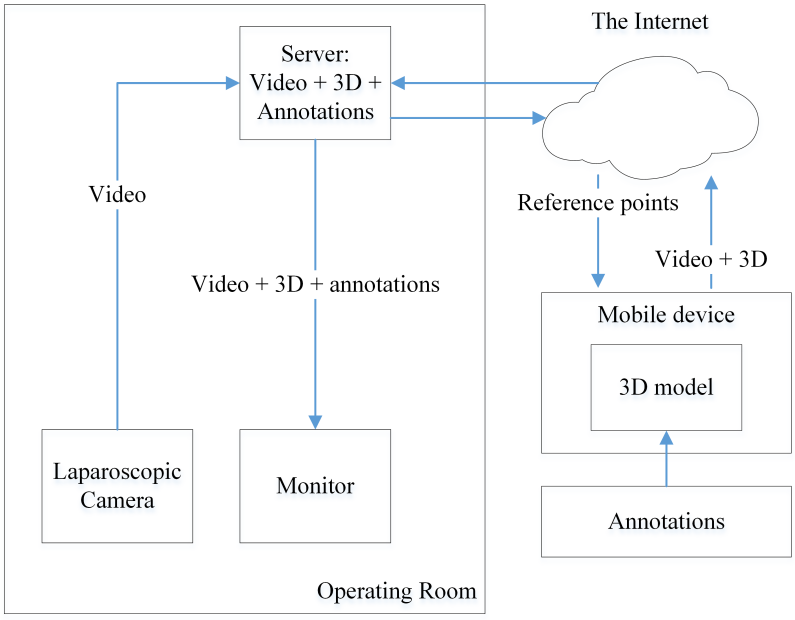

Figure 2- Architecture of a distributed telementoring system

and telestration technology, storing video streams and annotations separately and overlaying them when necessary [15]. The architectural design we present, models the approach discussed in section "3D Models for Laparoscopic Surgery". However, it could be easily adopted for the design and implementation using any of the approaches discussed earlier.

The system is divided into two parts (Figure 2): local (operating theatre) and remote (mentor). The local side is stationary and responsible for providing sufficient computational power for data processing. The remote side is mobile and acts as the representational medium to capture the reference points for annotations made by the mentor. The main procedures performed by the server on the stationary (local) side are:

1. Maintaining live audio-video conferencing between the operating theatre and the remote expert;
2. Overlaying 3D models of the tissue/organ on the laparoscopic video and aligning them according to the deforming surfaces observed in the laparoscopic video;
3. Recreating the annotations of the mentor received from the remote side in the form of reference points, combining the video, the 3D model and annotations;
4. Controlling the model on the mentor side, making it react to the tissue deformations.

The 3D model is developed before the procedure from medical imaging. It displays the internal anatomical structure and also functions as a coordinate system for telestration. The same model is used on both (local and remote) sides, to determine the accurate position of the annotations defined in reference points. Attaching annotations to the model eliminates the CMP, as the model maintains a constant position regardless of the instability of the operative field.

The main challenge is to accurately reflect the deformations of the operative field in the 3D model. It is a complex task requiring the computational resources delivered by the stationary platforms. As the system employs two instances of the 3D model, the mentor side is left with the representation of the results of the model deformation computed by the server side. Bandwidth consumption is minimized by only transferring the deformations of the model between the nodes and performing rendering locally.

Comparison to the alternative architectures

To highlight the advantages of the proposed architecture a comparison to other architectural approaches is provided bellow.

3D model on the client side

Utilizing a 3D model at the origin of annotations (the remote mentor side) seems like a straightforward solution anchoring the telestrations right after they were produced. Translation from 3D to 2D annotations would generate transferable artifacts for displaying them for the mentee in the OR. The same 2D representation can be displayed for the mentor, making sure both sides of the link follow exactly the same scene. Despite the technically feasible anchoring of telestrations, making the 3D model react to the soft tissue deformations seem to be too computationally intensive for the mobile device of the mentor. A non-responsive model in this case is as useful as a static grid placed over the dynamic video.

3D model on the server side

Placing the model on the server side provides the required computational and bandwidth resources. However, the annotations originate on the mentor side in 2D form, transforming them into 3D on the OR may not accurately communicate the message of the mentor. Moreover, mentor and mentee sides would be using different representations of the operative field, which may increase the ambiguities between the peers and result in patient safety threats.

3D model on both ends

Placing the 3D models on both ends was suggested in the previous section and visualized in Figure 2. Regardless a more complex distributed architecture, the proposal ensures the same representation of the operative field on both ends of the link and anchors the annotations eliminating their repositioning. Distribution of the computationally intensive tasks provides sufficient resources for enhancing telementoring experiences for the mobile users.

Discussion

The discussed advances of the communication system within the OR bring telementoring closer to the surgical navigation systems. Such solutions are common in the procedures, requiring extremely high precision, however often performed in less dynamic tissues (for instance, brain surgery). Mapping the surgical tools into the 3D model of the internal body structure enables the augmented perception and coordination of the moves based on the artifacts invisible for the naked eye. The overall representation (a responsive 3D model and tracked tools) provides a machine-readable documentation of the procedure. This vision not only introduces additional safety assurance procedures by adding the ability to warn the performing surgeon about the potential errors (cut of the blood vessel hiding inside the tissue), it also questions the utility of the human mentor.

Is it likely that an artificial intelligence system, trained on a high number of surgery cases would be able to provide a satisfactory advice for the surgeon? Does it make the machine "a trustworthy partner" in providing suggestions and making decisions, while the experience of the performing surgeon is exploited as a tool to complete physical actions?

Not only does it sound scary, but it also raises numerous ethical considerations. However, we cannot deny the efficiency of the artificial intelligence techniques in completing highly specific tasks, cost reduction and voiding of errors caused by the human factor. Regardless the futuristic scenario, the required technologies to support the workflow are available. The discussed ideas give an absolutely different meaning to telementoring, together with numerous computational challenges to cope with.

Conclusions

The paper looked into the attempts to integrate the computational image processing techniques into surgical telementoring to compensate for the instability of the laparoscopic camera. To the current date, the CMP has not been in a focus of the researchers, however, the importance of a reliable solution is fundamental in developing a comprehensive telementoring system, meeting the international regulatory requirements.

The reviewed publications point in one direction – 3D modeling of the operative field offers the biggest enhancements to telementoring, nevertheless it is associated with numerous challenges. Image guidance capabilities promise exceeding the benefits of onsite mentoring, making telementoring a preferred approach [16]. Such changes could have ground shaking consequences in the stagnated adoption of telementoring in surgery. The review and the proposed architecture emphasize the complexity of the solution to CMP and suggest the direction for further research and development.

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Near-Real Time Monitoring of Reports regarding Patient Safety Incidents in Hospitals using a Web-based Interface

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Abstract

Near-real time monitoring of patient safety incident (PSI) reports can be facilitated with automatic detection methods, which can improve timeliness of detection. Reduced PSI identification time would provide quicker feedback on PSI data to healthcare professionals and allow them to effectively adjust safety procedures at hospitals. A visualization of the PSI data can provide the user with feedback together with a PSI data exploration possibilities and analysis of the PSI patterns. Therefore, a web-based interface (wUI) was developed using web-development tools and provided PSI data from Australian healthcare system as a proof of concept. Usability theory was applied during design to facilitate a user-friendly and intuitive feedback tool. The implemented wUI was validated and the results showed that the systems requirements were fulfilled well, with possible optimization features.

Keywords:
patient safety, incident reporting, web interface, incident statistical output.

Introduction

Millions of patients worldwide have experienced deaths or disabling injuries due to errors in the healthcare system [1]. The World Health Organization (WHO) estimates that adverse events accounts annually for 850.000 PSI in the United Kingdom Department of Health. In the developed world around 10 % of all hospital admissions involve a patient incident of adverse character with one out of three incidents leading to patient death or disability [1, 2]. Medical errors are between 5th to 8th leading causes of death in the U.S. and the annual costs of patient safety incident (PSI) are approximate $38 billion [3–5]. Therefore, to overcome errors, healthcare systems need to learn from errors, with PSI reporting systems as a key tool to improve patient safety [6–8]. PSI systems have the potential to share and highlight trends and patterns in incident data and to detect potential emergency problems in near-real time [9, 10]. The fundamental challenge is to convert the large data set into comprehensible information, which could enhance response to patient safety problems as they emerge [9].

Background

When an incident occurs in a hospital, it is necessary to prevent reoccurrence. To benefit from the patient safety incident, a description of the event is required to an electronic incident reporting system. Therefore, a PSI report includes both a documented description and categorization of the incident event [11]. Since the structure of PSI reports varies between hospitals, the information from PSI reports needs to be extracted and classified into different types of incidents and levels of severity using Severity Assessment Code (SAC) [12, 13]. There are 20 different incident types in the incident management system used in the New South Wales public hospital system, for example falls, clinical management, medication/IV fluid, documentation etc. [14]. The SAC levels describe the severity of the incident from high risk (SAC 1) to low risk (SAC 4) and are based upon two categories: likelihood and consequence [15].

Voluntary reporting of PSI is a valuable source for studying and analyzing patterns of adverse events and near misses to prevent PSI reoccurrence and improve safety [16]. Therefore, the PSI reports are important means for identification of errors in the healthcare system. However, the reporting system has limitations and critical areas [17]. Utility and data collection systems, used for evaluation of PSI are negatively affected by an inconsistency in language, incompleteness and lack of accuracy in the reported data [13, 16]. Furthermore, several problems associated with incident reporting are e.g. participation bias, problems with form completion or with correct classification, but also lack of reporting the incident [17, 18].

Over 40% consultants (specialist doctors) and registrars have never submitted an incident report. Around 25% of hospital staff did not know how to access an incident report form. Only small percentages of doctors actually completed the incident report [18]. The possible reasons for lack of reporting include time pressure, unfamiliarity to the process, fear of blame, an approach that it is unnecessary to report, possibility of reports ending up in a “dark hole” and resource constraints. Additionally, workplace discrimination, fear of punitive action and legal ramification because of cultural issues may contribute to the lack of reporting incidents. However, the main problems related to incident reporting are probably the conception, that only bad doctors make mistakes, and a lack of clarification about what should be reported [18, 19]. Moreover, primary barriers for not reporting PSI might be issues related to an inconsistent language due to variety of the used terms and the lack of feedback [13, 16, 18]. An existing lack of feedback from the PSI reports is the main reason for lack of reporting [19–21]. It is reported that 2/3 of the respondents named the lack of feedback as the main obstacle for not reporting PSIs. However, by using newsletters or other feedback methods, the rate of reporting increased [18–20]. Therefore, mechanisms and forms of an effective feedback from PSI reporting were researched by Benn et al. [19]. The results revealed, that a feedback incorporating multiple modes of both information and action processes, would be the most beneficial for patient safety and risk management systems. Furthermore, the feedback must include corrective safety actions and be closed in order to ensure, that

the vulnerabilities identified from reporting, analysis and investigation are timely and correctly addressed in the environment at the healthcare [19]. In a study by Ratwani et al., a system level dashboard was developed to provide users with a visualization tool for the PSI to improve accessibility and awareness of PSI data [9]. The dashboards reduced burden of analyzing data and encouraged the data exploration [9].

Therefore, to improve the means for giving feedback, a web-based interface (wUI) was developed and described within this study. The wUI builds upon previous studies, which have demonstrated feasibility of statistical text classification to identify PSI types and severity [10, 22, 23].

Methods

Understanding of the IT systems and procedures in the Australian healthcare system was considered as important for the system development process. Therefore, an interview was performed with the Patient Safety and Quality Unit of a teaching hospital attached to the University, in order to gain practical knowledge about healthcare providers, reporting procedures and a familiarization with one of the Australian PSI reporting systems. The outcome of the interview together with guidance related to PSI research from the Centre for Health Informatics helped the researchers to perceive the structure of the PSI reports, system and data presentation.

System Description

The developed web-based user interface (wUI) provides assistance with PSI monitoring for the healthcare professionals and researchers (Figure 1). The obtained information from wUI can ensure the quality of the patient safety in the healthcare system and improve means of the given feedback to the reporting healthcare professionals.

The feedback provided by the wUI gives a quick insight and an overview of the reported PSI data. To aid monitoring and trend analysis of PSI data, a near real-time tracking of the PSI data can be added to the wUI.

The wUI can be accessed through the Internet and has no specific system requirements. Therefore, healthcare professionals can easily and quickly use it at any time and on any devices. To achieve a positive user experience, design elements are implemented with respect to usability theory and similarity to the existing PSI reporting systems in the Australian healthcare system. The usability describes the connection between the user's needs and the behaviour, and not the design choices, e.g. in the user interface (UI) [24]. Usability requirements in relation to healthcare system include: matching of real world and system, providing informative feedback to the user, clearly defined user control, error prevention, keeping consistency, use of minimalistic and intuitive design, easy to understand error messages and system can be used by both experienced and inexperienced users [25-27]. Functionality of the wUI includes monitoring, exploration and visualization of the selected PSI data. The possibility of selecting a specific PSI data, gives the user an opportunity to obtain a visualization and information about specific PSI prevalence and trends based on the chosen PSI incident types, SAC levels and time range. An example of the visualized PSI data in Incident Data UI is shown in Figure 1. The user has a chance to zoom in on the plotted PSI results, see highlights of the PSI data and filter the results from the graph, as shown in Figures 2-4. Additionally, the wUI allows users to learn about patient safety quality improvement, research programs and provides contact information to the research center. Due to the privacy restrictions and data safety requirements, the access in the wUI to some of the elements is limited to the registered users.

System Development

A sample of processed PSI data, i.e. output of statistical text classifiers was used to develop and validate the wUI [10]. The received PSI data was imported to the local MySQL database (MAMP 3.0.6 with phpMyAdmin 4.4.1) to allow manipulations and extraction of the PSI data using SQL syntax. To program connections and communication with the server and MySQL database, a Hypertext Preprocessor (PHP) was used and was also responsible for collecting the PSI data and controlling the login session.

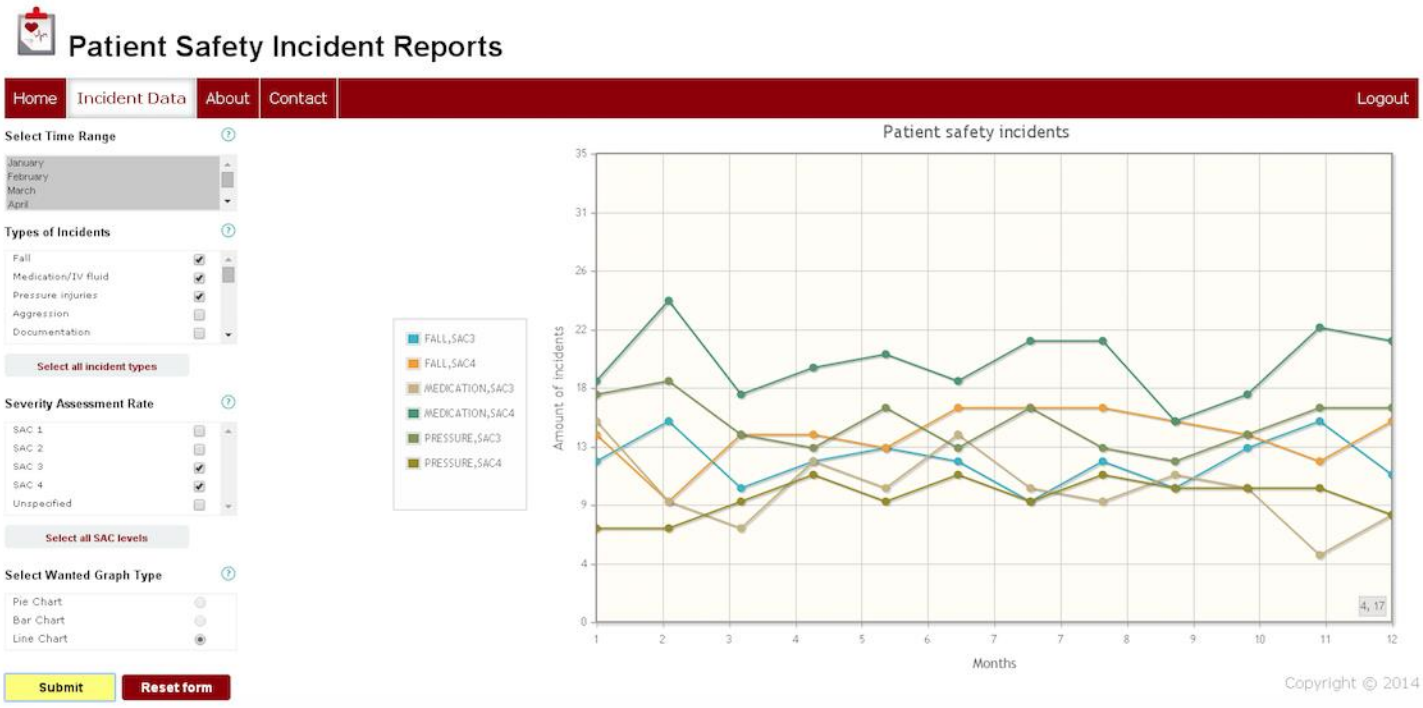

Figure 1 - Incident Data UI with the visualized PSI data

Figure 2 - Zoom

The development process of the wUI consisted of iterations and constant adjustments. Elements of both the Unified Modeling Language (UML) and Unified Process (UP) were used to document the development process of the system. To represent functionality of the wUI, functional and non-functional system requirements were specified. The requirements were further used for the analysis and design phase, where the architecture for the wUI was developed. Proposed design of the wUI was adapted to fulfill the usability requirements to achieve a user-friendly and intuitive layout. The visual aspects of the wUI were based on the gathered knowledge from the interview with the Patient Safety and Quality Unit in an Australia private hospital and guidance from the Centre for Health Informatics.

The wUI implementation of the identified elements was achieved using several web-development tools. The implemented wUI consisted of eight UIs: Home, Incident Data, three About, Contact, Login and Forgotten Password. Each individual UI consisted of architectural structure elements, which were accessed and manipulated with use of a HyperText Markup Language (HTML). The Cascading Style Sheets (CSS) was used to describe and give a consistent graphic design over all of the UIs. Two CSS files were created, where the different HTML elements' appearance and content were defined and described. User interactions with the wUI and a functionality of HTML elements were coded and defined in JavaScript (JS). Since the wUI should work on

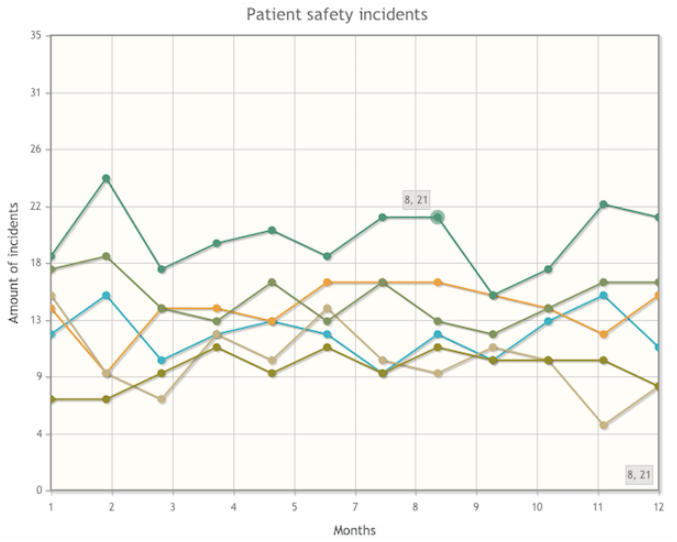

Figure 3 - Line marker

Figure 4 - Selected/deselected PSI data

different web-browsers, a JS library called jQuery was mainly used for programming of wUI functionality. The jQuery allowed to make an Asynchronous JavaScript and XML (AJAX) request, which processed the selected PSI data from the form in the Incident Data UI and its visualization in the UI by updating only the graph and without reloading the whole UI. The PSI data was stored and exchanged a JavaScript Object Notation (JSON), and was further processed in jQuery for visualization of the PSI data using a jQuery plugin called jqPlot.

During the implementation process of the wUI, iterative tests identified and allow correction of possible errors early in the implementation process. Performance tests were performed on the developed wUI according to a test protocol, to identify missing functionality and verify error prevention methods.

System Validation

Validation of the system is completed by verify the proposed solution using a usability and design validation, that was performed with three researchers from the Australian Institute of Health Innovation. The participants had wide knowledge and different perspectives of healthcare. Age of the participants varied to validate utilization of the wUI by users with different IT skills.

The participants were asked to perform tasks specified in the validation protocol, which were related to the use of wUI. Then the participants were interviewed by the researchers regarding evaluation of functionality, design, intuitiveness and user friendliness of the wUI with focus on visualization of the PSI data. The evaluation was conducted based on questions aimed to determine if implemented design choices fulfilled the specified requirements for the wUI. After the evaluation, possible improvements of the wUI were investigated.

The presented validation results included both positive and negative feedback about the implemented features and design choices. Missing features, which implementation would benefit the wUI, were collected as a list of possible optimization of the wUI ideas. Some of the validation results are presented in Table 1.

Table 1 - System validation results of the wUI.

Positive Feedback	Negative Feedback	Missing Features
Clear and simple design Easy navigation Understandable visualization Plot provides correct information PSI data given in perspective Helpful highlighter	Visually difficult to read text Lack of plot instructions Hard plot interpretation with lots PSI data Disturbing/not visible pop-ups	Print/Export button Selection of hospital/depart-ment/ward Sum of all SAC levels for plot Hoover bubbles instead of pop-ups Add bar, pie and stack graph types Assign a color to an incident

Discussion

The wUI was chosen to be a web-based interface, which can be used at several healthcare organizations. The chosen form for the interface was based on a need for a system that can be easily accessed by the user, as documented by Ratwani et al. [9]. The system developed as a web-based interface has no specific technical requirements, such as hardware, software and installation programs, which are needed for the wUI to work correctly. Therefore, the system can be used as an aid system at healthcare centers without influencing existing IT structures and systems. Additionally, maintenance of the system will be easier, since the user will not need to speculate about checking and installing possible updates for the system. Instead, the wUI programmers will apply updates, improvements or patches for the wUI and the users will automatically always use the newest version of the wUI.

Due to system implementation as a website and connecting it to the database, the near-real time monitoring and updating of the database is possible for all of the users. Behind the presentation layer, implementation of an algorithm, which would automatically process data, would improve incident identification and provide a quick update on the identified incident patterns. Moreover, statistical tools would be needed to monitor the database and indicate to the user, when new or alarming results are becoming available. The developed version however, does not have the algorithm implemented and only functions as a proof of concept on the extracted PSI data. Different types of automatic classifiers can be used for wUI. It does not matter, which classifier type processes the PSI data, because visualization method of the PSI data is still the same in the wUI. An example of an automatic classifier was described in a study by Ong et al., where a feasibility of automatic classifiers to monitor large amounts of incident reports and detection of extreme-risk events was researched [23]. Furthermore, such types of classifiers allow discovering new knowledge about the reported incidents from the large-scale descriptive incident text.

The validation of the implemented wUI was performed to investigate how well the usability principles were implemented. It was important that the final system would be user-friendly and intuitive, because the chances of a successful implementation of wUI in the healthcare would increase. The familiar design will help the user to avoid confusion and fear of how to use the system, since the adaptation process would be easier. Moreover, the system's functionality should be broad and give the user a possibility of the PSI data exploration. The researchers from validation group had different expertise field, which allowed gathering opinions about the wUI from three perspectives. Their comments were useful for future improvements of the system. However, the validation points are given from the researchers' point of view, which may differ from the healthcare professionals' and their expectations. Due to time constraints, which did not permit an opportunity to obtain ethical approval, the validation of the wUI at a healthcare center was not performed. However, if the ethical approval for the wUI validation at a healthcare center could be obtained, it would be feasible to conduct a validation of the wUI at the healthcare center.

The validation results proved that from the graphic design angle, the wUI was designed in a clear and simple way. There are thus documented navigational problems, especially at Incident Data UI, where two out of three participants commented that they lacked information about how to plot the PSI data, which selections are needed and how to select the PSI data. Therefore, help information for the user about the use and limitations of the system would be work in future.

Some of the visualization functionality was found missing. Mostly the requested functionality was concerning specific or missing graph types. Another comment regarding an additional functionality was to implement print and/or send the plot options. Those features would be helpful, if the user would like to share the data with others, but can cause security and privacy concerns, if the data would be send to someone without access to the wUI. It is possible to implement these functions, however some limitations should be added to prevent unauthorized access and compromising the confidentiality of the PSI data.
Several comments regarding readability of the data were provided and all of the persons in the validation group commented on the lack of larger variety of colors for the plot. A suggestion of attaching a specific color to an individual incident was made. To make the plot even more readable, a possibility to see a sum of SAC levels for the individual incident type would be beneficial. By applying those three comments, the visualization and readability of the PSI data would increase, since it would be more intuitive for the user.
The provided PSI data included number of incidents from different departments at the hospital. To enrich the information and provide the user with additional option for more specific PSI data search, the possibility of choosing hospitals, wards or departments was suggested. It could be beneficial for a user, which would like to obtain a very specific PSI data. However, it would reduce the anonymity of the reporting healthcare staff, since one would have access to a very detailed data, which could be misused by the user. A small overview of the PSI data would not reflect the major problem with the PSI, since the user would only receive a feedback on a small area of data and consider some of the incidents as not significant and by looking at the broader scale would prove to be crucial. Therefore, implementation of the wUI on the broader - regional, national, international - scale would provide more benefits and a better overview of the PSI problem. The user would then have a chance to explore broader scale of data and the PSI data would remain anonymous.

Conclusion

The wUI was developed as a proof of concept to provide healthcare professionals with feedback about PSI reports and visualization of patterns. By visualizing the PSI data, data exploration is possible highlighting trends and patterns in the PSI data. The patterns can be used to bring focus on safety issues in healthcare organizations. System usability was evaluated and was proved to be well carried out in the wUI design choices. The validation helped with identification of the missing functionality, which is advised to be implemented in the wUI. After implementation of the missing functionality, the developed wUI has a possibility of being implemented in a regional, national and international scale to detect potential patient safety and emergency problems. Moreover, the connection to the database of the wUI results potentially in establishing a near-real time monitoring of the PSI data, which could provide the healthcare professionals with almost immediate feedback on the PSI.

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Acceptance of a targeted exergame program by elderly

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Abstract

In a project a targeted exergame for elderly was developed and tested. The goal was to find out how our old elderly users received a combined exergame program, whether they felt that this was real exercise for them, and what type of exercises they preferred. The three-year project applied user centred design, and the exergame consists of seven mini-games. First the elderly users played them all, one mini-game at a time. Five of the mini-games were sequenced into a 4.5 minutes long exercise program, and ten elderly users played through the program and then went through a semi-structured interview about how they perceived the program. All seven mini-games were then used in the final twelve minutes long exercise program, and seven elderly users played through the program and then participated in group discussions about how they perceived the program. The users reacted positively to the combined exergame program. This paper describes the games and trials.

Keywords:
exergame, game theory, experimental game, video games, health services for the aged, exercise movement techniques, frail elderly, pilot study, user centred design, Microsoft Kinect camera

Introduction

While the population is getting older, the resources for care will be even more limited in the future than they are today. A continuous increase in the number of elderly aged 80 years old or more is expected [1]. The most common reason for loss of functional capabilities among elderly is inactivity. Physical activity can effectively delay this process [2, 3]. There is a need for solutions were elderly can manage themselves and stay fit as long as possible. Exergames are a promising solution that still faces a lot of open research questions before it can be applied properly in the target group of the oldest elderly (hereafter called elderly).

Exergames can be defined as "digital gaming systems with an interface that requires physical exertion to play" [4]. Exergames both record and instruct the users in how to exercise correctly and motivate the users by giving feedback on their achievements.

Exergames are already used for elderly by several institutions, but most commercial games are not suitable for elderly, and also they do not always give the exercises that are needed to help the players keep balance, strength and flexibility [5, 8].

Studies show that elderly enjoy playing commercial exergames [6], and that gameplay can be good for balance and rehabilitation [6, 7]. The Bleakley review [6] concludes that there is "preliminary evidence that games is a safe and effective medium to promote physical activity in elderly, and may be associated with a range of physical and cognitive benefits", and "there was no evidence of an optimal exercise dose in terms of exercise type, duration, or intensity". The Larson review [4] concludes that all the included studies have low to medium low methodological quality. Six out of the seven studies had positive results. Furthermore, there are no indications that exergames are worse than other training programs.

Trial goal

The main goal of the trials was to learn about the elderly's reaction to a targeted exercise program, from start to end. The combined exergame program consists of a set of different mini-games that are sequenced or queued. This included learning whether they felt that this was real exercise for them, what type of exercises they preferred, and whether the quick shifting of mini-games was overwhelming.

The sub goals were to find out whether the elderly users noticed information between the mini-games and the final score page and to get tips and ideas for further developments.

The exergame

The exergame has seven mini-games for balance, leg strength and flexibility and uses a Kinect camera as motion sensor. The mini-games have four difficulty levels, catering for different abilities. Speed, outreach and length can be changed. Many of the mini-games can also be played while seated. The physical movements required in order to play are all chosen by physio-therapists and are amongst those that are valuable in order to prevent falls in an elderly population.

In the three picking mini-games (ApplePicking, ChickenPicking, StarPicking), the player picks falling apples/chicken/stars with either the left or the right hand. In the easy level the items fall slowly and just right above the player's head while the player sits or stands in one position holding on to a chair. In higher levels the items fall more quickly and the player must walk sideways in order to reach them, and both speed and dis-tance vary between the three next levels. The items are of dif-ferent colours, and they are supposed to be dropped into a bar-rel that corresponds to this colour, one barrel on the left side and the other on the right side. The players are supposed to pick the items as high up in the air as they can. When an item is picked, the player may have to move it to the other hand by clapping the hands together to be able to put in the correct

barrel. For instance the red apples must be put in the red barrel and the yellow in the yellow barrel. Figure 1 show the game when a star is picked in the star picking mini-game.

Figure 1- Star picking mini-game detail.

In the PickVegetablesLeg mini-game the player stands and holds on to a chair, and slowly stretches the right leg sideways first to one side, as far as they can, and slowly back to the middle again. After a while the user is asked to switch leg. Each repetition grows a potato, a carrot or an onion. The higher the level, the further out the player must stretch the leg, and at higher levels a rabbit pops up at random intervals and disturbs the player. Figure 2 shows the game when the leg is in its outermost position in the PickVegetablesLeg mini-game. A help window in the bottom right corner shows the movements of the players to help them see how they are performing.

Figure 2- PickVegetablesLeg mini-game detail.

In the tip-toe (GrowFlowersHeel) mini-game the player stands and holds on to a chair, and slowly stretches up to stand on the tip-toes, as far as they can, and then slowly gets the heels on the floor again. This game can also be played seated in the easiest level, where the players lift themselves up of the chair with their arms, and then slowly get down into the seat again. Each repetition grows a different kind of flower. The higher the level, the further up the player must stretch, and also at higher levels a worm crawls across the field at random intervals disturbing the player.

In the knee-bend (FillWaterSquat) mini-game the player stands and holds on to a chair, and slowly bends the knees (squat), as far down as he/she can (or as the player in the right corner indicates), and then slowly rises up to a standing position again. It can also be played seated in the easy level, where the player sits in a chair and then stands up, and then sits again. Each repetition fills some more water into a glass. The higher the level, the further down the player must bend, also at higher levels cows pop up at random and disturbs the player. Figure 3 shows a screen from the FillWaterSquat mini-game to the right.

In the CutCornArms mini-game the players stand and imagine that they hold a scythe in their arms, and make movements like they are cutting the corn with the scythe – moving the upper body while the hips are still. This is an exercise for flexibility. This mini-game can also be played seated in the easiest level, where the player sits in a chair and turns his/her upper body from left to right. Each repetition cuts a row of corn in the

corn field. The higher the level, the further the player must turn, also at higher levels rabbits pop up at random and the player can only cut when there are no rabbits in the screen.

Figure 3 shows a screen from the CutCornArms mini-game to the left.

Figure 3- Details from the CutCornArms and the FillWaterSquat mini-games.

Methods

User centred design was used throughout the project, with a mixed method approach, and the methods depend on the phase of the project. Since this was part of a user centred design ap-proach with a small user group, the methods are qualitative. The tests described in this article were performed towards the end of the project, and was part of the evaluation phase.

The same test was done twice, the goal of the second test was to see if it gave the same results as the first time, now that the users had tried it once before and were more familiar with the concept.

The exercise program consists of seven mini-games all with exercises especially targeting those at risk of falling. The duration of each mini-game was initially set to two minutes by the project physiotherapist; this gives fifteen minutes playing time. We played with shorter playing time.

The first test with a 4.5 minutes program consisted of the following mini-games: PickVegetablesLeg, ApplePicking, GrowFlowersHeel, FillWaterSquat, and StarPicking. Each mini-game had duration of 50 seconds.

The second test with a twelve minutes program consisted of the following mini-games: PickVegetablesLeg, ApplePicking, GrowFlowersHeel, ChickenPicking, CutCornArms, FillWaterSquat, and StarPicking. All picking mini-games were 120 seconds, the others 50 seconds, except GrowFlowersHeel where the player use one leg at a time has 70 seconds which give 35 seconds per leg.

The user group

A regular elderly user group has been meeting every second Friday for almost three years to participate in user centred design in the project. They played commercial Kinect xbox360 exergames, with their activator present when there were no project tasks. When there have been tasks in the project to perform, they have done that instead. They are not very fit and many of them come to the gathering by taxi. Some of the users have been replaced for several reasons during the almost three years the project has been running. Figure 4 and figure 5 show the testing environment.

Figure 4 - One user is playing the exergame, notice the chair placed nearby.

In the first test there were ten elderly between 66 and 90 years old, with an average age of 81.7 years, three were men, and seven were women. In this user group six out of ten have par-ticipated from the start of the project.

In the second test the same users as in the first test participated, but with three persons less. The second test thus had seven elderly users between 73 and 90 years old, where two were men, and five were women. In this user group four out of sev-en have participated from the start of the project.

Figure 5 - Testing environment.

Data gathering

For the data gathering observations by the authors, semi-structured interviews and group discussion were used. All players were in the same large room, and the interviews were performed in the back of the room by one author while the rest of the participants were playing with the other author organiz-ing the gameplay.

Design of the trial

One big room was available for the project. In the front of the room there was a big TV screen used for the exergaming, and the participants were seated in a semicircle in front of the screen. One and one participant would play while the rest were watching, as shown in figure 5. The TV, PC and the Kinect camera were set up. Also a white tape was used to mark where to stand on the floor when playing. A chair was placed beside the standing zone so the player had something to hold on to while playing.

When it was a player's turn to play he/she would stand in front of the tape on the floor, and the exergame started automatically without any menu navigation, or use of buttons.

The trial was run as two physical tests, with a preparation phase before the tests were performed.

Early in the project the users played commercial Kinect exergames, so they were already used to gameplay. The commercial exergames do not have a tailored exercise program; they play one type of game at a time. Then the participants were introduced to the project developed exergame by presenting one mini-game at a time. All users have tried each mini-game. One or two mini-games have been presented per gathering. The overall game concept, namely farming, was explained and the farming tasks and the scenes between the mini-games were presented and explained. The last pages with a summary of the game results were also explained.
The users learnt how to play and gave comments on the playability.
This initial training revealed that running the full exercise program of fifteen minutes would be too much for the user group, since the test was to be run with an audience, the players do not pause or rest at all when they have an audience, and it was also too long for those waiting for turn.

For the first test a modified exercise program on 4.5 minutes with five different mini-games was made, in addition the duration of each mini-game was set to 50 seconds. The difficulty or intensity was also modified for some of the mini-games. During the first test the two authors were present, one controlled the gameplay and instructed the players, the other interviewed one by one in the back of the room. After all had played, there was a short group discussion while all the participants were seated.

To prepare for the second test with the full exercise program, the test notes regarding mini-game duration and difficulty while playing was examined. It was decided that two minutes was a suitable playing time for three of the mini-games but that for the last four mini-games the playing time was set to from 50 to 70 seconds depending on how strenuous they are. The difficulty or intensity was again modified slightly for some of the mini-games.

In the second test, the full exercise program with all seven mini-games in sequence and a playing length of twelve minutes was used. The elderly were also told to try to play without getting any help from the researchers or the audience. In the second test two and two players played one exercise program, the first player played the first three mini-games, while the second played the four last mini-games. After a short rest the user who played the first part played the last part. Af-ter all the participants had played through the whole exercise

program, there was a group discussion, using the same questions as in the interview in the first test.

Both authors have gone through the observation notes of the tests and the questionnaires from the structured interviews, and checked that results are correctly presented in this article.

Results

The first test

The first test was performed with the 4.5 minutes game consisting of five mini-games.

Exercise program

In the interview all ten of the elderly users said they liked to have an exercise game program made up of different mini-games, three very much and seven much. See figure 6. Those who commented on this said it was good to have some variation as opposed to play one and one game.

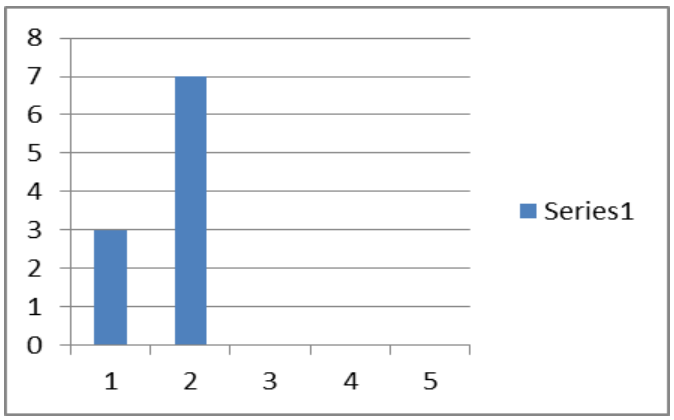

Figure 6 - How did you like an exergame with many exercises? 1–very good, 5-very bad.

It was a short discussion, about the game and whether it was fun, where all replied yes. One theme was whether the tip-toe mini-game should have a shorter duration, here also all were positive. When asked if they wanted to continue with the com-bined exergame program at the next gathering, all replied yes.

Also the observations confirm that they enjoyed to play and nobody stopped before the exercise program was over (it was repeated several times that they could stop if they wanted).

Impression of exercise

In the semi-structured interview we asked whether they feel that the exergames were good exercise, with the alternatives very good, a bit good, and no. See figure 7. One said no, three said a bit good and six very good. When asked why we had replies like “it was good for the calves”, “good for balance”, ”good for movement”, “moved the joints”, “bend, and balance”. One said it could have been longer. Most important: all are very positive, and four said that the combination was good.

We also wanted to know whether they found some physical movements in the game especially important for their health. Five replied that the combination was good, one answered the tip-toe, two the knee-bend, one said leg movements, one said balance, one to move the shoulders and one to bend down.

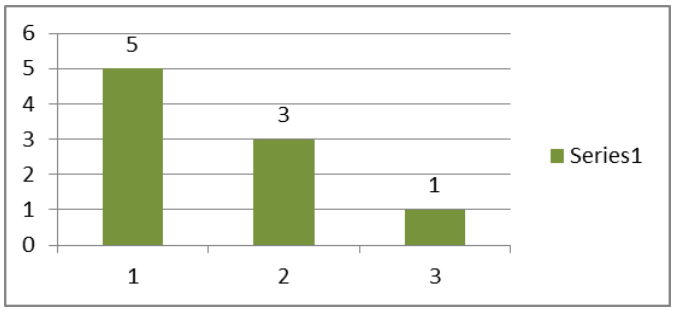

Figure 7 - Do you think this is good training for you? 1–very good, 2-a bit good, 3–no.

The users were also asked if they felt exhausted after gameplay. Here eight replied that they became a little bit exhausted and two that they were not exhausted, they commented that it was tip-toe and or knee-bend that was the most difficult. In the observations we could see that most of the participants got exhausted; they breathed quickly and became quite red. All except one got exhausted and all had to drink water after gameplay.

When asked if they found the mini-games too long, one said yes, and commented that it was the knee bend. Seven found the length of the mini-games suitable and two found them too short. One of those who found it suitable said;” it has to be this much”.

It was clearly observed that the length of several of the mini-game were not suitable, especially the picking games where some did not get time to pick any items at all.

Preferred games

When asked which mini-game they liked the best four said that they like the picking games the best, one the knee-bend and one the tip-toe game. None preferred the leg abduction. See figure 8.

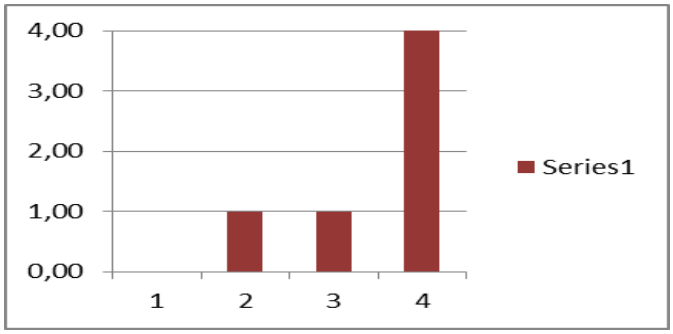

Figure 8 - Any exercise you like better than the other? 1-leg abduction, 2-knee bend, 3-tip toe, 4-picking games.

All commented on this question and five had positive comments on the combined exergame program; combination gave more movements, variation, and they found it “good with variation”,” nice with variation”. One said that it was nice that they also got to use their arms. One said all mini-games were good. One said; “got a lot out of it”.

When asked whether they would prefer to play the apple picking mini-game a longer period instead of the combined exergame program, three replied yes and six no. See figure 9. The ones that replied yes are the ones that have apple picking as their favourite. The ones that replied no commented with; “then I would not get to play the other mini-games”,” it would be too monotonous”, two want more variation, “want combina-

tion". One said "the combination makes it more challenging for the brain too" (which they find positive).

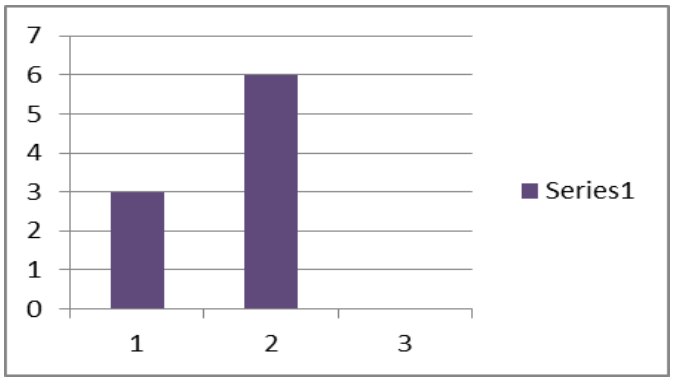

Figure 9 - Would you rather only play the picking games? 1-yes, 2-no, 3-uncertain.

How they managed changes

We had no direct questions about this, but we could clearly observe that the players did not have any problems with the changes.

Information between and after games

The players were asked about how they like the scenes between each mini-game, where a farmer non-playing character asks for help to gather potatoes, give water to the cows and so on. The text was in Norwegian but the voice was in English. Here two were positive, four were neutral and three were nega-tive. Some said it would be ok if also the voices were in Nor-wegian, two said it was childish, two had not noticed it, one had not given it a though, and one could not see it due to bad eyesight.
We observed that they do not pay any attention to the scenes between each mini-game, where the farmer asks for help, they just use that time to rest and get their breath back.

When asked if they were able to see and understand the overall summary at the end, three replied yes and seven no. The ones that said yes also comments on their actual score, so maybe they believed the authors expect them to remember the score, and said no if they had forgotten it?
In the group discussions the two summary pages where the current game score was compared to the average of the last five games that day, and to the average of the last ten days, were discussed. Many said it was too complicated to under-stand, and said they rather would see the sum of each mini-game on the last page.
From the observations we could see that many but not all look for the overall score at the summary in the end to check how well they did it. When they have the role of a cheering audi-ence they study it in more detail. Several just ask "are we fin-ished?" and go for the chair before the last screen is shown.

They all listen more to the sounds and dialogues in English, than they read the Norwegian dialog text or see things on the screens.

Since the mini-games were part of a garden game story, we also asked whether they felt they were doing garden work or that they were playing a game, all except two responded play-ing a game. One said as a comment that it was perhaps garden work too, but in a way that he might have wanted to please the authors. Here two did not respond, and one of those said she thinks most about holding on to the chair so she does not fall. One replied she plays it for the game points.

Tips for improvements

The players also gave valuable comments on how to improve the mini-games to get it more fun and make it more challeng-ing. Many mentioned that several levels are important, some wanted to be able to play two and two.

The second test

In the second test we had a twelve minutes long program with all the mini-games. This time we had no semi-structured inter-views, just observations and a group discussion, but in the group discussion we posed the same questions as in the inter-view in the first test. We also played the game without helping them unless they asked for help.

Exercise program

All seven of the players agreed that they liked to have an exer-cise game program made up of different mini-games, they re-plied good, very good, or good with variation on this question.

It looked like they enjoyed playing the combined exergame program. Comments like "I want to play one more mini-game" were common.

At the end our users discussed what they would like to do at the next gathering, play the exercise program or one mini-game at a time? All agreed that they would like to play this combined exergame program at each gathering but they were worried that it would be much waiting time in the semicircle then.

Impression of exercise

When asked how they found the length of each exercise; all said that now it was good. Then the users started to discuss the difference between playing at home and here in a group. All agreed that now the length of the whole exercise program with twelve minutes was suitable for home use. But here in the group, it became too boring for those that watched if one play-er was to play that long before the next player gets their chance.
The users were asked if they felt exhausted, some said they got very exhausted, and some said they became a little exhausted. They said that the knee-bend and then the tip-toe were the most exhausting mini-games.
When asked if they feel that the exergames are good exercise, some said yes and one replied that for him it was not good exercise. The others agreed that for him it was easy, he should have played on a higher difficulty level.

From observation the length and difficulty of each mini-game was more suitable, they had the time to get into it and at the same time it was not so long that they got too exhausted.

Preferred games

When asked if they liked any of the mini-games better than the others, five said that they like the apple picking mini-game the best, one the chicken picking and one the cut-corn game.

How they managed changes

It seemed that they did their very best on each mini-game now that they had learnt that they were not too long.

There were also very few playing errors, and the help needed was often because they did not get the chance to figure it out by themselves before the audience came with helping hints.

Information between and after games

The players paid more attention to the instruction scenes than before, now that they knew they would not get so much help.

The scenes between the mini-games are as in the first test more used to rest than to look at. But they do look at the mini-game result at the end of each mini-game and often comment on it too, since it was a new version with summary of the exercise program as they had asked for.

The overall new summary has a lot of information, the summary of each of the seven mini-game was interesting for some, but not for all. All were interested in the overall summary of the seven mini-games played, and commented on it; some of the teams of two players got a diamond and some a gold goblet.

Discussion

The exercise program in the first test only lasted for 4.5 minutes, and in the second test each player played for six minutes twice with a break between the sessions – since the full program was twelve minutes. Many said they were a little exhausted, versus the observation that they were quite exhausted. It could be that they do not want to admit that they are in a bad shape, so they tend to underreport.

Two users got very exhausted by observation in the first test; they did not participate in the second test. On the other hand one user did not get exhausted neither by observation nor in own reporting, he is 81 years old and is still in a very good physical shape. The tests were run on difficulty level 1 (easiest) for all, and the authors have earlier observed that this participant masters the most difficult level (level 4), but even this level does not make him exhausted. The importance of the correct game levels were also pointed out in the group discussion at the second test. To have a choice between levels is con-sidered to be extremely important by the participants, and we will add that this also applies if exergames shall be used with success at home by a large user group.

It seems that the participants like the combined exergame program, especially the chance do to a variety of movements and exercises. They are frail and many have problems with one or two of the mini-games, but when they do several, at least they did one that they could well. This was important due to the audience. This was also supported in the interviews; one said the combined exergame program was easier than playing only one of the mini-games.

One big difference between playing the exercise program and playing one game at a time was the menu/button interaction required to be performed by the user. Typically a commercial exergame starts by pushing a start button, and after some calibration scenes, the users go to the menu and choose a mini-game to play. After the game is finished the user again has to go to the menu and start a new game. Our user group finds all this navigation annoying. The exercise program starts automat-ically, with no calibration or menu interaction. The first mini-game starts when the camera detects a user in the playing area, and the next one in the sequence automatically starts after the previous is finished. (The calibration was done in the initial setup, and marked with a tape on the floor.) The user was in the control and did not need the activator to start the next game. Although not asked for in the questionnaires nor in the discussions, the authors think the automatic aspect added to the satisfaction score and that it also made the players say that the exergame program was suitable for home usage.

To the best of our knowledge there are not many research projects that have done long-term tests on elderly users in their own setting, and those we found that do [8, 10] or plan to do this [11] have given the elderly users the task of choosing the mini-games that they think will make up a good exercise program for them. They report [10] that the users play their favourite mini-games more often than those they like less... Our trials show that given a mixed program, the players will play through all and thus get more varied exercises. They also do not mind to play those games they are not so fond of as long as they are mixed with the most preferred games.

It is warned about giving the elderly users the chance to play commercial games before they try out the game to be tested [9]. This pre-experience indeed gives the users a knowledge that may give other comments to the game to be tested, but in the authors' opinion this is good. The user group knows that the project developed exergame is different than the commercial ones, it has one focus point at a time, not too high speed and it has tailored movements that are made to enhance the balance and give more strength. Also our participants knew that they were taking part in user centred design and development, and that their input was important for the final result. In the user group all except one prefer to play the project developed exergame and not the commercial ones. This is also maybe because the project game is new to them and they have played so long now, that they want to try out new games [8]. They were also aware of the fact that physiotherapists had rec-ommended the game's movements. Last but not least they also think that these games are a bit "their" games.

The last summary page with total results from all the mini-games was seen and understood by a few in the first test, and by some more in the second test. After gaming they often need to get their breath back, and also prepare to change player, so they are not in a mood to get a lot of information. When they have the role of being part of the audience they notice a lot more information on the summary pages. For the experience of playing a combined exergame program compared to playing one mini-game repeatedly, the summary was not so important. The authors assume the summary will become more important when played for a long period, but this has to be checked fur-ther.

The initial training of users before testing is very important, and our users spent about six gatherings on this training, and this was in a user group already familiar with exergames. The authors have earlier introduced commercial exergames both on elderly colleges and other groups of old retirees that were not used to playing computer games. This test showed that the concept of exergames is not so easy; your body has to move correctly while you at the same time have to pay attention to the game on the screen. Talking to the participants afterwards revealed that a lot of information was not noticed by them, their minds were occupied with mastering the movements.

We see that also old people like variation, and if the users should play for a long period it should be possible to get to higher levels or even open new mini-games. Since the user

group may not get better physically, higher levels could also mean new game challenges. If the gameplay leads to more physical activity for the elderly, it could also have a positive effect on their physical and mental health.

Conclusions

The elderly users were very positive to the tailored exercise program both the first and the second time they tried it. The trial has demonstrated that a varied game is more fun than just one game and one movement. In fact they wanted to play the combined exergame program on the next gatherings.

Due to the small user group it is not possible to generalize, but it is natural that variation is perceived as more fun.

These tests were also performed to prepare the ground for the real home tests, now that the project has an exergame with an exercise program with a suitable length and intensity. The users have proven to manage to play it by their own, given that they have learned how to use it beforehand by getting costumed to play exergames using Kinect as input device. Also the interface has been tailored to the user group.

Future work will be refinements on the exercise program and to test it in real home usage for a period. The project exergame was made with game elements that suits elderly users in their first interaction, such as one focus point at the time, simple graphics, and slow speed. The goal is that the exergame shall be fun to play at home for a long time; for this to be fulfilled more long term motivational elements such as more levels, more mini-games, scoreboards, and social elements must be added. Further research is needed on how elderly users can be motivated to play for a long period.

Also the exergame program should be tested with other user groups that have not participated in the design and development.

Acknowledgments

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Using Participatory Heuristic Evaluation as a Collaborative Backbone in Large-Scale Projects – preliminary experience from the eWALL EU-Project

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Abstract

Worldwide, the number of collaboration activities and large-scale projects (LSPs) increases. According to Harvard Business Review, LSPs contain several challenges related to strategy, interdependence, teaming, culture, norms, leadership, and different educational background. eWALL is an ongoing LSP with 14 partners where several evaluation methods are used, including Participatory Heuristic Evaluation. The applied method can be seen as a two-level approach: First, the eWALL system was evaluated using Participatory Heuristic Evaluation and, second, results of the Participatory Heuristic Evaluation were assessed by groups of project participants. Using the method and discussing the results in these meetings, not only focused on system improvements, but also facilitated fruitful discussions related to the overall goal, challenges, and progression in the project. Participatory Heuristic Evaluation proved useful for evaluating the system, and prompted the idea of using the formalism, i.e. as a collaborative backbone, at a higher managerial level to tackle some of the challenges associated with LSPs. In order to refine and prove the benefit of using Participatory Heuristic Evaluation as a collaborative backbone, further studies should be conducted.

Keywords:

collaborative backbone, participatory heuristic evaluation, preliminary project experience, large-scale project

Introduction

Worldwide, the number of collaboration activities and large-scale projects (LSPs) increases [1–5]. From 2007 to 2013 the European Commission allocated EUR 50.5 billion to the 7th Framework Programme for Research and Technological Development (FP7) [6]. FP7 is followed by the 8th Framework Programme for Research and Innovation running from 2014 to 2020, named Horizon 2020, which is estimated to exceed EUR 80 billion [7]. In addition to the EU funded projects, there are numerous other large-scale initiatives – both in research and industry.

Due to being highly complicated, planning and conducting, LSPs contains several challenges [2–4,8]. Some of the challenges are related to individual sub-agendas, costs overrun, schedule delays, and low performance [2,4].

The Harvard Business Review, owned by Harvard University, has over the years identified different reasons and explanations of why these challenges arise. They have documented that strategy, interdependence, teaming, culture, norms, leadership, and different educational background are some of the core elements in this [1,4,5,9–12].

eWALL, a large-scale project

An example of an ongoing LSP, which is financed by the FP7, is the large-scale European project eWALL for Active Long Living. The project has a duration of 36 months and a budget of EUR 8.8 million [13].

The aim of eWALL is to develop a device for monitoring health of older adults, provide easy access to doctors and sensing their daily activities with the goal to inform relatives if emergency occurs [13]. The users in eWALL are people with chronic obstructive pulmonary disease, mild dementia, and elderly with age related impairment.

eWALL is a joint venture where 14 partners from 14 different European countries have to manage all the challenges of running an LSP [11]. The work is divided into eight work packages; all being strongly connected and dependent on each other. The main technical and user requirements for the eWALL platform are unobtrusiveness in monitoring functions and seamless interaction with the primary and secondary end users (i.e., patients, and healthcare professionals and family, correspondingly). In the eWALL project, several evaluation methods are used, some of which are designed to provide an initial feedback on the user-friendliness of the adopted technology.

One of the evaluation methods is the so-called Participatory Heuristic Evaluation. Using this method has not only proven very useful for evaluating the system, but has also prompted the idea of using the formalism at a higher managerial level to tackle some of the challenges associated with LSPs. During the process, we found that using the method and discussing the results in meetings among project participants facilitated fruitful discussions related to the overall challenge and progression of the project.

The aim of the present paper is to report the results of performing a Participatory Heuristic Evaluation on the eWALL system and how this lead to the hypothesis that Participatory Heuristic Evaluations might be one of the collaborative backbones when running LSPs.

Materials and Methods

The applied method can be seen as a two-level approach: First, the eWALL system is evaluated using Participatory Heuristic Evaluation and, second, results of the Participatory Heuristic

Evaluation are assessed by groups of project participants with respect to both implications for the system design and with respect to challenges and progression of the project. The two steps are repeated in loops during the project duration.

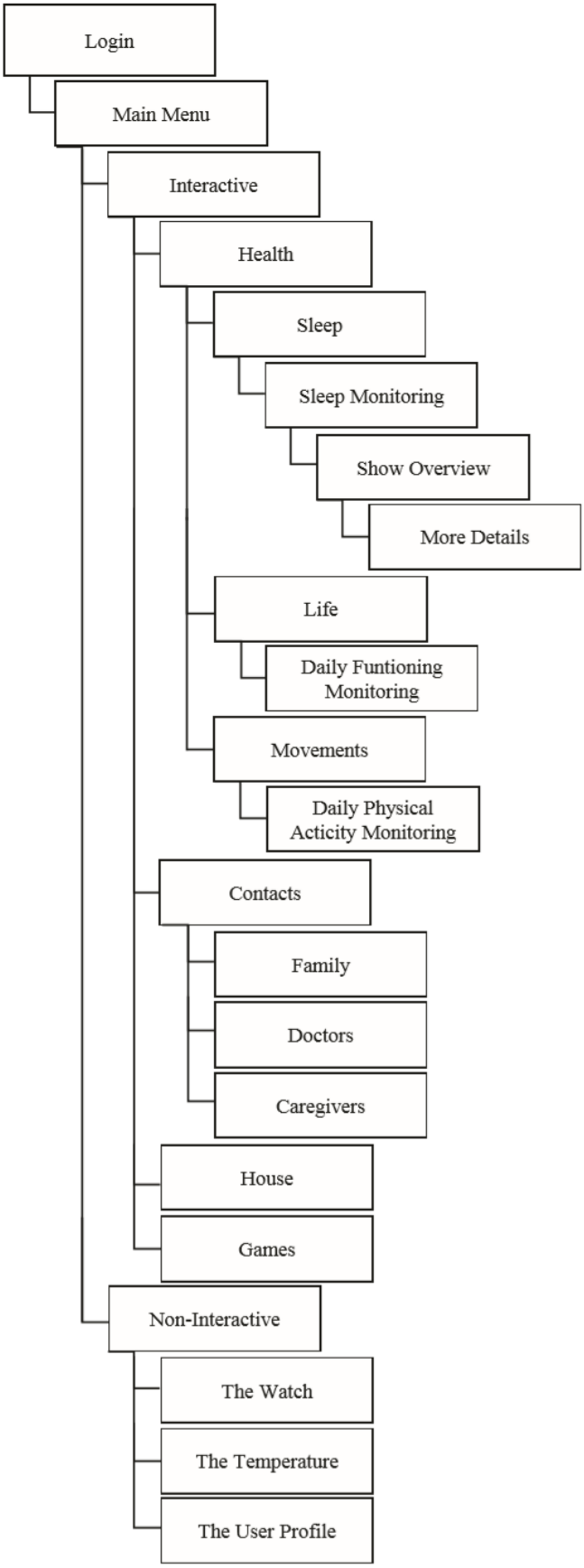

Figure 1- The architecture for the functionalities in the eWALL system

The eWALL system

The eWALL interface application is a part of the final product, which is a prefabricated wall with incorporated functionalities and features for elderly citizens.

The functionalities and features of the eWALL system can be divided in the groups [13]:

- risk management and home safety
- eHealth
- lifestyle management

To illustrate these functionalities the initial layout of the menu structure in the interface software used by the citizens is shown in Figure 1. It should be noted that this is the first version of the interface and that major revisions and improvements will follow.

After logging into the eWALL system, the users are met by the main menu (Figure 2). The main menu contains two types of elements: 1) permanent widgets, and 2) start buttons for applications (Figure 3 and 4).

The permanent widgets show data of continuous and constant level of importance, produced and aggregated in service bricks. Widgets are reduced size display panels and do not require interaction. An example of one of the widget can be found in Figure 3.

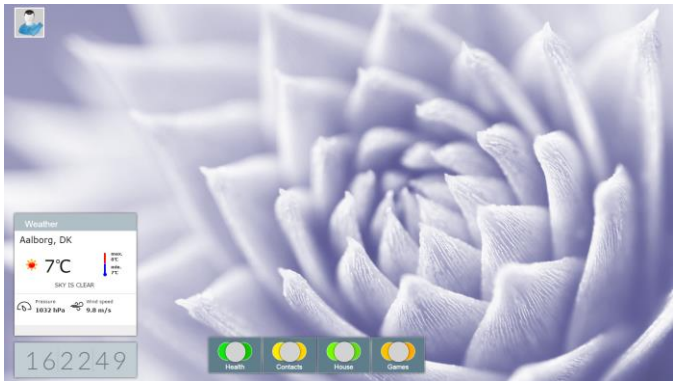

Figure 2- A screenshot of the experts and work-domain professionals in the Participatory Heuristic Evaluations

Figure 3- The weather-widget and the watch shown in the main menu of the eWALL system

The main menu contains four groups of applications – for example, for the group 'Health' there are three subgroups (see Figure 4).

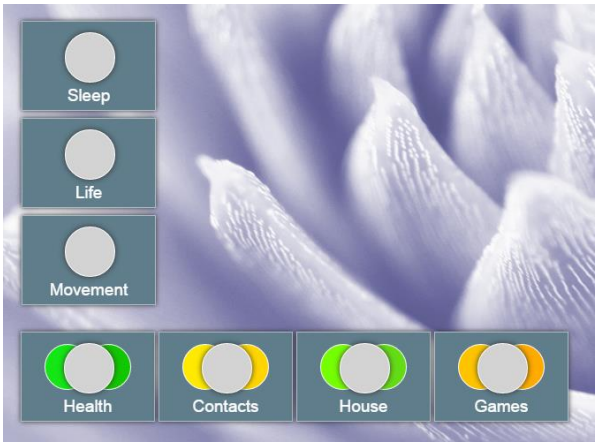

Figure 4- The four start buttons for applications available from the main menu. As shown on this figure, there are three subgroups of applications placed under 'Health'

Participatory Heuristic Evaluation

Participatory Heuristic Evaluation is a participatory inspection technique that serves as an extension to heuristic evaluation defined by the well-known usability expert, Jakob Nielsen [14,15]. In Participatory Heuristic Evaluation, experts in usability do an inspection as in traditional heuristic evaluation. The term traditional refers to the use of heuristics, a severity rating scale, and a log-schema [14]. After this, work-domain professionals are added as a group of users performing the same inspection. The purpose of extending the heuristic evaluation with these work-domain professionals is to complement the traditional inspectors' more abstract knowledge with very specific knowledge from the work-domain professionals.

Usability experts

Five usability experts were recruited. Their educational background was Masters in Biomedical Engineering. Furthermore, three of the experts were ongoing PhD fellows and two of the experts were Associate Professors. The five usability experts were recruited from the Department of Health Science and Technology at Aalborg University.

Work-domain professionals

Two nurses were recruited to participate as work-domain professionals in the Participatory Heuristic Evaluations. Both of the nurses were Masters in Clinical Science and Technology and were ongoing PhD fellows. The two work-domain professionals were recruited from the Department of Health Science and Technology at Aalborg University. Both of the nurses had tried Participatory Heuristic Evaluations before. Despite the prior experience, they received a full introduction to the procedure.

Severity rating scale and 15 heuristics

The usability experts and the work-domain professionals were asked to categorize and comment on usability issues by means of Muller et al.' 15 heuristics as shown below [15].

1. System Status
2. Task Sequencing
3. Emergency Exits
4. Flexibility and Efficiency of Use
5. Match Between System and the Real World
6. Consistency and Standards
7. Recognition rather than Recall
8. Aesthetic and Minimalist Design
9. Help and Documentation
10. Help Users Recognize, Diagnose, and Recover from Errors
11. Error Prevention
12. Skills
13. Pleasurable and Respectful Interaction with the User
14. Quality Work
15. Privacy

After identifying each usability problem the usability experts and the work-domain professionals were asked to grade the usability problem, be means of the following four severity rating scale [14]: 1) *cosmetic problem only*, 2) *minor usability problem*, 3) *major usability problem*, and 4) *usability catastrophe.* The goal of grading each usability problem was to get information about how severe the identified usability problems of the eWALL applications were.

Assessment of Participatory Heuristic Evaluation results in groups of project participants

After performing the Participatory Heuristic Evaluation, the results were assessed in a meeting among groups of project participants with respect to both implications for the system design and with respect to challenges and progression of the project. There was no detailed formal reporting of this activity – the outcome of the discussions can, explicitly, be seen in the minutes of the meetings and, implicitly, seen in how the participants handle the challenges related to a common goal, individual sub-agendas, costs overrun, schedule delays, and low performance.

Results

The results are divided in direct qualitative results, quantitative results from using the Participatory Heuristic Evaluation, and indirect qualitative findings from the group discussions among project participants.

Qualitative results

The following results are linked to the main screen functionalities at the eWALL interface application (Figure 1).

- The font size is too small
- The font is unclear
- The colour contrast is too low
- If you do not speak English, it is difficult to choose language
- A keyboard is missing
- Required password is missing
- The watch is unclear to understand
- Information overload regarding the weather-widget

- There is no log-out button
- The symbols of the buttons are not easy to understand
- The main screen seems empty
- The grey buttons look moveable, but are not
- It is not possible to customize the weather-widget

Quantitative results

From the Participatory Heuristic Evaluation, the usability experts and the work-domain professionals identified several usability problems by using the heuristics. Figure 5 illustrates the aggregated number of heuristics used by the usability experts and the work-domain professionals.

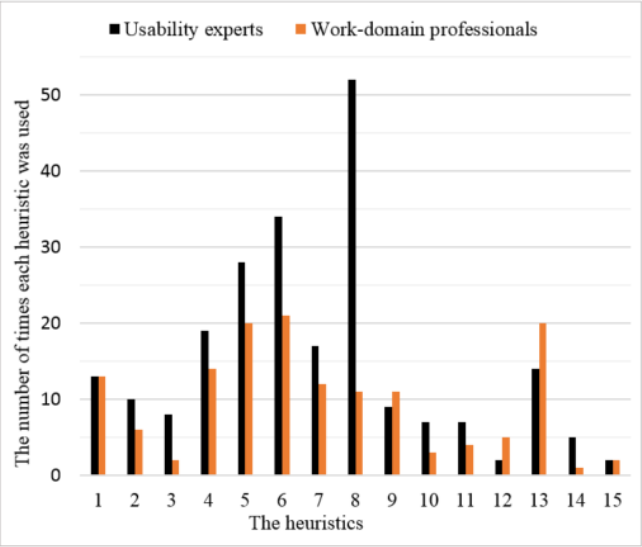

Figure 5 – The number of times each heuristic was used by the usability experts and work-domain professionals during the Participatory Heuristic Evaluations

Each usability issue identified by the usability experts and the work-domain professionals was rated using a four-scale severity rating. The result is presented in Table 2.

Table 2 – The table illustrates the number of times each severity grade was used by the usability experts and the work-domain professionals

Severity grade	How many times each severity grade was used			
	Usability experts		Work-domain professionals	
1	49	21,6 %	9	6,2 %
2	49	21,6 %	33	22,6 %
3	67	29,5 %	68	46,9 %
4	62	27,3 %	35	24,1 %
Total	227	100 %	145	100 %

Outcome of the Participatory Heuristic Evaluation discussions among project participants

An example from the project work in two very different departments at Aalborg University will be used to illustrate the process and the results of assessing the findings from the Participatory Heuristic Evaluation.

The project participants in the two departments did not know each other before the Participatory Heuristic Evaluation was organised and conducted. This means that none of the partners knew each other's individual agendas, goals, norms etc. The involved partners came from the Department of Electronic Systems and the Department of Health Science and Technology. The former has a strong focus on technology as a discipline and the latter has a strong focus on health as a domain using technology as a tool to solve problems. They have very different educational background, different working methods and perspectives on technology.

The partners from the Department of Electronic System did not know the Participatory Heuristic Evaluation method beforehand. In the meetings afterwards, they described how they felt that the usability experts and the work-domain professionals had identified several unknown usability problems and they said that the method seemed to be very useful. The partners from the Department of Electronic System also said that they felt overwhelmed by the many usability problems that had been found – but they liked the way it was categorised and collected. Just reading the Participatory Heuristic Evaluation results, they felt that 'their baby' was under an attack, but during the discussions with the domain oriented partners they felt that they were able to have an objective approach to the eWALL system, because they could see the relevance and importance of the identified problems.

The partners from the Department of Health Science and Technology to begin with felt that the domain always is more important than the technology but that this view was not shared with the other department. They felt that the partners in the other department had the idea that domain experts knew far too little about technology to have a say on the design and testing of technology.

During the discussions both partners realised that the usability experts and work-domain professionals could be regarded as neutral third parties – that the results from the Participatory Heuristic Evaluation should not be regarded as 'the truth' but more as a starting point for a fruitful discussion on both the system and the goal of eWALL. From discussions of the higher-level aspects of eWALL, both partners realised that several aspects of the challenges of running a LSP were included. Both partners felt that, much better than formal presentations of other partners' competencies and contributions, the Participatory Heuristic Evaluation had served as an informal means of collaboration.

The partners from both departments agreed to the need of more rounds of system development, Participatory Heuristic Evaluation, and assessment in groups of the results from the Participatory Heuristic Evaluation – successive loops – in order not only to evaluate and improve the system, but also to overcome the challenges related to strategy, interdependence, teaming, culture, norms, leadership, and different educational background in a large scale project.

Discussion

From the qualitative Participatory Heuristic Evaluation results, we saw that the usability experts and the work-domain professionals had identified several severe issues regarding the main functionalities of the eWALL interface application. The qualitative problems were very different in nature ranging from missing elements on the screen to lack of customisation to the

end users and to general usability problems due to not following the heuristics.

From the quantitative Participatory Heuristic Evaluation results we saw that the heuristic no. 8, *Aesthetic and Minimalist Design*, was the most frequently used heuristic among the usability experts. The second and the third most frequently used heuristic were no. 6, *Match Between the System and The Real World*, and no. 5, *Consistency and Standard*. In comparison, the most used heuristic among the work-domain professionals was no. 6, *Consistency and Standards*. The second and the third most used heuristic among the work-domain professionals were heuristic no. 5, *Match Between the System and The Real World*, and no. 13, *Pleasurable and Respectful Interaction with the User*.

It should be noted that the four heuristics, which the usability experts and the work-domain professionals used the most, are closely related. Basically, they all focus on pleasurable and respectful interaction between the user and the system. If the design and the aesthetic of the system is unclear and unattractive, and the layout of the system does not follow usual standards, then, according to the usability experts such as Jakob Nielsen, it is very likely that the users will experience troubles with the system and thereby skip the system [16].

For the heuristic no. 8, *Aesthetic and Minimalist Design*, we see the largest difference between the two groups of experts. There is no obvious explanation to this difference and other studies have not found the same significant difference [17]. The result that heuristic no. 8 is the most frequently used heuristic, is in line with Nielsen who talks about the 'importance of first impression' and the number of seconds users stay on a page before they leave it [16,18].

The fact that usability experts and work-domain professionals have a very different professional background and, therefore, are likely to have different priorities is reflected by the differences in their findings thereby illustrating the point of using both types of professionals.

In Table 2, it is illustrated how the usability experts have a quite uniform distribution between the four severity grades and how the work-domain professionals grade very few problems as cosmetic and almost half of the problems as major, indicating that work-domain professionals may have a tendency to express their opinion on these issues more strongly.

Overall, it is not surprising that the usability experts and the work-domain professionals identified very severe, and numerous, problems during the Participatory Heuristic Evaluation. According to usability expert Jakob Nielsen, this is almost always the case. He, therefore, recommends an iterative approach allowing larger problems, which may take the focus away from smaller problems, to be solved first, after which the system is updated before being tested again [19].

From Participatory Heuristic Evaluation discussions among project participants, we saw that the individuals from different partners slowly began to change their view on what they could get out of the interaction. They changed their view from the perception that the purpose was to agree, on which findings were the most important and how the issues could be solved, to realising that they as a side-effect got more insight into other aspects of the project and a wider understanding of a common goal. The partners began to collaborate as a team with the same goal rather than act as competitors.

Inspired by our findings and experience in eWALL, and by the findings of Harvard Business Review [1,4,5,9–12], we have derived at the hypothesis that Participatory Heuristic Evaluations might be one of the collaborative backbones when running LSPs, not only in eWALL but also in other projects. In eWALL, we have taken the first step in the looping process: i.e. rounds of system development, Participatory Heuristic Evaluation, assessment in groups of the results from the Participatory Heuristic Evaluation. Whether such successive loops can be a backbone for not only evaluation and improvement of the system, but also can be a way to overcome the challenges related to strategy, interdependence, teaming, culture, norms, leadership, and different educational background in a large scale project, is to be seen when, in due time, we evaluate eWALL. If we succeed in eWALL, further studies might be conducted in order to refine and prove the benefit of using Participatory Heuristic Evaluation as a collaborative backbone.

Conclusion

Participatory Heuristic Evaluation was proved very useful for evaluating the eWALL system and, in addition, prompted the idea of using the formalism, as a collaborative backbone, at a higher managerial level to tackle some of the challenges associated with LSPs. Further studies should be conducted to demonstrate the benefit of the approach.

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End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data in a Telehealth Trial System for Remote Supervision of COPD-Patients

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Abstract

The security and privacy of personal, health-related data in emerging telehealth and telecare systems is crucial, in particular under consideration of additional requirements. On the one hand optimal usability of the devices and applications provided for the monitoring of the health condition is desirable for the supervised patient. On the other side the different health and care organizations require co-operative access to the common infrastructure for storage, transmission and provision of the data from the patients.

In this paper we analyse the different types of security related issues and requirements of the telehealth trial system developed for a Norwegian implementation of the EU funded United4Health project, and describe a solution concept for functionalities and policies addressing those requirements. Identified design limitations of the security concept and initial results from the trial operation are discussed.

The paper concludes with the general relevance of the proposed security concept also for telehealth systems for remote monitoring of other patient groups by potentially other types of services, and an outlook on expected infrastructure evolutions and corresponding security considerations.

Keywords:

Security, privacy, telehealth, telecare, EHR, NHN, cloud, health information technology

Introduction

The amount of personal, health related data that are collected, transmitted, stored, processed, and provided by data systems connected to the Internet (or in the *Cloud*), is strongly increasing (as indicated e.g. by the increasing adoption of EHR systems [1]).

On the one hand this is driven by telehealth and telecare systems for professional health and care service providers, which typically support the remote supervision of home-based patients. As the average life span of people is increasing, an increased percentage of the worldwide population is affected by ageing-related chronic diseases [2]. Chronic Obstructive Pulmonary Disease (COPD), for example, will be the fourth most common cause of death by 2030, according to a projection from the World Health Organization, only behind ischemic heart disease, cerebrovascular disease, and HIV/AIDS [3, 4]. It will be the fifth most common cause of chronic disability worldwide by 2020 [5]. In order to keep such patients independent and autonomous within their own living environment as long as possible, patient-centric and efficient supervision and care solutions are needed. And in order to secure the future of health and care systems around the globe, such solutions must provide the best balance between high-quality medical support for individual patients and cost for the society. Medical routine supervision and remote follow-up of patients with chronic diseases is one area that has a high potential for efficiency gains, by giving optimal personalized support to patients within their own private environment, while avoiding unnecessary consultations [6].

On the other hand, commercial, cloud based services for end consumers (as e.g. Apple Health, Fitbit, Jawbone UP, Nike FuelBand, Polar, Samsung, Sony; see [7]) are getting momentum. Such services allow to collect certain health and fitness related data (as typically pulse / heart rate, motion / activity, body temperature, blood pressure, etc.) and to illustrate those on gadgets (as SmartPhones, SmartWatches, etc.) and on corresponding vendor-specific Web-based portals.

Personal medical data about health and care conditions are privacy-critical on the one hand, and a functioning health information service infrastructure as a whole is of potentially life-critical relevance on the other hand. Due to that, there are a number of security aspects to be considered when collecting, accessing, transmitting, and providing different types of information via the distributed components of the health infrastructure.

The general focus of this paper is on the privacy protection of patient data within the components of the end-to-end infrastructure of a telehealth and telecare system. The security aspects to be considered when developing of a security concept for the Information and Communication Technology (ICT) solution are manifold:

- The *patient* (or in general the supervised person) must be reliably authenticated.
- The devices (as e.g. dedicated sensors) for the acquisition of medical, health and care related information from the patient must be reliably authenticated.
- The communication between the measurement devices (sensors) and the patient application device (e.g. a tablet-PC) must take place via a secure connection.
- A clearly defined *relation management* must be in place between the patient, the patient application device, and the measurement devices, in order to reliably relate the personal data from the patient (as sensor measurements or other data gathered via the patient application device) to the corresponding patient.

- The access of the patient to the patient application device must be authorized.
- The access of the patient application device (and the applications running on it respectively) to the communication infrastructure must be controlled.
- The transmission of data between the patient application device and any Electronic Health Record (EHR) or Personal Health Record (PHR) service component in the health information infrastructure must be secured (encrypted).
- The access (e.g. from any telehealth or care service provider) to any personal patient data in the health information infrastructure (i.e. stored and processed in any EHR or PHR system) must be controlled.
- If components in a dedicated national health network as the Norwegian Health Network (NHN, [8]) infrastructure are involved, specific authentication and authorization rules for access control might apply.
- The communication between the information access devices of telehealth and other medical and care service providers and the EHR or PHR systems in the health information infrastructure (as in a NHN) must be secured (encrypted).

As basis for a more detailed analysis of security related requirements, and for the development and discussion of a security concept, we look at the telehealth trial system developed for the EU-funded project "UNIversal solutions in TElemedicine Deployment for European HEALTH care" (United4Health, or just U4H), and especially at the solution developed for the specific Norwegian requirements [9]. The aim to support a close cooperation of professional health and care providers from different organizations, and to involve even informal care providers as relatives, puts specific requirements on the system, in particular with respect to the security of the patient data. Another focus point for the development and evaluation of the U4H trial system has been the usability of applications and services for the different involved user groups (namely patients and care providers), and we address also the specific impacts of security mechanisms on the usability in this paper.

Within the following *Materials and Methods* section we will give a short overview of the U4H trial system and its main use cases. As part of that we will provide a detailed analysis of the security-related requirements within the different architectural domains of the end-to-end (e2e) system. In the *Results* section we will explain the security concept, which has been implemented in the U4H trial system. In the *Discussion* section we will then look at covered security requirements and potential security limitations, and address improvement potential with regards to usability. In the *Conclusions* we will explain the general relevance of the security concept (proposed for the ongoing U4H trial system) for other telehealth and telecare services for the collection and communication of health data.

Materials and Methods

Figure 1 shows the systems architecture of the U4H trial system with its main domains, the Point-of-Care (PoC) environment of the patient, the Health Information Services (HIS) infrastructure, and the infrastructure for the Health and Care Sources, i.e. the different sources of health and care services.

The U4H Trial System

The overall purpose of the U4H trial system is the remote supervision and follow-up support for COPD patients in their home after being discharged from hospital, following a stationary treatment. We will subsequently explain shortly the main functionalities of the system along the different system domains.

Point-of-Care:

A software application on a tablet-PC supports the patient to carry out daily (at least) measurements of his pulse and blood oxygen level (SpO_2). The SpO_2 sensor device communicates the measurement values through a wireless Bluetooth (BT) connection to the tablet-PC. Additionally, the breathing quality of the patient can be measured with a Spirometer device.

The patient application on the tablet-PC provides furthermore a user interface (UI) with questionnaire forms for the daily reporting of COPD-symptoms of the patient.

The data (SpO_2 values, optionally Spirometer values, questionnaire answers) are stored in a local database on the tablet-PC. From there they are used for an information UI for the patient, and are transmitted to the HIS infrastructure.

Within the U4H field trial, each COPD-patient uses the tablet-PC for a temporary period of one month. After that period the device is provided to another patient participating in the field trial.

Health Information Services Infrastructure:

The data from all remotely supervised patients are transmitted and stored in a personal electronic health record system (P-EHR). A dedicated telehealth service provides a Web-based information portal for telehealth and care service providers. This service takes the patient data from the P-EHR system,

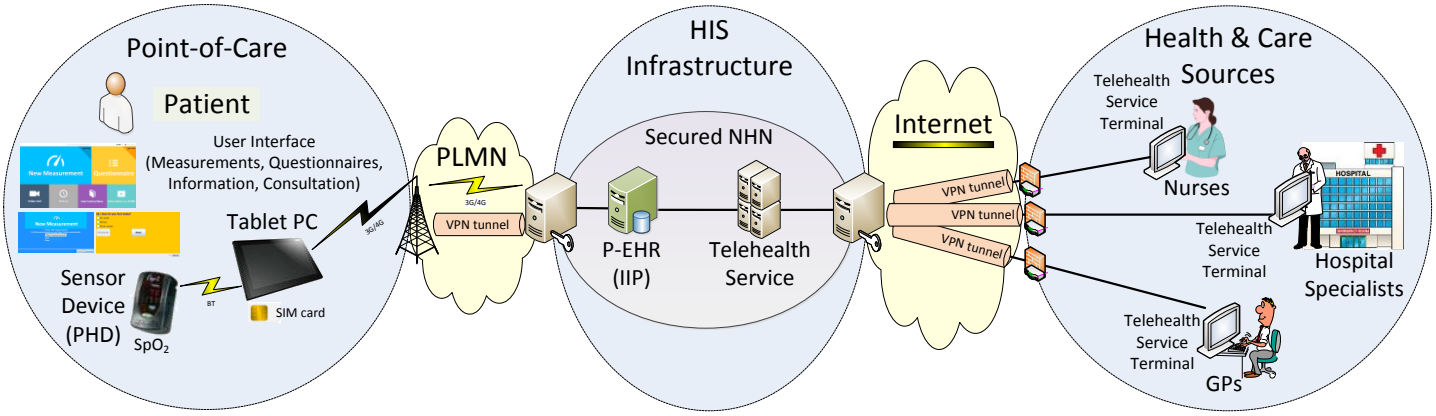

Figure 1- Architecture overview of United4Health telehealth trial system for COPD patients

evaluates the data according to "red (critical) – yellow (attention) – green (normal)" conditions ("Triage"), and provides overview pages with the triage-results of all supervised patients, as well as detailed condition pages with all information from a specific patient, collected during the supervision period.

Health and Care Sources:

Health and care professionals from different organizations have collaborative access to the telehealth data (i.e. measurements and questionnaire answers) from patients they are responsible for. This includes specially trained telehealth nurses (potentially located in dedicated telehealth center facilities), medical specialists in the hospital where the patients have been treated before discharge, and also general practitioners (GPs) that take care for the ambulatory care of the patients.

With a telehealth service terminal the health and care service providers get access to the Web-portal containing the overview of patients' status and the history of detailed monitoring data, provided by the telehealth service in the HIS infrastructure.

The U4H trial system also supports video consultation between the patient and the health and care service providers for the remote check-up and follow-up support. The security of the video consultation system is not considered in this paper.

Information flow through the U4H system

When a patient answers the daily questionnaire on COPD-symptoms on the tablet-PC, the answer-values are stored on the tablet-PC, together with an identifier of the patient and the date/time when the questionnaire took place (Figure 2).

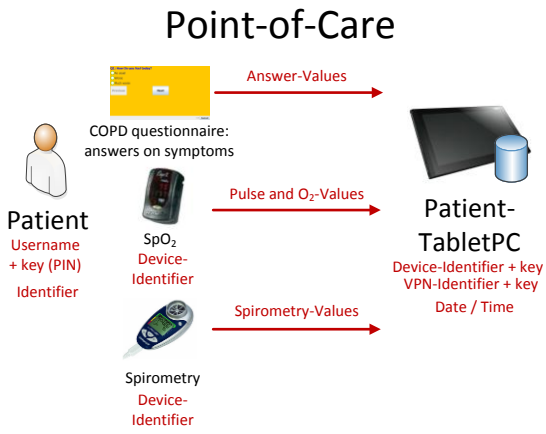

Figure 2- Information Flow in the Point-of-Care

Similarly, pulse and O_2-values from a pulse-oximetry measurement or the measurement-values from a spirometer-measurement are transmitted to the patient-tablet-PC, and are stored there together with the patient-identifier and the date/time of the measurement.

The patient-related information from each distributed patient-tablet-PC is transmitted to a Personal Electronic Health Record (P-EHR) system in the Health Information Service infrastructure (Figure 3). This information includes a patient-identifier, the answer-values from the COPD-symptoms-questionnaires, the pulse- and O_2-measurements-values, and the spirometry-measurements-values, all combined with the date/time of their acquisition, and the device-identifier of the patient-tablet-PC that was used for the acquisition of the information. In the P-EHR service the data is stored in a database, and is made available to the telehealth service.

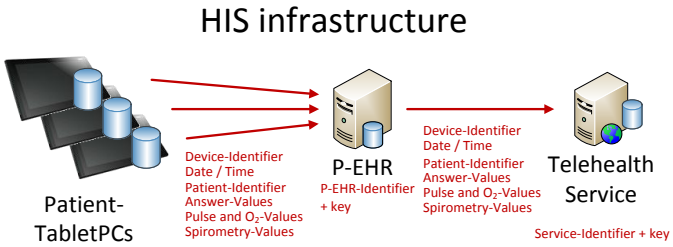

Figure 3- Information flow through the HIS Infrastructure

The telehealth service is the central Web-based access point for the questionnaire and measurement data from all supervised COPD-patients. Also the results from the Triage-evaluation, carried out by the telehealth service and using the raw patient data, are provided via this Web-portal (Figure 4). Different telehealth & care services, hospitals and also general practitioners use telehealth service terminals, which are shared by all staff of the corresponding institution. For example, all telehealth nurses of a telehealth & care service organization might share one terminal, the staff of a specific hospital (or a department respectively), or the staff of a GP office.

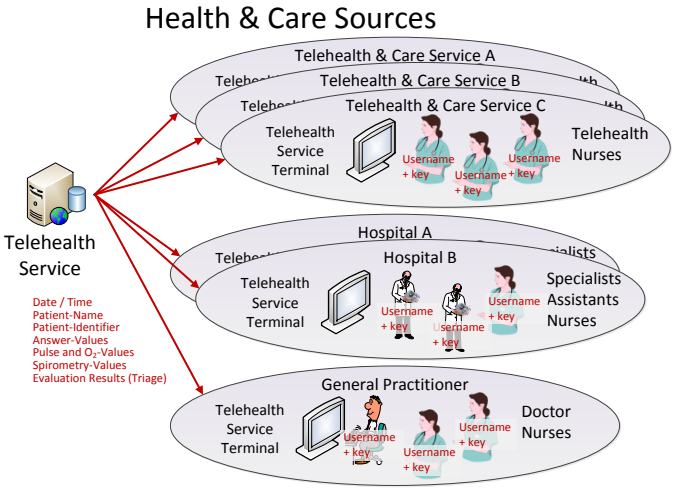

Figure 4- Information Flow to the Health & Care Sources

Analysis of Security Requirements

The fundamental objective of computer security is to protect the confidentiality, integrity and availability of the data and services of the system looked at [10].

Within this paper we focus in particular on the confidentiality of the patient data when being gathered, stored and communicated through the ICT infrastructure of the U4H trial system. Hence, we address the e2e confidentiality of the patient data from the point-of-care to the health and care service providers. Besides the confidentiality (as basis for the patients' privacy protection) we also address the system integrity.

Potential threats within the different domains of the U4H e2e system and requirements for corresponding countermeasures are identified in Table 1, Table 2 and Table 3 below.

Further security-relevant requirements, as the availability of the ICT system components for any U4H services, and a thorough analysis of possible attacks and risks, are not within the scope of this paper.

Table 1 - Threats and Requirements in Point-of-Care

# no	Threat	Requirement
Req1	Confidentiality threat: wrong person gets access to patient data (e.g. when tablet-PC is handed over from one patient to another)	Access control = authentication and authorization of patient to telehealth applications and personal data
Req2	Misuse of sensor device interface of patient-tablet-PC, to get access to data and services	Secure authentication of sensor device(s) and secure connection to tablet-PC
Req3	Unintended use of applications and services on patient-tablet-PC for purposes not related to telehealth supervision (e.g. installation of any software, access to Internet, etc.)	Patient is authorized for access to a secured desktop environment on the tablet-PC only, that contains the telehealth applications and services, and personal data
Req4	Physical or mental limitations or disabilities of patient limiting the intended use for remote supervision	Enable a high level of usability, in particular of any security related functionalities

Table 2 - Threats and Requirements in the HIS Infrastructure

# no	Threat	Requirement
Req5	Confidentiality threat: unintended access to personal patient data at transmission from patient-tablet-PC to P-EHR system	Encryption of communication between patient-tablet-PC and P-EHR system
Req6	Confidentiality or integrity threat: Misuse of patient-tablet-PC interface of P-EHR system, to get unintended access to data and services or to send false data	Access control = authentication and authorization of patient-tablet-PC at the P-EHR system
Req7	Confidentiality threat: Misuse of service interface of P-EHR system, to get unintended access to data and services	Access control = authentication and authorization of telehealth service at the P-EHR system
Req8	Confidentiality threat: unintended access to personal patient data at transmission from P-EHR system to telehealth service	Encryption of communication between P-EHR system and telehealth service
Req9	Confidentiality or integrity threat: Misuse of P-EHR system interface of telehealth service system, to get unintended access to data and services or to send false data	Access control = authentication and authorization of P-EHR system at the telehealth service
Req10	Compromise national laws and policies for information security ensuring interoperability of services and systems for exchange and storage of health and care data	Enforcement of rules for the deployment of the P-EHR and telehealth service systems within the NHN infrastructure (Code of Conduct, [11], e.g. storage of personal health data within national boundaries of Norway)
Req11	Availability threat: unavailability of patient data when inter-changed between different EHR systems	Unique Patient-Identifier to be used in all EHR- and service systems (cooperating in the HIS infrastructure)

Table 3 - Threats and Requirements at Health & Care Sources

# no	Threat	Requirement
Req12	Confidentiality threat: wrong person gets access to patient data through the telehealth service Web-portal	Access control = authentication of individual person at any cooperating health and care service provider (i.e. medical specialists, GPs, nurses, assistants, etc.) and authorization to access personal patient data only as required for their responsibilities towards the patient
Req13	Confidentiality threat: unintended access to personal patient data at transmission from telehealth service to telehealth service terminal at health care service provider	Encryption of communication between telehealth service and telehealth service terminal

Related Work

According to a report on e-health strategies published in January 2011 by the European Commission (referred from [12]), trust in eHealth systems by both citizens and professionals had been identified as one of, if not the key challenge in all countries. Privacy had been recognized as the most sensitive aspect of eHealth records systems.

Due to their high importance, significant efforts have been put into research studies of different security and privacy aspects of eHealth systems.

Fernández-Alemán et al [13] have carried out a systematic literature review of articles dealing with the security and privacy of EHR systems, most of them addressing standards or regulations related to the privacy and security of EHR data.

Kaletsch and Sunyaev [14] have examined a theoretical foundation of Personal Health Records (PHR) for the deployment in a Cloud environment. Along a few case studies the top-threats for patient's privacy have been identified.

Zhang and Liu [15] proposed a reference model for EHR security, focusing on EHR sharing and integration in healthcare clouds. The model has not been proven in a test or trial system.

Goldman and Hudson [16] study consumer-focused Internet services for online-access and distribution of health information. One finding is, although the Internet appears to offer anonymity and a safe place to seek and share information (what obviously attracts many health care consumers), that many eHealth business models depend on identifying and tracking users for different purposes.

Terry and Francis [17] argue, that acceptance from patients and physicians is the initial requirement for the nationwide transition to EHRs, which depends at the forefront on privacy and confidentiality concerns. They propose an autonomy-based EHR system, giving the patients full control over personal information.

Kluge [18] addresses the risk management of patient health data under consideration of international and global interoperability, and calls for "professional health information organizations", that should lead the development and harmonization of security protocols, and of principles for the certification.

Results

The analysis of security requirements and potential threats has resulted in a security concept and corresponding mechanisms, which we have deployed along the different components in all domains of the U4H trial system.

Point-of-Care Security

Req1 + Req4

At the start of the patient device (switch-on of the tablet-PC), the telehealth application for remote supervision starts automatically, and the patient has to authenticate himself towards his user account with a personal identification number (PIN) assigned to his user name (=account name). Discretionary Access Control (DAC) is carried out, based on the authenticated identity of the patient. All personal data, including all sensor measurements and questionnaire answers, are stored in a database located within the user account of the patient (and are transmitted to the P-EHR system in the HIS infrastructure). When the telehealth supervision of the patient comes to an end, the user account of that patient, including the database with any personal data, is deleted by an administrator, before the tablet-PC is being prepared for another patient.

To improve the usability, the PIN is only 4 digits long. Also it is known to the telehealth nurses, that are in charge for that patient, so that they can remind it to the patient on demand via phone or video conference, e.g. in case the patient has forgotten the PIN.

Req2

Only sensor devices following the Continua alliance specification are supported for the measurements. The communication with the patient-tablet-PC device goes via Bluetooth (BT). The one-time link configuration between the sensor device and the tablet-PC requires a specific Bluetooth device PIN, which has to be configured in the tablet-PC by an administrator. For that a specific administrator account is configured in the tablet-PC, requiring a corresponding administrator password for authentication. Other devices than the linked sensor devices cannot communicate with the tablet-PC.

Req3

A secured desktop environment[1] is installed within the Windows operating system of the patient-tablet-PC, which only contains the applications required for the telehealth supervision of the patient. That environment is automatically started when the tablet-PC is switched on, and prevents the patient (or anyone else) from using unauthorised resources. Only a secret key sequence, known to the administrator, allows switching to the Windows desktop environment.

Health Information Services Infrastructure

Req5

For the communication of the patient-tablet-PC through a public land mobile network (PLMN) infrastructure with the P-EHR system deployed within the National Health Network (NHN) infrastructure, a multi-layered security concept has been developed. For the U4H trial an Information Integration Platform (IIP, [19]) has been utilised as implementation of the P-EHR system.

On link layer, a Virtual Private Network (VPN) tunnel is established between the mobile broadband communication module of the patient-tablet-PC device and a secure access gateway at the NHN[2]. Using the VPN-Identifier of the patient-tablet-PC (refer to Figure 2) and a corresponding symmetric key, stored in the tablet-PC and known to the secure access gateway, the tablet-PC device is authenticated to the gateway. Subsequently, bidirectional encryption of all traffic through the underlying PLMN and Internet infrastructure is established.

On application layer, the HTTPS protocol [20] is utilized for the e2e communication between the telehealth application on the patient-tablet-PC and the P-EHR system (IIP) within the VPN infrastructure of the NHN. The device-identifier of the patient-tablet-PC (refer to Figure 2) and a corresponding symmetric key known to the P-EHR system (IIP) is used for authentication, and for the establishment of bidirectional session encryption. By this, the transmission of all personal patient-related data from the telehealth application to the P-EHR system (IIP) is protected. In a potential future real deployment, asymmetric keys could alternatively be used to establish the session encryption, utilizing a Public Key Infrastructure (PKI). In that case, digital certificates would be issued and validated by a Certification Authority (CA) for the authentication of all patient tablet-PCs and for the P-EHR system (IIP).

Req6

As the communication of any client with the P-EHR system (IIP) via the interface for the patient-tablet-PCs is carried out through HTTPS (refer to the security solution for Req5 above), only authorized clients (authenticated by the correct device-identifier + key pair) can communicate with the P-EHR system (IIP). For that, the P-EHR system (IIP) carries our DAC based on the authenticated identifiers of the communication devices.

[1] For the U4H trial system, the "Secure Exam Browser (SEB)" (http://sourceforge.net/projects/seb/, free under GPL license) is used. It has been developed as Web-browser-environment to carry out online-exams safely, but allows changing any computer into a secure workstation.

[2] For the U4H trial system, a VPN solution from the Norwegian mobile network operator Telenor is being used, called Mobile Data Access (MDA) (http://www.telenorfusion.no/makeit/communication apis/mobiledataaccess/mdatechnicaldetails.jsp)

Req7

Similarly to the communication of patient-tablet-PCs with the P-EHR system (IIP) (refer to Req6), also the communication of any application or service node with the P-EHR system (IIP) utilizes HTTPS. The telehealth service component has to provide the valid service-identifier + key pair (refer to Figure 3) for the authentication towards the P-EHR system (IIP), in order to get authorized for corresponding data access. The DAC mechanism in the P-EHR system uses the authenticated service-identifiers.

In order to protect the privacy of personal patient data stored in the P-EHR system (IIP), an arbitrary patient-identifier is sent from the patient-tablet-PC together with all telehealth data, instead of the patient's name or any identifier that can easily be related to the patient. Only the telehealth service can map the patient-identifier to a specific patient, and hence pseudonymization of the patient data is applied when being communicated from the patient-tablet-PC to the telehealth service, and stored in the P-EHR system (IIP).

Req8

The P-EHR system (IIP) requires communication via HTTPS, in order to authenticate any application or service node, and to authorize incoming requests (refer to Req7). This also establishes bidirectional encryption of the data traffic between the P-EHR system (IIP) and the telehealth service, protecting the data against eavesdropping.

Req9

The HTTPS protocol is used for authentication of the telehealth service to the P-EHR system, and for bidirectional encryption of all messages exchanged between them (refer to Req8). Correspondingly, the P-EHR system uses its P-EHR Identifier + key pair (refer to Figure 3) for the authentication at the telehealth service, and the telehealth service use DAC based on the authenticated P-EHR identifiers to control the access.

Req10

Norway has developed a legally-binding "Code of Conduct for information security in the healthcare and care services sector" [11], defining an information security policy to ensure a secure interoperability of information system from all organizations operating within the National Health Network (NHN).

As the HIS infrastructure components for the U4H trial system, namely the P-EHR system (IIP) and telehealth service, are deployed within the NHN (refer to Figure 1), those components had to be compliant with the code. The code requires (as one example besides many other rules), that the information system components for the storage of any personal health-related data have to be physically installed on Norwegian territory. This excludes for example cloud-based solutions relying on storage systems being located outside Norway.

Req11

A unique patient-identifier, to be defined for all patient devices (as the U4H patient-tablet-PCs), is crucial for the availability of patient data when being inter-changed between cooperating EHR systems and health and care service systems (as the U4H telehealth service) within the HIS infrastructure (see Figure 3).

Such an identifier should be anonymized from other public known identifiers (as the patient name or the social security number), to protect the privacy of the patient data within the EHR systems (see also Req7). The mapping of that anonymous patient-identifier to a specific patient should only be technically available for the patient devices and the health and care services.

Health and Care Sources

Req12

The efficient and secure access to health and care related data from the remotely supervised patient is crucial for the cooperative approach of the U4H trial system. In order to achieve that, a Role-Based Access Control (RBAC) [21] approach has been chosen. Each individual health and care service provider staff uses the telehealth service terminal to authenticate her-/ himself at the common (i.e. shared by all health and care sources organizations) Web-portal of the telehealth service with her / his username + key pair (refer to Figure 4). Based on their authentication, the individual service providers are grouped according to their organization or institution, and get authorized to access personal data of those patients that are assigned for supervision by that organization.

A more detailed definition of access groups also allows distinguishing between specific access rights of different groups within each organization. For example, authenticated doctors can be authorized to perform different operations on the patient data than assistants or nurses.

Req13

The communication between the P-EHR system (IIP) and the telehealth service is secured by using the HTTPS protocol (refer to Req8 and Req9 above). Now, HTTPS is not used for client authentication and access control of the telehealth service terminals (which is done by RBAC at the telehealth service), but only for encryption of all messages between the telehealth service and each telehealth service terminal.

Discussion

The requirements towards the security policies and functionalities of the telehealth e2e system for the U4H trial have been addressed in the system development as described within this document. Compared to most other related work (see above) about security and privacy of eHealth systems and EHR data, we have followed a more practical approach towards the implementation of the proposed security concept. The trial operation will also be analysed with respect to security limitations or issues in the design, implementation or operation of the system.

During the design and development of the U4H trial system, which has followed a User-Centered Design (UCD) approach [22], the dependencies between security and usability became obvious. Usability is critical in particular for patients with physical or mental disabilities or limitations. Long (and presumably more secure) passwords are subject to be forgotten, or are problematic to be entered on the touch screen of a tablet-device for people with motoric difficulties. For telehealth services providers, as the nurses in the U4H telemedicine central (and also for other health and care sources), the efficiency of the system in the daily usage is crucial. The telehealth service terminal is shared by potentially many individual persons within one organization (as a telemedicine central), and the authentication and authorization procedure must not limit the timely access to potentially life-relevant information from supervised patients. Other methods, as e.g. biometric authentication or the use of personal SmartCards, or other devices, as

mobile phones supporting RFID technology [23] or NFC technology [24] for authentication, are subject to be integrated and tested in evolutions of the current trial system.

With regards to the general information architecture of the system, other alternatives would have been possible when it comes to the storage, transmission and processing of the patient-related information. Two potential extremes would have been to (1) collect, store and process all information in the PoC environment, e.g. on the patient's tablet-PC, or to (2) transmit all information directly to the Health & Care Sources (Figure 4), and to store and process it there. The main requirement of the telehealth system is to provide the different, collaborating health and care services with secure and efficient access to the patient information. In case of alternative (1), each telehealth service terminal would need e2e on-demand access to the patient-related information on a specific tablet-PC in the PoC environment. This would not be efficient for various reasons, as the unsynchronized data collection by the patient and the information request by the health and care service provider, due to the complex addressing of the data on each distributed patient-tablet-PC, and due to the risk of a specific tablet-PC lacking connectivity or just being switched-off when the health and care service provider requests information from that specific tablet-PC. The required robustness of the system makes it necessary to cope with a (temporary) loss of connectivity, and to retransmit any new patient-related information as soon as connectivity is recovered. Furthermore, the patient application on the tablet-PC shall provide autonomous recommendations to the patient in case of critical conditions, also when communication is not possible. Those requirements need the data to be stored and evaluated also on the tablet-PC, which is not the case in the alternative (2).

Alternative (2) would allow e2e security, i.e. the transmission of encrypted patient-related information from the patient-tablet-PC to the health service provider. In that case, each of the co-operating health service provider devices / applications would have to carry out the evaluation and decision support separately, and the data and information from the patient would either have to be forwarded from one service to another, or would have to be transmitted again, e2e from the patient-tablet-PC to the next health care service(s). Also, the patient-related data and information would not be available for other services in the national health network infrastructure if desired. For those reasons we have chosen a Services Oriented Architecture (SOA) approach with a cloud-technology-based infrastructure in the national health network, consisting of the P-EHR system (IIP) and the Telehealth Service, which provides a central, secure, Web-based access for the cooperating health and care sources. The e2e security in the proposed architecture is realized as secure chain of a few communication legs (Figure 4).

We have not carried out a formal study of vulnerabilities and potential attacks, nor a risk analysis, as this paper focusses on the initial security requirements and the corresponding system design and policies.

Further security related requirements, and also potential vulnerabilities and attacks, will arise with the integration of the P-EHR system (IIP) with other EHR systems or healthcare service components within the NHN, following the goal of system cooperation and integration. The P-EHR system (IIP) interface for the communication with the telehealth service via HTTPS provides for an easy and secure integration also with other services, though the content format of the messages transmitted securely via that interface will have to be adapted to the target system.

The patient-tablet-PC device for the U4H trial is provided and maintained by IT administrators of the trial partners, ensuring compliance with security policies in terms of software installation and configuration. In the deployment of real telehealth systems for large numbers of patients, this might lead to scalability-challenges related to the operation and maintenance (O&M) of the system. Such challenges can e.g. be the manual administration of patient accounts (refer to Req1 above), or the one-time connection of BT sensor devices to each patient tablet (refer to Req2). In future telehealth and telecare systems, it will be desired that also freely-available, off-the-shelf consumer devices can be utilized. In that case, the patients will have to install provided software on their tablet-PCs, or use the by default installed browser application. This bears the risk that - intended or unintended - malicious code gets installed in the patient device. That can potentially open a back-door into a secured national health network. It is therefore necessary to make precautions in the HIS infrastructure, to protect against potential vulnerabilities or attacks from patient devices. One potential option is to incorporate security precautions together with the patients' user credentials into a certified, secured app that would allow the patients to use their own device (as e.g. their personal smartphone). From the HIS infrastructure perspective only such a certified app would be required, instead of a defined and pre-configured mobile medical device.

Conclusion

The proposed security concept fulfils the identified security requirements for the U4H trial system. The system for the U4H trial, which is planned to run until summer 2016, has been developed according to the proposed security concept. The trial will help to identify potential security limitations and vulnerabilities, and further usability limitations (in particular related to security functionalities and policies) might be identified and utilized for improvements of the security concept.

Although the security concept and implementation has been developed for a specific trial system, the use cases and corresponding requirements of the telehealth services for remote patient supervision that are subject of the U4H project, represent typical characteristics of telehealth services. For that reason, the proposed security concept and the results and findings from the trial operation are also applicable for telehealth services for other patient groups, involving potentially other measurement devices, other questionnaires, other patient device types, and also other health and care service providers.

Emerging consumer market devices and applications for the collection of fitness and health related data, and for the transmission, evaluation and illustration on Web-portals, provided by cloud-based services, have similar security requirements as the studied telehealth service within the public health infrastructure. Consequently, the proposed security concept and trial results are also applicable for that type of services.

Security-related usability improvements can be expected from authentication mechanisms for patients and healthcare personal making use of biometric or Internet-of-Things (IoT) technologies (using RFID or NFC), and are subject for further studies.

Further impacts on the security requirements will arise from the expected integration of consumer health devices and services with the public telehealth services, and from the in-

creased integration and cooperation of EHR systems for various health and care services within the public HIS infrastructure.

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Emnet: a system for privacy-preserving statistical computing on distributed health data

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Abstract

Reuse of health data for epidemiological and health services research have enormous benefits for individuals and society. However, patients' and health institutions' have privacy concerns. Yet, the commonly used de-identification and consent-based privacy-preserving methods have limitations.

In this paper we described three generic requirements for privacy-preserving statistical computing on distributed health data. Then, we described building blocks for implementation on horizontally partitioned data.

For each research project, a set of participant health institutions locally store data extracts for the researchers' criteria. The data across the institutions collectively make the project data, which we refer to as virtual dataset.

We decomposed count, mean, standard deviation, variance, covariance, and Pearson's r into summation forms and described as an abstract computation graph, where sub-computations are nodes. Generic APIs that can be invoked at runtime to execute a node against a virtual dataset are defined. Then we described a proof of concept implementation called Emnet.

Emnet demonstrates that horizontally partitioned data reuse can be possible while preserving patients' and institutions' privacy. More statistical analyses can easily be included into Emnet as far as they can be decomposed into summation forms.

Keywords:

Computation Graph, Data Reuse, EHR, Health Information System, Health Services Research, Privacy, Secondary Use, Statistical Computing, Secure Multi-party Computation, Secure Summation, Virtual Dataset

Introduction

The increasing use of electronic health record systems led to collection of a large amount of electronic health data at health institutions. In Norway, electronic health record (EHR) was first introduced in the late 1970s and now the usage has expanded to all GPs [1,2]. Reuse of health data collected for patient treatments have a huge potential for individuals and society through epidemiological and health services research including comparative effectiveness research, population-based surveillance, treatment safety, quality assurance [3,4]

However, misuse of data released for research could harm individuals and health institutions. Therefore, the privacy concerns remain to be the main challenges that have limited wide reuse of health data. Several jurisdictional, national and international ethical and legal regulations [5–8] have been passed to protect individual's privacy while enabling data reuse for research. In general, most regulations including the Norwegian Health Research Act [9] allow reuse of personal identifying data through informed consent and de-identified data without consent. In addition, a research ethics committee (e.g. REK in Norway) could allow reuse of personal identifying data without consent under certain conditions.

Informed consent could result in data bias due to demographic differences between consenters and non-consenters [5–8]. In addition, the time and cost requirements are often not feasible for large studies [10]. Data de-identification is a very important method for privacy protection. However, it is often challenged between minimizing probability of re-identification and increasing data utility [11]. In addition, these techniques do not protect the privacy of the health institutions, which is also considered a factor that limits data reuse [12,13].

The data available in one institution may not give sufficient statistical power, especially for rare diseases where there are only few cases at individual institution. In addition, it may not be diverse enough to address population heterogeneity. Population-based surveillances require data from multiple institutions that cover broad geographical area. Therefore, the data required for epidemiological and health services research is often distributed across multiple institutions.

Secure multi-party computation (SMC) techniques deals with the problem of a set of health institutions $H = \{H_1, H_2, \ldots, H_m\}$ who wish to jointly compute on their private data, while ensuring security properties, such as data privacy and correctness of output. These techniques only reveal computation results at the end of a computation [14]. As a result, both individuals' and health institutions' privacy can be protected.

Various statistical query tools and distributed research networks such as SAFTINET [15], EHR4CR [16], SHRINE [17], PopMedNet [18], and SCANNER [19] have implemented statistical analyses on data distributed across multiple health institutions. These tools, except SCANNER, only support statistical count. In addition, they do not protect the privacy of the health institutions, as individual institution level count is disclosed. In contrast, SCANNER supports more statistical analyses and has implemented computation techniques that release aggregated statistics of multiple institutions' data, which also protects individual institutions privacy.

In this paper we described a framework for privacy-preserving computing on distributed health data using SMC techniques, and its implementation called *Emnet*. *Emnet* enables statistical

analyses on data horizontally partitioned across multiple health institutions' EHRs. Currently, commonly used statistical analyses are implemented including *count, mean, standard deviation, variance, covariance,* and *Pearson's r*. However, the framework enables to easily add statistical analyses that can be decomposed into summation forms.

The remainder of this paper is organized as follows. Materials and Methods section describes the privacy requirements, building blocks of *Emnet*, and the Result section describes the design and implementation of Emnet and an experiment performed. The Discussion section discusses the main results of the implementation, and strength and limitation of the work presented in the paper.

Materials and Methods

In this section we have described the privacy requirements, and building blocks of the framework, which is divided into data preparation and statistical analyses.

Requirements for privacy preserving computing

We have formulated three requirements for privacy-preserving statistical analyses on data distributed across multiple institutions:

1. Any entity should not learn a combined statistics of < k number of institutions data. To protect the privacy of both individuals and health institutions, a computation should not reveal individuals' information and statistics on a single institution's data. Therefore, information revealed during a computation contains aggregate of individuals' data from $\geq k$ number of health institutions. The value of k depends on the privacy requirements of the health institutions.

2. *Semi-honest trust model.* Health institutions can be trusted to follow SMC protocols with their true data. However, no institution should be able to learn private information about individuals and health institutions from the messages exchanged during a computation.

3. *Must not depend on trusted third party.* No third party should be trusted to collect personal identifying sensitive data from health institutions. However, semi-trusted third party (STTP) could be used in a computation to improve computation efficiency and coordination. The STTP is only trusted not to collude with health institutions and follows SMC protocols. The STTP role can be given to the Norwegian Institute of Public Health or any other public authority.

Virtual dataset

As specified in the above requirements, a tool cannot use a trusted third party that collects the data required for a given research project. Therefore, each institution executes a project data query that contains inclusion and exclusion criteria, and the required data extracts. Then, data extracts are locally stored in a separate database. The data sets at all institutions collectively make the data required for the research project. A unique `project_id` is assigned to virtual datasets to correctly identify during analyses. Since the data are not stored in a central repository, we refer to these data sets as virtual dataset.

The focus of this paper is on horizontally partitioned data, therefore, each institution independently execute data query. However, for vertically partitioned data, virtual dataset creation requires record linkage techniques [20] to identify eligible patients and extract required data sets. Even when the data are horizontally partitioned, patients at the health institutions might not be mutually exclusive, especially when the health institutions are in geographically close area. For example, in Norway, residents can change their GP twice a year. As a result, an individual's data could be available at multiple GPs. Thus, virtual dataset creation on horizontally partitioned data also might require record linkage in order to identify and remove duplicate records. Duplicate detection is outside the scope of this paper.

OpenEHR is open standard specifications for EHR that enable to attain semantic interoperability. DIPS ASA[1], an EHR vendor that covers 70% of Norwegian hospital EHR market, is implementing openEHR based EHR. Norwegian ICT also deployed a Clinical Knowledge Manager (CKM)[2] registry for archetypes management and governance. Therefore, we assume that there is a drive towards wide use of openEHR archetype based EHRs in the health institutions.

Archetype Query Language (AQL) is the language developed to perform queries on openEHR based EHRs. It is neutral to specific implementation of EHRs, as far as the EHRs are based on openEHR specifications. Therefore, following our assumption of openEHR based EHRs across the health institutions, we have used AQL as a language to specify research projects' data query in the virtual dataset creation.

In this paper, we have implemented *Emnet* using an openEHR repository called Think!EHR[3]. Think!EHR is Java implementation of the latest openEHR specification. We persist openEHR compatible EHR extracts into the platform and execute queries specified using AQL.

Secure summation protocol

Yao introduced SMC in 1982 and since then it has been widely studied [21]. However, until the last decade practical implementation has been missing due to lack of efficient protocols. Specialized protocols (i.e. secure summation [22–24], and secure scalar product [25]) are designed to achieve better efficiency by utilizing specific properties of a computation. Protocols using generic techniques (i.e. garbled circuit [26], Homomorphic encryption [27,28], and secret sharing [29]) are also improving. Therefore, practical implementation of SMC tools are starting to appear [30].

SMC protocols are designed to provide security guarantee against a specific adversarial model (i.e. semi-honest, covert, or malicious adversary). Complex techniques are used to ensure stronger security guarantee (covert and malicious adversary), often at the cost of computation efficiency [31]. Therefore, protocols secure against semi-honest adversary are more efficient and scalable, and sufficient for joint computation between health institutions, as we assume health institutions can be trusted to follow an SMC protocol.

Secure summation is one of the most commonly studied protocol and a building block for several secure computations [32]. Secure summation protocols are designed using different techniques, such as secrete sharing [33,34], Homomorphic encryption [35], and adding random number on a private value. Two random number based protocols that are secure against semi-honest adversary are presented below.

[1] https://www.dips.no/
[2] http://arketyper.no/ckm/
[3] http://www.marand-think.com/

Simple Secure sum

Simple secure sum protocols are implemented based on adding random number on a private value before sending to another institution [24,36]. A coordinator sends a random number R to the first node. The first node adds its private value S_1 on R and passes the result $R + S_1$ to the second node. The second node does the same and passes the result $R + S_1 + S_2$ to the third node. Finally, the coordinator subtracts R from the value received from the last node $R + S_1 + S_2 + \ldots + S_n$ to find the true sum of the private values $S_1 + S_2 + \ldots + S_n$.

The protocol is efficient because it: (1) uses a simple technique; (2) only require equal number of communication as the number of nodes; and (3) has linear increase in number of communications with increase in number of nodes. However, the protocol does not ensure privacy, if node i and $i + 2$ collude to find a private value of node $i + 1$. Ensuring privacy against colluding nodes is a common challenge [33].

SINE (Secured Intermediate iNformation Exchange)

Shuwang et al. [37] implemented a random number based protocol with a better collusion resistance. A coordinator sends a random number R_c to the first node. The first node adds its own random number R_1 on R_c and passes the result $(R_c + R_1)$ to the second node. The second node does the same and sends the result $(R_c + R_1 + R_2)$ to the third node. Finally, the coordinator subtracts R_c from the value received from the last node $(R_c + R_1 + R_2 + \cdots + R_n)$ to find the sum of the random numbers $(R_1 + R_2 + \cdots + R_n)$. Subsequently, all nodes send the sum of their private value and their random number $(R_1 + S_1, R_2 + S_2, \ldots,$ and $R_n + S_n)$ to the coordinator. To find the sum of private values, the coordinator sums together these values and subtracts the sum of random numbers $((R_1 + R_2 + \cdots + R_n) + (S_1 + S_2 + S_n)) - (R_1 + R_2 + \cdots + R_n)$.

The SINE protocol only reveals the sum of all institutions' private value. The protocol provides security guarantee even when $n - 1$ nodes, other than the coordinator, collude with each other. However, if a coordinator collude with node $i + 1$, it is possible to learn private information of institution i. For example, if the coordinator receives $R_c + R_1$ from node 2, it is possible to calculate R_1 and consequently calculate S_1 from $R_1 + S_1$ received from node 1. Therefore, unless the coordinator colludes with other nodes, the protocol remains secure. The protocol only trusts that the coordinator follows the protocol and don't collude with other nodes.

In the simple secure sum protocol, collusion of any two (i and $i + 2$) nodes enables to learn private information of node $i + 1$. However, in the SINE protocol, the collusion should be between the coordinator and another node. We argue that it is easier to keep one node (the coordinator) secure from outside adversary, therefore, the protocol have stronger security guarantee. This is achieved at the cost of increased number of communications $(2n - 1)$ and arithmetic additions. In general, choice of a secure protocol requires a balance between the required security guarantee and computation efficiency.

As a result, in this paper, we chose the SINE protocol for our implementation of privacy preserving distributed computing tool as it satisfies our requirements described above. And the coordinator in the protocol is designated as STTP in the requirements.

Computation graph

A large number of linear and non-linear statistical analyses can be decomposed into sub-computations of summation form [38]. Therefore, each sub-computation can be computed with subset of the available data and the results can be sum together to find the overall result. This makes sub-computations suitable to be parallelized [39–41].

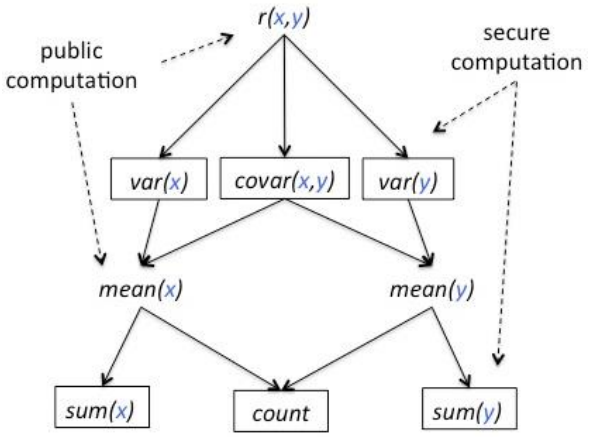
In this subsection, we have described decomposition of *count*, *mean*, *variance*, *standard deviation*, *covariance*, and *Pearson's r*, and how the decomposed statistical analyses can be computed in a privacy-preserving manner.

Let us assume three health institutions $\{H_1, H_2, H_3\}$ have horizontally partitioned data where each health institution has data of a unique set of patients that satisfied an inclusion and exclusion criteria. Let us further assume that the patients' ids at each institution are in the range of $[1, i]$, $[i + 1, n]$, and $[n + 1, m]$ (where $i > 0, n > i$ and $m > n$) respectively. The values of variables x and y are required for analyses.

Abstract computation graph

The statistical analyses chosen in this paper depend on one another: (1) *mean* x (y) depends on *sum of* x (y) and *count*; (2) *variance* of x (y) depends on *mean* of x (y); (3) *covariance* of x and y depends on *mean* of x and y; and (4) Pearson's r of x and y depends on *covariance* and *variance* of x and y. These dependencies are described as abstract computation graph shown in Figure 1. In the computation graph, the nodes represent statistical computations and the edges point to the direction of dependency between nodes. The dependency indicates that a node can be computed after computation of all the lower nodes that it depends on. For example, variance can be computed after summation and count.

As shown in Figure 1, there are two types of computations, such as secure and public computations. Computations that are in a box should be securely computed on individuals' data; and computations outside a box can be computed anywhere since they are based on only lower level nodes' results. Note that computation results of the nodes are considered as non-sensitive information.



The arrows point to the direction of dependency.

Figure 1 – Computation graph of summation, count, variance, covar-iance, and Pearson's r

The abstract computation graph does not have concrete information, such as where the input data are, and how the computation on each node is executed. How each analysis can be securely computed is described in the following subsection.

Table 1 – The operations provided by APIs that are implemented by different components of Emnet

Operations and parameters	Description
$LocalCompute\ (project\_id, equation,$ input$_values, variables, result_id)$	Locally executes an equation on individual patients' data
$SecureSum(project\_id,$ protocol$, addresses, result_id)$	Jointly run secure summation protocol on the results of $LocalCompute()$
$PublicCompute(project\_id, equation,$ input$_values, variables)$	Locally executes an equation on results of lower branch nodes on the graph

Concrete computation graph

Summation is the smallest statistical analysis; and other statistical analyses will be developed based on it. Summation of patients' values of x is shown in equation 1a. It can be expressed as equation 1b, where each institution locally sums their patients' values of x_j and then the local summation results of all institutions will be added together to find the total sum. The summation result from individual institution contains aggregate of its patients' data. Therefore, releasing it will not risk individuals' privacy. However, it can be considered private information of the health institution. Institutions privacy concerns can be avoided by using secure summation techniques that enable joint summation between institutions on their local summation results and only reveal the total summation result.

$$\boldsymbol{sum}(x) = \sum x_j \tag{1a}$$

$$\boldsymbol{sum}(x) = \sum_{j=1}^{i} x_j + \sum_{j=i+1}^{n} x_j + \sum_{j=n+1}^{m} x_j \tag{1b}$$

Therefore, the summation is divided into local computation and secure joint computation. Summation of individual level value is moved to where the data are located and can be computed much more efficiently. In contrast, since secure computations are more resource demanding, they are only used to aggregate local summation results.

A total count of eligible patients is a secure computation that is calculated from the sum of eligible patients in each institution. As shown in equation 2, each institution counts their local patients and then the local counts from all institutions are summed together using secure summation protocol.

$$\boldsymbol{count} = \boldsymbol{count}(H_1) + \boldsymbol{count}(H_2) + \boldsymbol{count}(H_3) \tag{2}$$

As shown in equation 3, *mean* of x is a public computation that is calculated from $sum(x)$ and $count$ results.

$$\boldsymbol{mean}\ (x) = \frac{\boldsymbol{sum}(x)}{\boldsymbol{count}} \tag{3}$$

Variance of x is a secure computation that is calculated from individuals' value of x_j and *mean* of x, as shown in equation 4a. Variance of an individual patient's value x_k is expressed in equation 4b. Variance can be expressed in equation 4c by substituting equation 4b into 4a, which becomes a summation problem and can be calculated in the same manner as the summation in equation 1a.

$$\boldsymbol{var}(x) = \frac{1}{count}\sum(x_j - \boldsymbol{mean}\ (x))^2 \tag{4a}$$

$$\boldsymbol{var}(x_k) = \frac{1}{count}(x_k - \boldsymbol{mean}\ (x))^2 \tag{4b}$$

$$\boldsymbol{var}(x) = \sum \boldsymbol{var}(x_j) \tag{4c}$$

A shown in equation 4d, standard deviation of x is a public computation that is calculated from variance of x result.

$$\boldsymbol{sdv}(x) = \sqrt{var(x)} \tag{4d}$$

Covariance of x and y is a secure computation that is calculated from individuals' value of x_j and y_j, and *mean* of x and y, as shown in equation 5a. Covariance of an individual patient's values of x_k and y_k is expressed in equation 5b. Covariance can be expressed in equation 5c by substituting equation 5b into 5a, which becomes a summation problem and can be calculated the same as the summation in equation 1a.

$$\boldsymbol{covar}(x,y) = \frac{1}{count}\sum(x_j - \boldsymbol{mean}\ (x))(y_j - \boldsymbol{mean}\ (y)) \tag{5a}$$

$$\boldsymbol{covar}(x_k,y_k) = \frac{1}{count}(x_k - \boldsymbol{mean}\ (x))(y_k - \boldsymbol{mean}\ (y)) \tag{5b}$$

$$\boldsymbol{covar}(x,y) = \sum \boldsymbol{covar}(x_j,y_j) \tag{5c}$$

Pearson´s r of x and y is a public computation that is calculated using covariance and variance values, as shown in equation 6a. Substituting covariance and variance equations (4a and 5a) into equation 6a, Pearson's r will be simplified to equation 6b.

$$\boldsymbol{r}(x,y) = \frac{\sum(x_j - \boldsymbol{mean}(x))(y_j - \boldsymbol{mean}(y))}{\sqrt{\sum(x_j - \boldsymbol{mean}(x))^2 \sum(y_j - \boldsymbol{mean}(y))^2}} \tag{6a}$$

$$\boldsymbol{r}(x,y) = \frac{\boldsymbol{covar}(x,y)}{\sqrt{\boldsymbol{var}(x)\boldsymbol{var}(y)}} \tag{6b}$$

The abstract computation graph shown in Figure 1 has a high level of abstraction and does not contain concrete computation details. It should be mapped to concrete computation graph for privacy preserving computing on a distributed data. Based on the discussions above, we have defined generic Application Programming Interfaces (APIs) for mapping from abstract to concrete computation graph at runtime. The APIs support the operations shown in Table 1.

As we have discussed above, execution of the secure computations on the abstract computation graph contain local and joint secure computations. Therefore, we have defined an API, called SecureComp API. Secure API includes two operations, such as $LocalCompute()$ and $SecureSum()$. Each secure computation node on the graph is mapped to consecutive execution of these operations. Since the secure computations are on private data, the API will be implemented at the health institutions.

1. $LocalCompute(project\_id, equation,$ input$_values, variables, result_id)$:

`project_id` is the id for a project that identify the virtual dataset on which the computation run; `equation` is name of the equation to be computed; `variables` are names of the variables to be computed on; $input\_values$ are results of lower level statistical analyses on the graph that the `equation` depends; and `result_id` is a unique id that will be assigned to the execution result. For example, to calculate variance of x, the `equation` is $var(x)$, $input\_values$ is value of *mean* of x, `variables` is x, and the `result_id` is a unique id.

2. $SecureSum(project\_id,$ protocol$, addresses, result_id)$:

`project_id` is the id for a project that identify the virtual dataset on which the computation run; `protocol` is name of a secure computation protocol to be used; `addresses` are addresses of peer health institutions that jointly compute the protocol; and `result_id` is a unique id for $LocalCompute()$ results that are jointly sum together. For example, to calculate variance of x, `addresses` are lists of addresses of $\{H_1, H_2, H_3\}$, `protocol`

is SINE secure summation protocol, and `result_id` is the same id assigned during execution of `LocalCompute()`.

As we have discussed above, execution of the public computations on the abstract computation graph are computed using only lower level nodes' computation results as input, that are not sensitive. Therefore, these computation can be computed either at the health institutions, STTP or client application, where the inputs are available. Therefore, we have defined an API called PublicComp API that includes `PublicCompute()` operation.

3. `PublicCompute(project_id, equation,` input`_values, variables)`:
`equation` is name of the statistical analysis to be computed; `input_values` are results of lower level statistical analyses on the graph that the `equation` depends; `project_id` is an id that enable to identify the `input_values` of a project; `variables` are names of the variables to be computed on. For example, to calculate *mean* of x, `equation` is *mean*, `variables` contain x and `input_values` are $sum(x)$ and *count* values.

Results

Design and Implementation

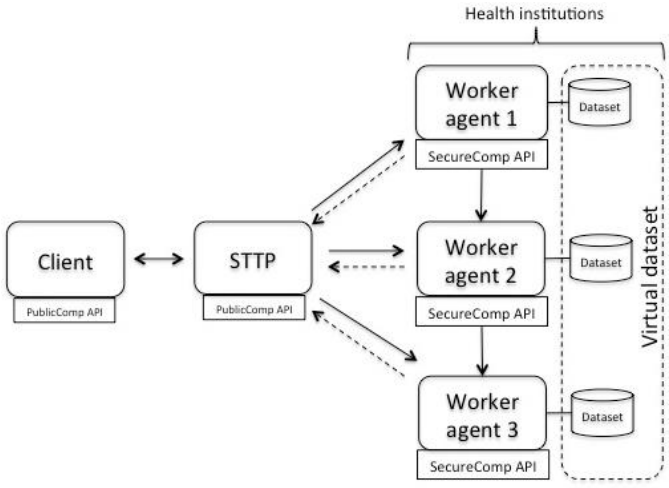
This section describes the design and proof of concept implementation of *Emnet* using the framework described above. Figure 2 shows main components of the tool.

Client – The Client is a web client application interface into *Emnet* and enables to specify a research project's data query, and statistical function and variables. It implemented the abstract computation graph and the Public API.

STTP – The STTP is a Java application gateway between the Client application and the health institutions, and it coordinates the overall executions. It implemented abstract computation graph, secure summation protocol and the Public API.

Worker agent – The Worker agent is a Java application that will be deployed at each health institution. It implemented secure summation protocols and the Secure API.

Emnet supports data preparation (*Virtual dataset creation*) and statistical analyses phases that are often required by research projects.



Client = Web application
STTP = Semi-Trusted Third Party

Figure 2 – Overall architecture of Emnet

Virtual dataset creation – a researcher specifies a data query on the Client application using the interface shown in Figure 3. The Client transforms into AQL and submits the query to the STTP who broadcasts it to each Worker agent. The Worker agents execute the AQL query against local openEHR and store the results locally in a MySQL database. Then, Worker agents reply the status of the query to STTP. The STTP executes descriptive statistics (currently only count of eligible patients)on the virtual dataset and returns results to the Client application.

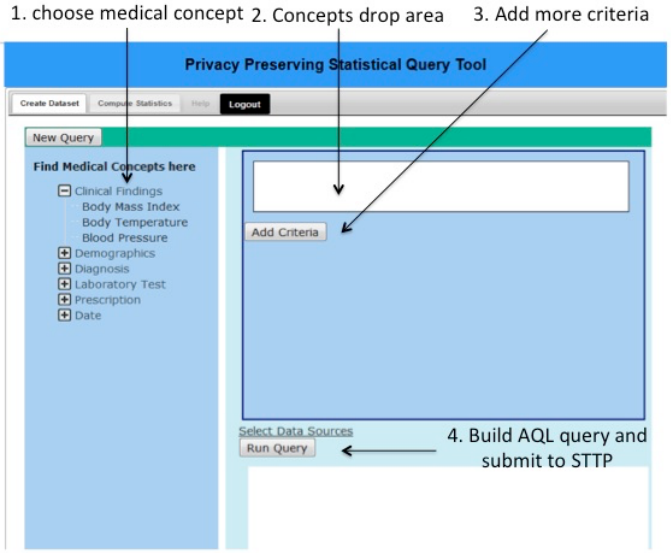


Figure 3 – Client interface to specify and execute virtual dataset cre-ation

Statistical analyses – similar to traditional statistical analyses tools, such as R[4] and SPSS[5], the user can specify the statistical function and variables on the Client application using the interface shown in Figure 4. If the requested statistical function is a public computation, for example *mean* of x, and if the lower branch of the abstract computation graph, such as count and $sum(x)$ are already calculated, the Client calls the public computation API. Otherwise the Client application submits the request to the STTP. STTP maps the required nodes on the abstract computation graph into concrete computation, by calling either the local Public API or Secure API at the Worker agents. The Worker agents execute the API calls on the local database. Finally, STTP returns the results to the Client.

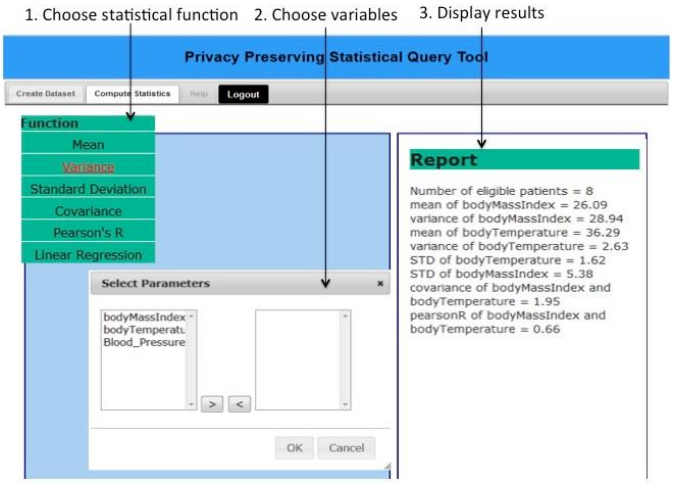


Figure 4 – Client interface to specify and execute statistical function on a virtual dataset

[4] http://www.r-project.org/

[5] http://www.spss.co.in/

Communication technology

In this section the technology used for communication between the different components of the architecture is described. *Emnet* is part of the Snow project[6], which is a distributed health data processing infrastructure deployed at multiple health institutions and labs in Norway [42]. The system implemented message-oriented communication using the Extensible Messaging and Presence Protocol (XMPP) [43]. The choice of the XMPP is due to the following reasons.

All healthcare service providers (i.e. GPs and hospitals) in Norway are connected via Norwegian Health Network, which is aimed to enable secure electronic communication between health institutions[7] The local networks of health institutions are considered more secure. Therefore, an institution should initiate all communications requests. The Snow system (40) has several software agents running at the health institution. Thus, each agents need to have its own address to receive requests sent to it.

XMPP technology is based on client/server architecture, similar to the SMTP protocol, where clients are interconnected through relaying servers. Therefore, each component contains an XMPP client identified by Jabber Id (JID) for communication. Each client authenticates using signed certificate and connects to the server, and the connection lasts long. Therefore, a client has address and connections are initiated from the health providers. In addition, XMPP enables point-to-point (i.e. between STTP and Worker agents, between Worker agents, and between Client and STTP), and multi-user (i.e. STTP broadcasts to Worker agents) messaging. In this paper, XMPP clients of the Worker agent and STTP are implemented using Smack library and on the Client web application Strophe library is used. Openfire server is used as XMPP server.

XMPP is a simple protocol that communicates over TCP sockets using XML messages. In addition, we have designed an XML message protocol that defines virtual dataset and statistical analysis requests and responses. The XML messages are sent inside XMPP XML message stanza.

Experiment

An experiment has been done based on a use case scenario designed to compute the correlation between human body temperature and body mass index. First, the two necessary archetypes, *Body Mass Index* and *Body Temperature*, were selected from Norwegian CKM and a template containing these archetypes was designed. Then, we prepared test openEHR data sets using the template and a virtual environment that simulates the real working environment with three distributed EHRs. On this virtual environment, we computed *Mean, Variance, Standard Deviation, Covariance* and finally *Pearson's r* (correlation) of Body Mass Index and Body Temperature.

Discussion

We have described a generic framework and implementation of *Emnet* for computing on horizontally partitioned distributed health data. The developed framework satisfies the three privacy requirements we defined to preserve the privacy of both individuals and health institutions. In addition, it enables institutions to maintain strong control over who compute, what analyses, and on what data. However, access control is outside the scope of this paper.

Currently, *Emnet* implements *count, mean, standard deviation, variance, covariance,* and *Pearson's r.* It can easily be extended to include more statistical analyses as far as they can be decomposed into summation form.

The building blocks for the framework can be divided into data preparation and statistical analyses phases. For each research project, health institutions locally store data extracts for criteria specified by the researchers'. These data extracts across the institutions collectively make the project data, which we refer as virtual dataset. Since a common data model is required across the health institutions, we make an assumption that the health institutions have openEHR-based health record systems.

We decomposed the statistical equations into sub-computations of summation form and created dependencies between them. We expressed these dependencies as an abstract computation graph, where each node represents a sub-computation. In order to execute a statistical analysis against a virtual dataset, all the lower level nodes should be executed first. We have described how the nodes can be executed using simple arithmetic and/or secure summation protocol. Then, we created an abstraction using APIs that can be invoked at runtime to execute a node on the abstract computation graph.

Comparison of *Emnet*'s computation efficiency with traditional statistical analyses tools such as R and SPSS, where the data are centrally stored, is invaluable. Evaluation of the computation efficiency will be a future work. However, we hypothesis that Emnet is efficient, because (1) computations that require individual patients data are computed locally and all health institutions compute in parallel; and (2) only aggregations of local results are computed using simple secure summation protocol.

In general, as the number of participating health institutions increases, efficiency of statistical analyses might decrease. However, in [44] we have described a technique to maintain constant efficiency independent of the number of participants. As a result, *Emnet* can be scalable. Implementation of the technique into the tool will be a future work.

Despite the benefits of health data reuse, quality of data and their suitability for research is a concern [45]. The main benefit of the virtual dataset is that it enables to do either clerical review or run computer programs to improve the data quality without modifying the original data. In addition, it supports to store preprocessing and intermediate results of statistical analyses.

In contrast to de-identification [11], the technique presented in the paper preserves privacy without modifying or removing data variables. As a result, the quality of research data is not affected due to the privacy-preserving computation.

Both the public [46] and healthcare professionals [47,48] demonstrated positive view towards reuse of health data for research as long as the privacy and other concerns are addressed. Emnet could increases health institutions' and patients' willingness for reuse of their data for research. As a result, enormous benefits of health data reuse can be unlocked.

[6] The Snow system client application is available at http://snow.telemed.no/

[7] https://www.nhn.no/english/Pages/about.aspx

In general, Emnet will increase researchers' access to health data with the following added benefits, (1) better privacy; (2) quality of data; and (3) minimized time and cost to collect data. More health research enables to improve effectiveness, efficiency and quality of care. Consequently, the public will benefit.

The framework described in this paper can be applied for any domain outside health, where there is a need for joint computation on private data while maintaining privacy. In addition, it is light weighted for implementation on small devices, such as smart phones to jointly compute on apps' data of a set of individuals.

Acknowledgments

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Recommendations on a Test Infrastructure for Evaluation of Touchscreen Assistive Technology for Visually Impaired Users

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Abstract

Mobile technologies' touchscreen allows the use of choreography of gestures to interact with the user interface. Relevant aspects in mobile technology design become crucial when targeting users with disabilities. For instance, when assistive technology is designed to support speech interaction between visually impaired users and a system, accessibility and ease-of-use of such technology should be included in the usability and technical evaluation of their effectiveness. This paper presents the analysis of the technical and physical infrastructure of a controlled laboratory environment for user evaluations made in the research project "Visually impaired users touching the screen - A user evaluation of assistive technology" where VoiceOver, a screen reader in Apple Inc. products was tested. The paper reports on challenges related to the use of the test infrastructure, such as how to obtain valuable data when interactive high-speed gestures are performed and how to optimise the recording and synchronisation between audio and video data. The lessons learned by the research group showed that there are effective alternatives for each challenge, and these should be customised for each particular test, type of participants and device.

Keywords:
eInclusion, visually impaired users, speech-assisted navigation, touch gestures, accessibility, assistive technology, laboratory infrastructure, usability, health in-formatics

Introduction

Mobile technology is used today in people's life [1][2][3] for information and communication purposes. Mobile technologies usually incorporate touchscreen for the interaction between the user and device's interface. Touchscreen technologies [4][5] allow users to interact with a system through touch gestures made with their fingers. However, this type of interaction becomes a challenge for visually impaired users who cannot see the screen with sufficient detail to distinguish interface dimensions, elements inside the interface and buttons without tactile feedback [6]. Globally, the number of people with visual impairment is estimated to be 285 million. The main impairment causes are uncorrected refractive errors, such as myopia, hyperopia or astigmatism, and cataracts. 39 million people are estimated to be blind because of cataracts [7][8]. The International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) provides a categorisation for visual impairments: *normal vision*, *moderate visual impairment*, *severe visual impairment* and *blindness* [9]. WHO estimates that about 65 % of visually impaired people are older than 50 years and 90% live in developing countries [7].

In order to improve the accessibility and the interaction with the user interface, several solutions of assistive technology are available in the market for visually impaired users [10][11]. In this context, the research project "Visually impaired users touching the screen - A user evaluation of assistive technology", aimed to evaluate the interaction of visually impaired users using VoiceOver, a built-in screen reader in Apple Inc. products (provided by default since April 2005, Mac OS X 10.4) that allows users to interact with the user interface (UI) through gesture-based (since June 2009, iPhone 3GS OS 3.0) speech-assisted navigation. One of the major aspects of the evaluation of touchscreen assistive technology is how accessible the UI is for users with and without visual impairments. For an optimal gathering of test data, a physical and technical infrastructure is essential to support a multiple visual and audio perspective for data collection of such interaction. The collected data will form the basis of a retrospective analysis where touch interaction details observed in the recordings can be coupled with comments and observations obtained during the test. It is relevant to note that because users are visually impaired, the touch gestures will be only seen by the researchers, and therefore a slow pace observation of them is necessary after the test to build up a meaningful analysis of the interaction. Another key requirement of a mobile device with assistive technology is the usability of the system. Considering the sensory limitations of the target user group, the assistive technology should be intuitive, with an optimal presentation of the information facilitating a general understanding of the functionality and distribution of the UI.

This paper presents the challenges related to the testing of touchscreen assistive technology from the perspective of how the technical aspects of a laboratory infrastructure can be used in an Information and Communication Technologies (ICT) and Health Informatics research environment. It reports on the lessons learned by the research group exploring how to effectively carry out accessibility and usability evaluations of the mobile applications and technologies used in the research project.

The research questions (RQs) of this study were:

RQ1: What technical infrastructure is suitable for evaluation of touchscreen assistive technology with disabled users?

RQ2: What are the learned lessons transferable for testing other mobile technologies?

Following this introduction, an overview of related research is presented. Analysis of the use of the technical and physical test infrastructure for user evaluations of touchscreen assistive technology and reflections on lessons learned during the project are presented in the next sections. Later, the discussion section highlights the benefits of having an optimal infrastructure for the type of the evaluation carried out. Finally, the conclusions regarding the characteristics of a technical infrastructure for accessibility and usability evaluations of touchscreen assistive technology are drawn.

Related Research/Background

Assistive technology [12][13][14] includes devices or technological solutions that assist people with disabilities. Assistive technology is used as an alternative way of performing actions or interactions with technology. The accessibility [15][16] of a technology refers to how accessible a technology is regardless of user's ability. Leporini *et al.* [17] investigated the interaction between Apple touchscreen devices with preinstalled VoiceOver screen reader through a usability inspection of the UI and an online survey with feedback from 55 blind users. They found that VoiceOver made the devices more accessible, but operations such as writing long text took too long or were uncomfortable for users. McGookin *et al.* [6] presented a study with 12 visually impaired participants operating two different touchscreen-based MP3players. They found that participants could generally use the devices but they encountered problems in doing short time operations. They evaluated the touchscreen accessibility and provided guidelines for touchscreen technology design for visually impaired users. Phillips and Zao [18] did a study on user acceptance of assistive technology. They found that almost 30% of assistive devices were rejected by the users. Factors such as *device performance, procurement* and *user need* played an important role because they were related to the acceptance of technology. They concluded that involving users and focusing on their long-term needs would enhance user satisfaction. Demers *et al.* [19][20] described the development of a clinical instrument for evaluation of user satisfaction with assistive technology devices. They described several variables used to help user assess and rate the degree of satisfaction with assistive technology in a structured way. Svanæs *et al.* [21] presented a study on mobile ICT in clinical settings. They showed that the design of the graphical user interface (GUI) affects usability, ergonomic and social aspects. They concluded that usability tests of mobile ICT should be performed in a simulation environment with a high level of realism. Further, they stated that usability testing of mobile ICT for healthcare requires new ways of designing, recording and analysing the data collected.

Test Infrastructure

In order to test the infrastructure for evaluation of touchscreen accessibility, 6 visually impaired users participated in a study where they individually performed representative tasks related to gesture's performance and task solving using the screen reader VoiceOver.

The Research Group

The evaluation research team consisted of three members with multidisciplinary background: one member with experience from teaching and supporting visually impaired students with assistive technology; the other two members with professional experience in health, ICT and human-computer interaction (HCI). All had professional experience in working with visually impaired people. One team member was the moderator in all the tests. In addition, an external senior researcher advised regarding planning and execution of the research study. A technician provided technical expertise and was available in case of need for assistance during the tests.

Test Environment Infrastructure

The evaluation of mobile assistive technology was held in the Usability Laboratory at the Centre for eHealth and Healthcare Technology of the University of Agder, Norway. The Usability Laboratory had two rooms: the Test room and the Observation room, connected through one-way mirror (visualisation from the Observation room towards the Test room). The complete infrastructure is described in details in [22].

The technical infrastructure for the usability evaluation is illustrated in Figure 1. The moderator and participant were in the Test room, while the other two members of the research team were in the Observation room. The moderator sat down on a table in the middle of the Test room with the participant besides. The elements used in the room were a smartphone, a task list, a table microphone and a tablet for additional sound-recording. The participant had the smartphone in their hands. The room had 2 IP cameras, 1 fixed and 1 portable with an external microphone. The Observation room had a desktop PC connected to three monitors. The observers followed the evaluation, remotely controlled the zooming of the fixed camera and made recordings and annotations of the test sessions.

The Observation room and the Test room were connected with a dedicated segment of the LAN infrastructure of the Centre for eHealth and Healthcare Technology, making use of VLAN technology. This connection was used for the IP-based streaming of video and audio signals from the Test room to the Observation room, using Wirecast [23] as capture and encoding software.

Materials

The material used during the study is presented below grouped by rooms for reproducibility and information purposes.

Test room:

- Apple Inc. iPhone 4 MD128B/A iOS 7.1.2 with VoiceOver activated.
- Fixed Camera: SONY BRCZ330 HD 1/3 1CMOS P/T/Z 18x Optical Zoom (72x with Digital Zoom) Colour Video Camera.
- Portable Camera: SONY HXR-NX30 Series.
- Apple Inc. iPad MD543KN/A iOS 8.1 for additional sound-recording.
- Sennheiser e912 Condenser Boundary Microphone.
- Landline phone communication

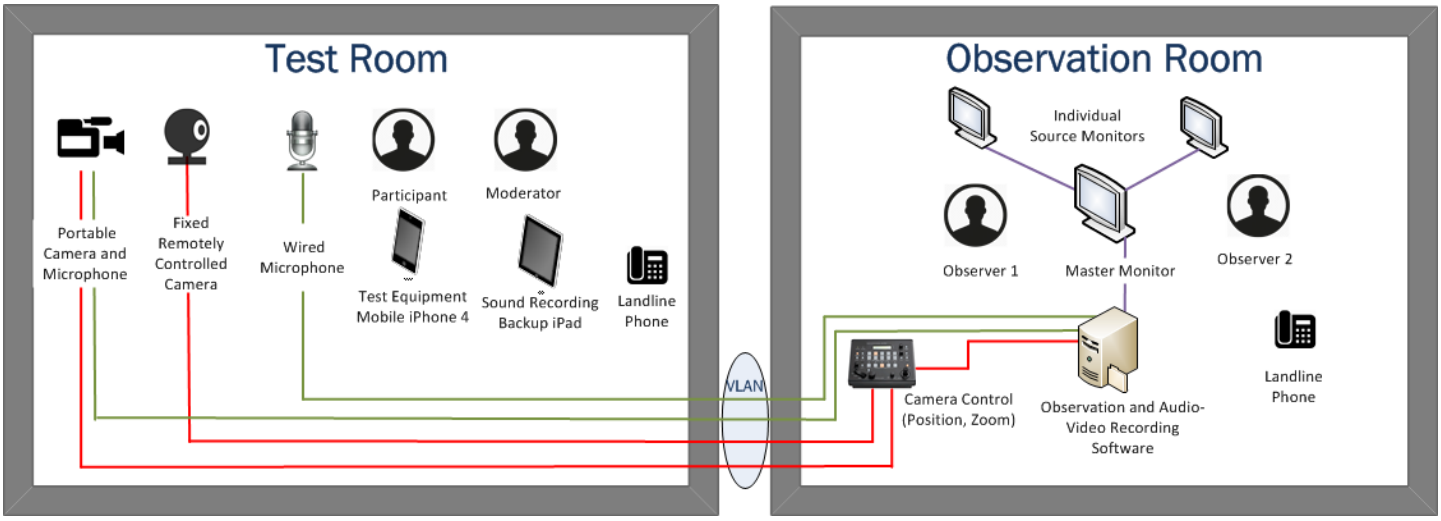

Figure 1 - Scheme of the technical infrastructure for evaluation of mobile assistive technology

Observation room:

- Stationary PC: HP Z220 CMT Workstation, Intel Core i7-3770. CPU@3.4 GHZ, 24GB RAM, Windows 7 Professional SP1 64 bit.
  Monitor: 3x HP Compaq LA2405x
- Remote controller: SONY IP Remote Controller RM-IP10.
- Streaming: 2x Teradek RX Cube-455 TCP/IP 1080p H.264.
- Software Wirecast 4.3.1.
- Landline phone communication.

Data Collection

The test sessions were audio-visually recorded in the F4v video file format, exported to the Windows Media Video (WMV) format and then imported from QSR NVIVO 10 [24]. The recordings from two independent audio-visual sources were merged into one video file using the software Wirecast v.4.3.1, with multiple video perspectives and a single audio channel. In addition, annotations were made by the evaluation team during the test. After the evaluation, all recordings were transcribed verbatim and divided into categories for a qualitative content analysis [25]. The data collection of the study was approved by the Norwegian Social Science Data Services (NSD) [26] with the project number 40636.

Lessons Learned from the Test

This section presents the challenges and lessons learned about the technical infrastructure in the laboratory through the evaluation of touchscreen mobile assistive technology.

Optimisation of the Test Environment

Before the start of each test session, participants were asked to sit in a natural and relaxed position with the mobile phone in their hands. The cameras were then adjusted for optimal recording of the screen and hand gestures. The remote controlled camera zoomed on the mobile interface, visualised in full screen on one of the PC monitors in the Observation room. The portable camera was placed near the participant's side. In general, both cameras were slightly angled from above to record the interaction and provide the best possible shot of mobile user interface and participant's hands.

Moderator's View

The moderator was sitting beside the test participant to guide them through the tasks on the smartphone. Two factors negatively influenced the accurate observation of the interaction between participant and the device: the mobile device's small-size screen and the high speed of gestures.

In order to improve the moderator's view and allow the possibility of following the actions of the participant and screen response on-live, a screen capture tool (e.g., software Mirroring 360 [27], Apple Airplay [28]) could be used to show the screen interface on a larger external screen in the Test room. The screen interface could be simultaneously recorded by a screen recording program (e.g., software Snagit [29]). In order to observe and record the finger interaction and the system's response a screen capture tool (e.g., UX Recorder [30]) would also allow detecting, in time, when the hand interaction touches the interface. To closely observe gesture choreography, one common alternative in mobile usability testing is to place a macro-focused camera on the mobile phone to record user's hand gestures. Its signal could also be displayed on an external screen in the Test room if necessary. However, its suitability for testing visually impaired users has not been yet tested by the researchers.

Clarity of Screen Reader Sound for Moderator

In the Test room, the moderator had in some cases difficulty to adequately listen the feedback from the VoiceOver, even when the settings were at maximum volume for the screen reader.

In order to improve the sound quality, Bluetooth or dedicated software such as Mirroring 360 could be used for transmission of sound to an external loudspeaker in the room. The use of external loudspeaker could increase the perception of sound for the moderator. However, this would create a new different setting for a test participant that would not directly hear the sound as usual from the mobile device, but instead from an external loudspeaker.

Effective communication between research team members was essential to perform on time any readjustment of equipment or task necessary during the test. The landline phone communication was available between the two rooms and used when the test was being recorded and none of the researchers could leave the Observation room. In order to improve the communication, an ear plug to connect moderator

to observers watching the recordings would allow instant 1-way communication to do the adjustments without interrupting the test session.

Quality Optimisation of the Recordings

A high level of quality of the recordings is generally recommended for an optimal retrospective analysis of data in usability studies. The audio-visual recordings in the usability evaluation had a F4v video file format and were converted to the WMV format to be imported into the qualitative analysis program QSR NVIVO 10, used for watching and transcription purposes. Several factors associated with the quality of video and sound were identified that influenced the analysis in detail of the actions performed by participants during task execution. They are next described in 4 subcategories: visual improvements, sound improvements, video and sound synchronisation and storage.

Visual Improvements

In the Test room, the light source was directed down to the floor. Some footage showed glares that impeded the correct view of the mobile interface during the analysis. An alternative would be to have a light source directed to the walls of the Test room instead of directly down to the floor. In addition, a *dimmer* device could be used to reduce the brightness of the light sources that produced the glare. The Test room had one remotely controlled camera and another that was controlled manually. An advantage would be to also have the second camera remotely controlled for adjusting the angle and the zooming in case of glare or unexpected movement by a participant. Participant's gestures were usually performed at high speed. This impeded the ability to accurately distinguish the finger gesture several times when retrospectively analysing the video at normal speed. In those cases, instead of using QSR NVIVO 10 that only allowed reducing up to 50% of the speed, the software Cyberlink [31] was chosen to show the footage even at lower speed, down to 20%.

Sound Improvements

In the recordings, in spite of the fact of having one wired microphone placed on the table and another on the external camera, the quality of sound reception was not sufficient at times. When testing mobile assistive technology, it should be taken into consideration that the VoiceOver of the smartphone gives a speech feedback that may interfere with other sounds listened during the test, e.g., participant's answers or comments. For instance, there were up to three sound sources (i.e., moderator's voice, participant's voice, smartphone's VoiceOver speech) recorded simultaneously in several occasions. Recording overlapped sound sources obstaculised the accurate perception of the sound during the analysis phase. It would be then advised to try to implement the policy of speaking one at time during the test, even though the VoiceOver could interfere at any point. A wireless microphone worn by participant and moderator would increase sound reception quality in addition to a stable sound source place nearby. This would remove the constraint of placing the participant beside the table microphone and allow them to freely move around.

In the case of insufficient quality of sound recordings, an additional sound recording during the session is recommended as a backup. In the usability evaluation, a tablet device was used as backup for sound recording; very useful when sound recordings from the main sources were not optimal. To improve the sound during the analysis, the VLC media player [32] was used to adjust frequencies of sound.

Video and Sound Synchronisation

When analyzing the recordings, video and sound signals were not perfectly synchronized, with a delay of the video signal of approximately 0.5 s. regarding the audio one. This was probably due to the network latency added to the video signal streaming. This issue that may seem generally unimportant, is however especially relevant when the study includes rapid movements and actions of high order of magnitude. A potential solution could be to record all sources separately with digital audio workstation software (e.g., ProTools by Avid [33]) and transfer them to an editing program (e.g., Cyberlink [30], Final Cut Pro X [34] or Adobe Premiere Pro CC [35]). In such programs, the synchronisation can be adjusted frame by frame. This software also allows discretionary switching between the different video and sound recordings and zooming. However, substantial technical knowledge is required for the correct use of these digital audio edition programs. Due to the network latency, data transmission through direct wire is usually better than streaming. A FireWire cable [36] could be used for high-speed and synchronous real-time data transfer; this also would separate the storage into different files.

Storage

In order to reduce the risk of data loss, a redundancy in the data collection system is advisable. During the test sessions, one incident resulted in 10 minutes of footage loss due to a recording software error. In that case, the portable camera provided an additional recording that made the analysis possible without repeating the task. Test repetitions should be avoided when possible, because of the risk of biasing the data collection when repeating the same task and the inherent difficulty of recruiting visually impaired participants. An additional solution would be to record the data gathered in two independent hard disk drives from two different computers. This alternative solution has been implemented into the technical infrastructure of the laboratory after the incident. A high level of quality of the recordings is generally recommended when a sufficient storage space is available. In other case, a trade-off between space and video quality should be made in advance.

Discussion

This paper has presented a technical and physical infrastructure to carry out evaluations of mobile assistive technology with visually impaired users. The preparation and the execution of the laboratory test led to a series of reflections and lessons learned by the research team that are considered useful for future usability and accessibility research with visually impaired users. In addition, several lessons can be inclusively applied when testing touch interaction with able-bodied users.

An infrastructure suitable for the evaluation of touchscreen assistive technology with disabled users (RQ1) would be one that firstly optimises data collection; secondly, allows the research team to do an effective retrospective analysis under different and more demanding conditions than when testing able-bodied users; and thirdly does not interfere or trouble the comfortability, safety and trust of the users. Having in mind that sensory-limited users do not have the same level of access to information, leaving aside that not all information channels are designed with this type of users in mind, their

comfort and tranquillity are crucial to avoid interference and distortion of the test and results.

The proposed infrastructure contributes to a controlled scenario for evaluation; however, it is not exempted of potential improvements that can qualitatively benefit future tests and be applied to other mobile technologies and able-bodied users (RQ2). For instance, to evaluate the accessibility of touchscreens and the choreography of gestures associated, the video recordings require a sufficient quality that allows zooming in with great detail and professional software video visualisation to substantially reduce the speed for optimal viewing. In addition, the data should be collected through multimodal channels (e.g., video and audio), having the necessary tools to synchronise audio and video signals, which, if streamed over a network, usually incorporate latency. This synchronisation is the key to detect and understand the correlation between the sounds of the interface related to participant's touch on the screen. Finally, due to the inherent difficulties of recruiting disabled users and the discomfort of having to unnecessarily repeat tasks and test sessions, redundancy in data collection is strongly advise through the use of two or more independent sources of data storage, i.e., two different computers.

Conclusion

Mobile assistive technology for touchscreens is widely used by multiple user groups. When designing, testing and evaluating technology with sensory-limited users, there is a specific need to balance the interface design and functionality on the one hand and the usability and accessibility of mobile assistive technology on the other. Accessibility and usability evaluations are essential in order to improve not only the interface design of the mobile assistive technology, but also the interactions between devices and users. These evaluations are enabled by a laboratory environment, where the research team has full control over all steps of the test scenario, including tasks and interactions between the test participants and the technology used. In particular, for mobile assistive technology that involves visually impaired users, accessibility and usability evaluation aids to identify interaction issues that lead to uncover design flaws, obstacles to successfully use the device and potential adjustments of the system to accommodate user sensory limitations. This paper has analysed the physical and technical infrastructure used for evaluating a mobile user interface using a gesture-based speech-assisted interface navigation system, Apple Inc. VoiceOver., within the research project *"Visually impaired users touching the screen - A user evaluation"*. The test infrastructure provided sufficient control over the factors involved in the test at the same time that brought the flexibility to dynamically adjust the environment for adequate data collection.

Empirical research data obtained from the usability and accessibility evaluation using the infrastructure described in this paper will be published and available for the research community. Future research in the agenda of the authors includes the test of the infrastructure including the technical improvements proposed in this paper with other user groups, including other vendors and solutions of assistive technology for operating mobile user interfaces.

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Diabetes Automata: Software Engine for Blood Glucose Level Simulation

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Abstract

For individuals with diabetes to live a healthy life, they must balance carbohydrate intake, insulin injections, physical activity, and monitoring of blood glucose levels. For adolescents with diabetes, this can be challenging – measuring blood glucose and injecting insulin often feels awkward, especially in public areas. In the long run, the result of not managing the factors affecting their diabetes can cause serious consequences. In order to motivate this particular group with diabetes to maintain recommended levels of blood glucose, serious games can be used. The Diabetes Automata project is a part of the research being done on serious games for diabetes at the Norwegian Centre for Integrated Care and Telemedicine. In the project, we have developed a prototype version of a software engine on which diabetes-related serious games, simulators and other tools for diabetes management on various platforms can be based. The Diabetes Automata calculates blood glucose levels based upon relevant patient-gathered data such as insulin, carbohydrates, physical activity, and the user's biometry. The prototype is not yet evaluated.

Keywords:

Blood Glucose Simulation, Diabetes, Mobile Application, Software engine

Introduction

Diabetes mellitus is a group of metabolic diseases characterized by high blood glucose (BG) levels resulting from defects in insulin secretion, its action, or both. It is a chronic disease that occurs either when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. WHO estimates that 347 million people worldwide have diabetes [1]. Type 1 diabetes (T1D) is characterized by absolute deficiency of insulin production, daily administration of insulin, and occurs in about 10% of the cases [1]. The cause of type 1 diabetes is not known and it is not preventable, according to current knowledge about the disease [1].

Good management of one's BG levels makes living with diabetes much easier. Most people with T1D use a blood glucose meter for BG monitoring and insulin pen or pump for insulin injections. Through frequent measurements and injections of different types of insulin, people with diabetes can generally maintain a BG level within the recommended range. For adolescents with T1D, managing this important element can be a challenge. Measuring BG and taking insulin can be perceived by adolescents as stigmatising activities. Sometimes patients forget to administer insulin injections or underestimate the effect of the amount of carbohydrates they have eaten.

However, neglecting the disease leads to serious long-term consequences. Therefore, adolescents must be made aware of the long-term consequences of poor blood glucose management and be motivated to adequately manage their diabetes– for example, using their own media channels. One such channel for achieving this is serious games.

Diabetes Automata is a master's project under development that will be finished during the summer 2015. In this project, we have developed a software engine prototype that can be used in diabetes-related serious games, simulators and other tools on various platforms. The engine calculates and provides the blood glucose level based upon relevant patient-gathered background data such as insulin, carbohydrates, physical activity, along with the user's biometry such as age, gender, height and weight.

Materials and Methods

The design of the Diabetes Automata has been divided into two parts: the engine itself, and a demonstrator application (app) that is used to test the engine's functionality and illustrate its potential use. The engine is developed in Java to make it possible for external applications to use it through the engine's API (Application Programming Interface).

The Diabetes Automata offers the opportunity to run blood glucose simulation at various speeds that can be set through the demonstrator application's user interface: from 1 second per second (real-time) to 99 minutes per second. The demonstrator app is an Android-based simulator with a simple design, which displays various types of output information in a form of text, numbers, and graphs. The prototype can run a customized simulation with the opportunity to save the current state of the simulation and then load and continue it later. In addition, simulations can be based on records from the Diabetes Diary, a mobile self-management application for people with diabetes developed by the Norwegian Centre for Integrated Care and Telemedicine (NST) [2-4]. See Figure 8.

The Diabetes Automata has a modular architecture, which provides certain advantages. For example, it is easier for the engine developers to add, change, and edit code to play with different formulas and equations, and to run the modules in parallel. The architecture is shown in Figure 1.

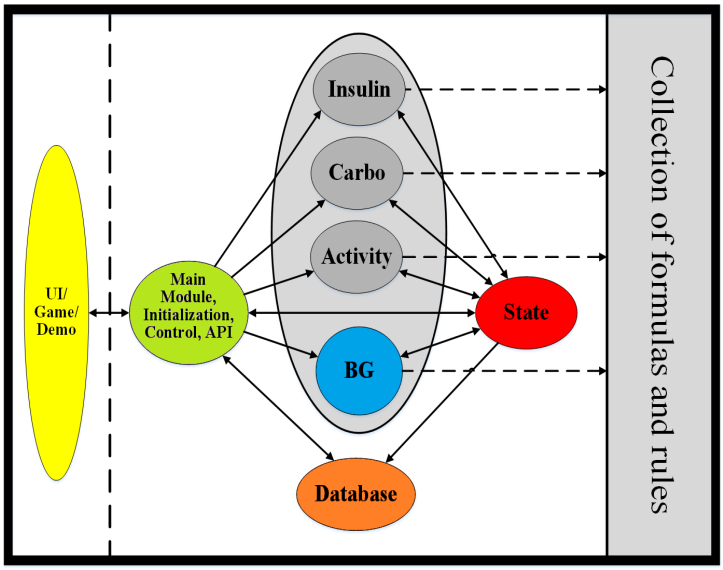

Figure 1 - Diabetes Automata Engine Architecture

The engine contains several modules that are described below.

Carbohydrates Module

First, the engine calculates the user's glucose sensitivity, which is the number of grams of glucose (or carbohydrate with glycaemic index (GI) = 100) that increase the blood glucose level by 1 mmol/L. The calculation of Glucose Sensitivity is based upon Table 1 and the set of functions represented in Figure 2.

Table 1 - BG rise by 1 g glucose depending on body weight. (Source [5])

Body weight (kg)	1 gram glucose will raise BG by (mmol/L):
16	1.11
32	0.56
48	0.39
64	0.28
80	0.22
95	0.18
111	0.17
128	0.14
143	0.12

Glucose Sensitivity (g/mmol) is calculated as follows (see Figure 2). The engine calculates the number of mmol increased by 1g of glucose (y) for the user's weight (x), and then divides 1 by the result.

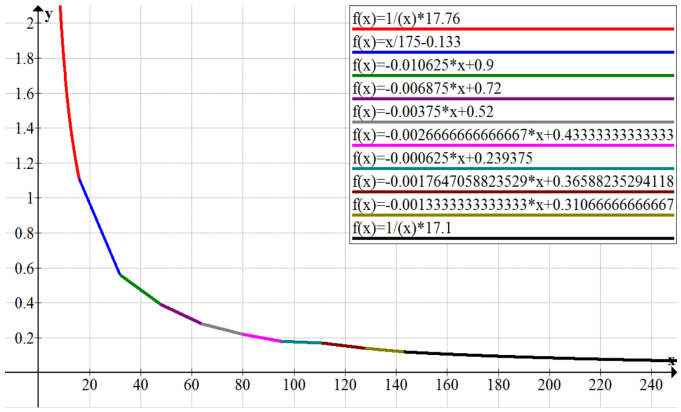

Figure 2 - Glucose Sensitivity in mmol/L per gram of glucose, where x is weight and y is a number of mmol increased by 1 gram of glucose. Figure is created by the authors and based on the data from Table 1 (the data is used as (x,y)-coordinates joined to each other).

Further the duration of action is calculated. The duration depends on GI (see Figure 4) of the engine record and is calculated by the function represented in Figure 3.

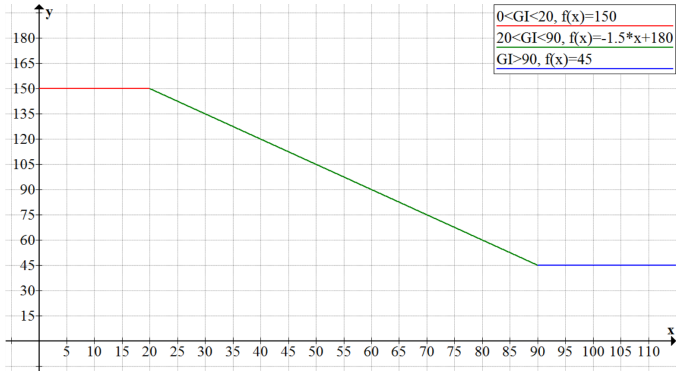

Figure 3 - Calculation of the duration of action of a carbohy-drate simulation record. X-axis represents GI, Y-axis repre-sents minutes.

Figure 4 shows the difference between the duration and the effect of high GI and low GI, for a non-diabetic person.

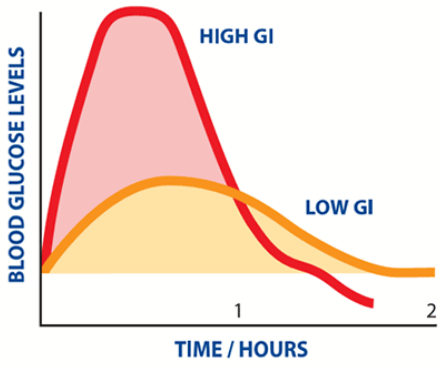

Figure 4 - Duration and action of high GI and low GI, gener-ally. (Source [6])]

Next step of the algorithm is to calculate the influence of work done for the current moment in time, in percent. The result

depends on the duration, the example curves for 45, 60, 90 and 120 minutes are represented in Figure 5.

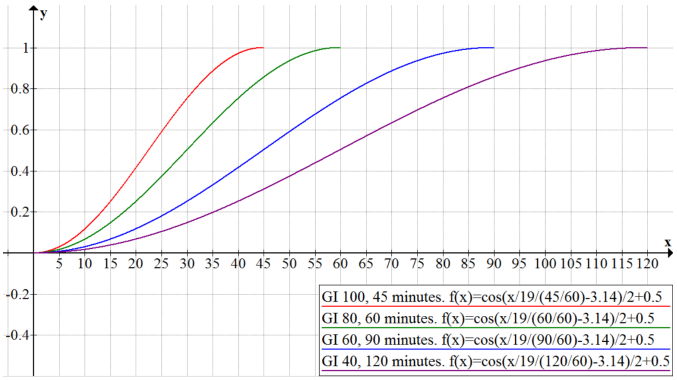

Figure 5 - Percentage BG increase from high GI food over time, where x is time in minutes and y is the effect. 1 on Y-axis represents 100%.

The last step done by the Carbohydrates Module is to calculate the rise in blood glucose in the current moment in time. The calculation is as follows.

```
BG Rise (mmol/L) =
Number of carbohydrates in the record (g) *
GI / 100 (%/100) *
Work done for the moment in time (%/100) /
Glucose sensitivity (g per 1 mmol/L)
```

Before the module finishes its execution, it calculates the additional module values, such as the total module current influence on blood glucose level for the current moment in time, the total module influence for the whole activity time, the relation those two values in percent, the number of currently active records, the remaining module action time, and the history of BG influence value for future purposes. All this is stored to the simulation state. If the action time of the current record is over, it is marked as deleted.

Insulin Module

First, durations of action of an insulin simulation record are defined, which varies between different types of insulin.

The next step is to define the peaking value (1) in mg/min/kg for the defined number of IU/kg (2). Authors found curves representing glucose utilization rate for Humalog, Novolog, Regular, NPH, Levemir, Lantus (see Figure 6) from information sources, and took the maximal glucose utilization rate values for each mentioned insulin type. That was 6.5 mg/min/kg for 0.2 IU/kg for Humalog, 6.8 mg/min/kg for 0.2 IU/kg for Novolog, 5.(6) mg/min/kg for 0.2 IU/kg for Regular, 3.4 mg/min/kg for 0.3 IU/kg for NPH, 3.0 mg/min/kg for 0.8 IU/kg for Levemir, and 0.95 mg/min/kg for 0.3 IU/kg for Lantus.

These values were used to calculate respective coefficients, which will be used in the next step.

```
Coeff (mg/kg/min) = number of IU in the
record * (1) / ((2) * weight)
```

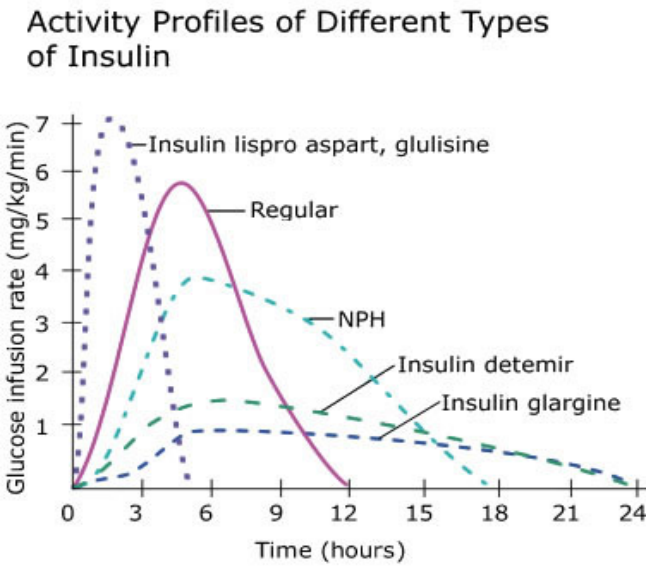

Figure 6 - Glucose utilization rate for different types (examples) of insulin. Rapid-acting insulin is represented by Lispro and Aspart. Short-acting insulin is represented by Regular. Intermediate-acting insulin is represented by NPH. Long-acting insulin is represented by Detemir and Glargine. Source [7]

The next step is to find the current influence and the full influence of the record, by calculating the area under the action curve for particular type of insulin. This is implemented as a loop that iterates through the whole duration line: from zero, when the record was made, until the defined duration, and outputs a sum in mg/kg. The influence is measured in mg/kg/min, so each iteration step is defined as 1 minute.

Each iteration is as follows.

```
Res += Coeff (mg/kg/min) * Influence by
the moment in time (%/100)
```

The functions used for calculating the influence over time build the action curves, which are estimated versions of the curves described in the previous step (see Figure 6 as general example). An example of such estimated curve for the insulin type Humalog is shown in Figure 7.

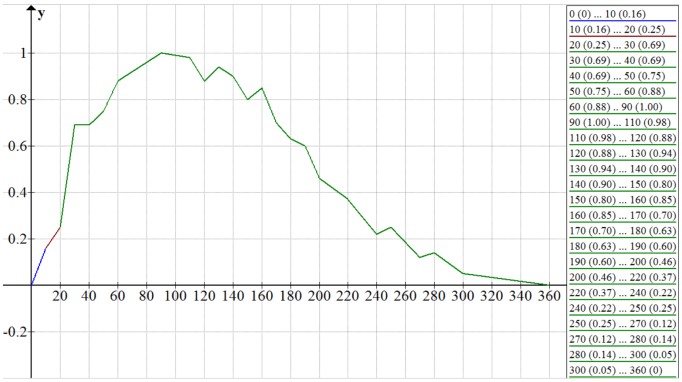

Figure 7 - Estimated action curve for Humalog. X-axis repre-sents minutes; Y-axis represents action from 0 to 1.

The result of this loop is the total influence during the given time in mg/kg. Current influence is calculated in the same way but with one difference – the loop runs not until the end of the duration, but until current moment.

The last step is to convert the results into mmol/L. We know that 1 mole of glucose is 180.15588 g of glucose, or 1 mmol of glucose is 180.15588 mg of glucose. In addition, both insulin and glucose are distributed in the extracellular space in the body. Extracellular space consists of interstitial space (~16% of weight) and blood plasma (~55% of blood volume). So the following conversion was implemented:

```
# (mmol/L) = # (mg/kg) * weight (kg) *
(0.16 + (0.55 * blood volume / weight)) /
     (180.15588 * blood volume (L))
```

Now, we have the current influence and the total influence that will be made by an engine insulin record. Before the module finishes its execution, the same algorithm as in the end of Carbohydrates Module runs. All calculated values are written to the state, and the records which action is finished are marked as deleted.

Activity Module

Aerobic and anaerobic activities have different effects on BG level. According to Bacchi and coauthors [14], aerobic activity causes 30% increase in Insulin Sensitivity because muscles absorb more glucose (which causes a drop in BG) [9] [10] [11]. This increase lasts for the next 24-72 hours after the exercise, depending on the duration of the exercise. During the first 1-3 hours, anaerobic (resistance) activity increases BG by 2 to 4 mmol/L [8], and sometimes even more [13], which is caused by adrenalin [12]. After this, the 15% increase of Insulin Sensitivity [14] takes effect and lasts about 14-20 hours [8]. This information is the basis of the Activity module algorithm.

Blood Glucose module

This module calculates the resulting blood glucose from the Insulin, Carbohydrate and Activity modules.

Additionally, every time the module is called, it subtracts a small value representing the constant glucose consumption by brain (about 100g per day, or about 4g per hour [15]).

Next steps will be to implement at least two other important elements that the Engine should have: Hypoglycemia unawareness option, and Dawn Phenomenon simulation (the rise in blood glucose during the night caused by the hormones). If they are implemented in the future, they will be developed in Blood Glucose module.

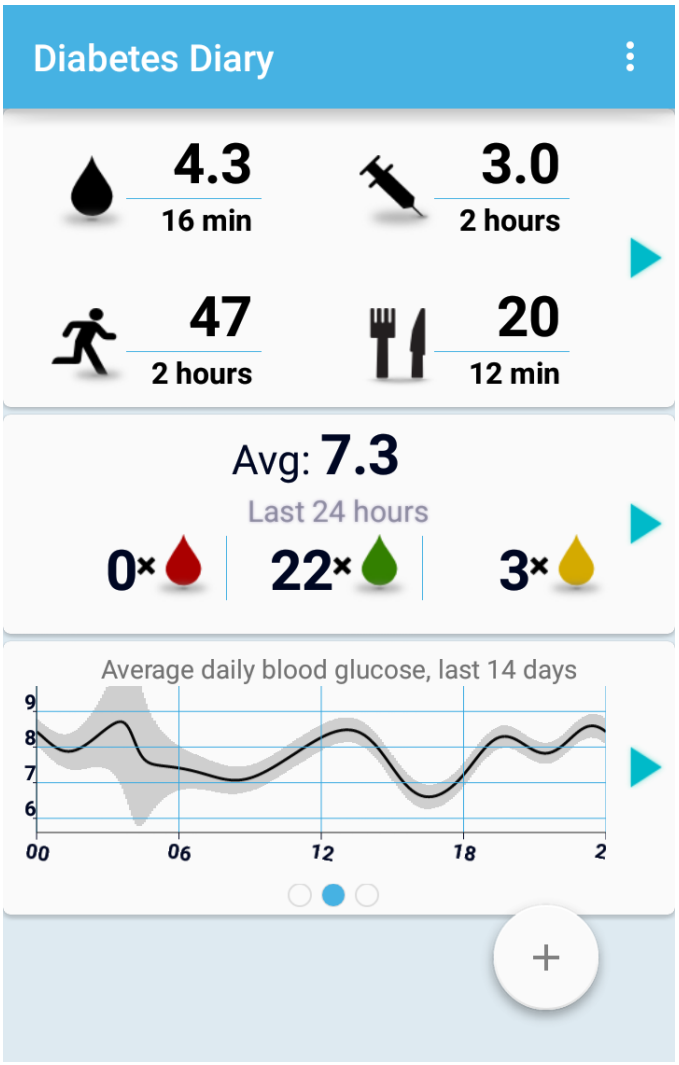

Figure 8 - Diabetes Diary, a mobile self-management applica-tion for people with diabetes by NST.

Main Module

The main Diabetes Automata module initializes the engine and runs the simulation loop repeatedly where it calls Insulin, Carbohydrates, Activity and Blood Glucose modules with the user-specified frequency. For example, it is also possible to run one simulation-hour per minute. Additionally, it provides the API (Application Programming Interface) for external applications to use the Engine code in e.g. serious games or simulation-based self-management applications.

Results

The current version of the Diabetes Automata is a functioning prototype, presented in Figure 9 - Figure 16. Figure 9 presents the page for engine customization (settings), which includes age, gender, height, weight, insulin types used, preferred language, and other parameters.

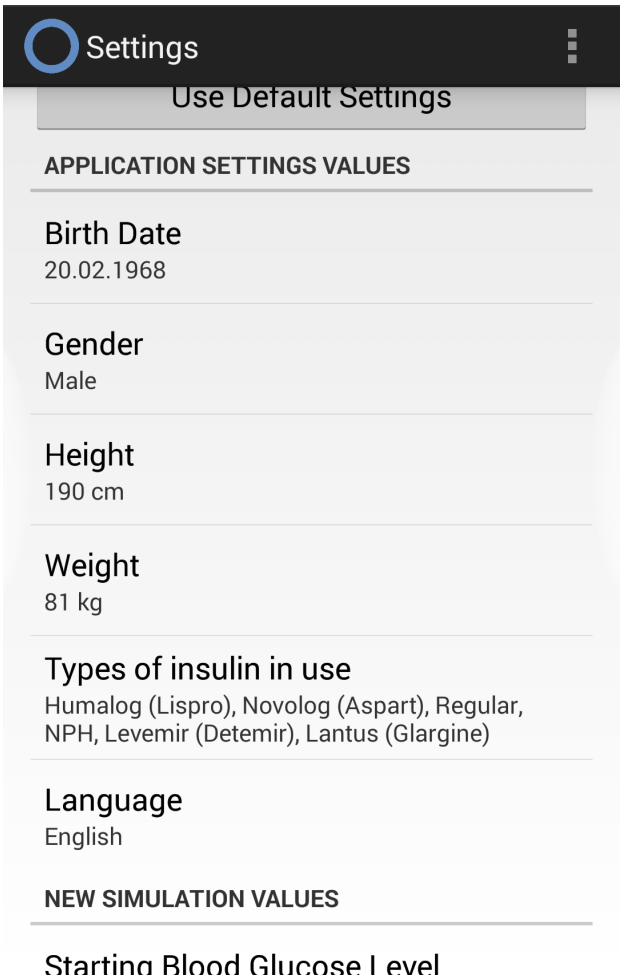

Figure 9 - Settings screen

The prototype provides three simulation modes (see Figure 10). The first mode is the usual simulation where the user inputs new records into the Engine by him/herself. The second mode is the simulation that uses records from Diabetes Diary database by fetching the database records and inputting them into the engine automatically, during the simulation time. This mode is currently personalized for one of the test persons, and has the following default settings: the Engine takes records from Diabetes Diary, use of insulin, long-lasting insulin is Lantus, carbohydrates have medium GI, and physical activity is aerobic. The third mode is a real-time simulation paired with Diabetes Diary. It starts from scratch without the opportunity to change the simulation speed or pause. From this, every time user makes a new record in Diabetes Diary, the record is automatically added to the running simulation.

Figure 11 and Figure 12 show the main screen of Diabetes Automata with started simulation, offering all information necessary to understand the simulation. We can see that the simulation is set to 10 Min / 1 Sec. This means that for each second the result for a ten minute interval is presented. The duration field presents the progress in simulation-time. Time 01:39 (see graph) is the current simulation time between 00:00 and 23:59.

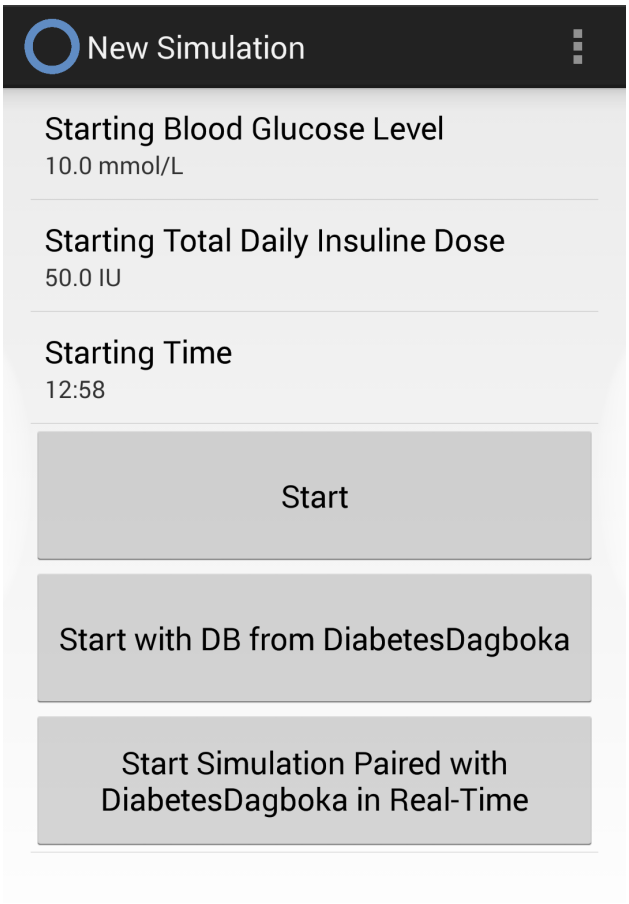

Figure 10 - New Simulation screen

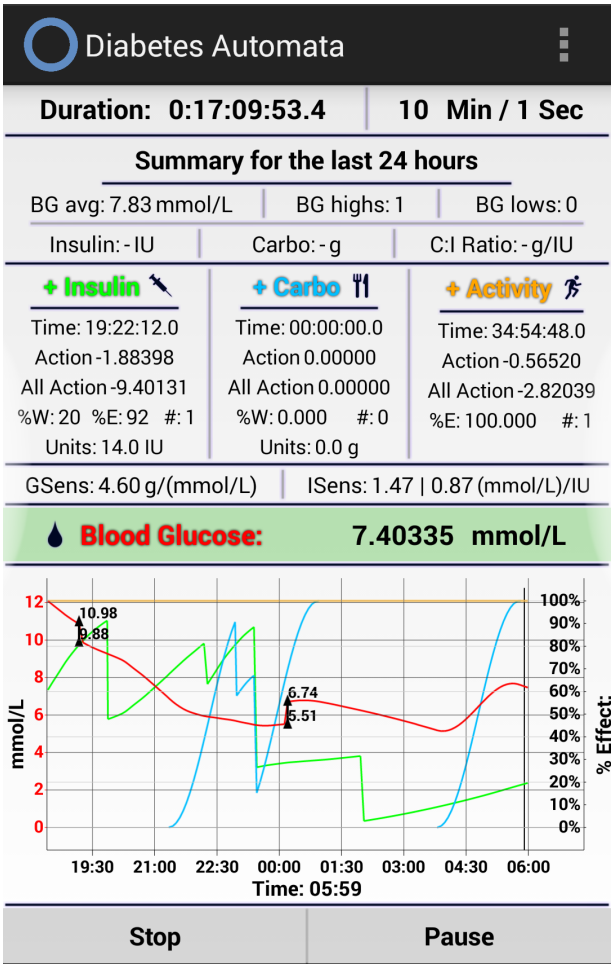

Figure 11 - Simulation. Main Screen

The meaning of presented Insulin, Carbohydrates and Activity values in three columns on the main screen follows these calculations. The first value in each column is the time until that the longest effect of simulation records will last. The second value shows current effect of these simulation records on BG level. The third value is the expected maximal effect of these simulation records on BG. The set of values after, displays the work (%W) and the current effect (%E) of these simulation records on BG level in percentage, and the number (#) of currently active simulation records. The last value in Insulin, Carbohydrates modules is the number of currently active module units.

Blood glucose is represented in mmol/L, and insulin, carbohydrates, and activity curves are represented in percentage of influence. The small black triangles with values (see graph) mean that a user manually calibrated the BG level.

Several functionalities are available for the user on the main screen. One can make a new simulation record by pressing on Insulin, Carbohydrates, and Activity, manually calibrate BG level by pressing Blood Glucose, change the simulation speed by pressing on the time field above Summary, change the graph mode by pressing on the graph, and stop or pause the simulation by pressing the buttons below the graph.

The user can also save the entire current simulation, load it later and continue. This can be done via the options menu in the upper right corner of the screen (see Figure 11). This option is available only for the first simulation mode.

The graph can be set to display the last 1, 2.5, 6.5, 12, 24, 48 simulation-hours, or set to the automatic drawing mode which sets the zoom to one of these values depending on the simulation speed. The graph also has different curve modes. First mode (see Figure 11) represents blood glucose levels, together with action progress (in %) for Insulin and Carbohydrates, and the action strength for Activity. The second mode (see Figure 12) differs with the insulin representation. It is represented as the action strength over time (in %). The third mode is just for blood glucose levels. The user may adjust the graph size by selecting a size menu, presented after holding a long-tap during the simulation (see Figure 13).

When the Pause button is pressed, the graph on the screen contains all information from the beginning of the simulation, which can then be zoomed in or out and scrolled within. The default pause graph shows the last 24 hours. The “Summary” shows the number of blood glucose lows, highs and average level, as well as the total amount of grams of carbohydrates, IU of insulin, and the relation between the latter two, for the last 24 hours.

One of the effects that can be studied with the help of Diabetes Automata is the different types of insulins’ influences on the blood glucose level (Figure 14). The challenge for this project was to handle the complexity and variety of insulin types.

The Diabetes Automata aims to emulate the body’s metabolism. The key input parameters for the engine are insulin, blood glucose, carbohydrates and physical activity. Each of these parameters has a set of alternatives, as illustrated in Figure 14 - Figure 16.

The final version is expected to be completed during the summer 2015.

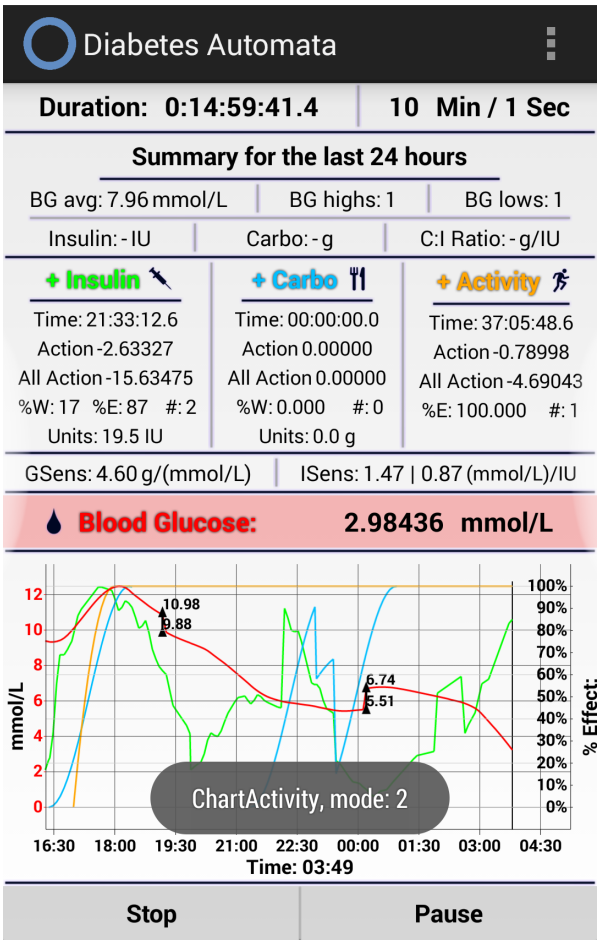

Figure 12 - Main Screen, Simulation

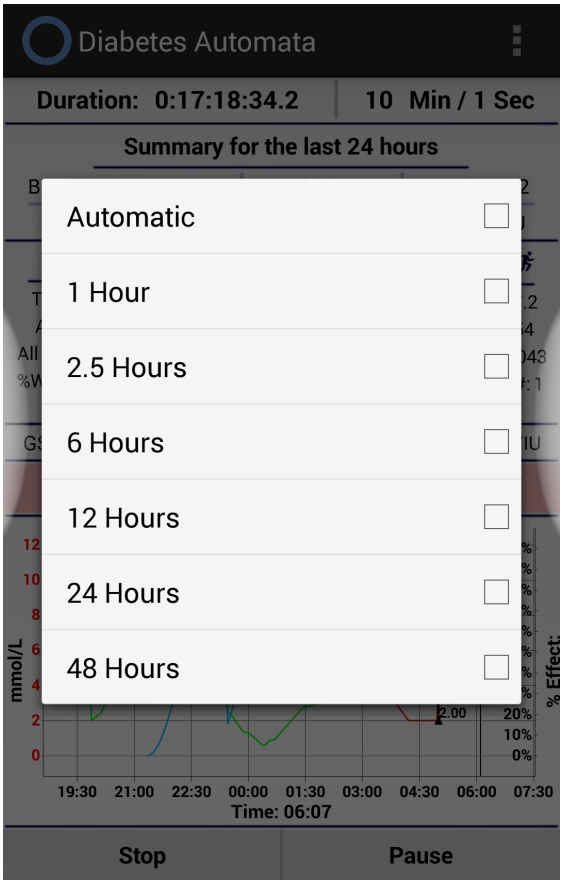

Figure 13 - Choosing the graph zoom modes

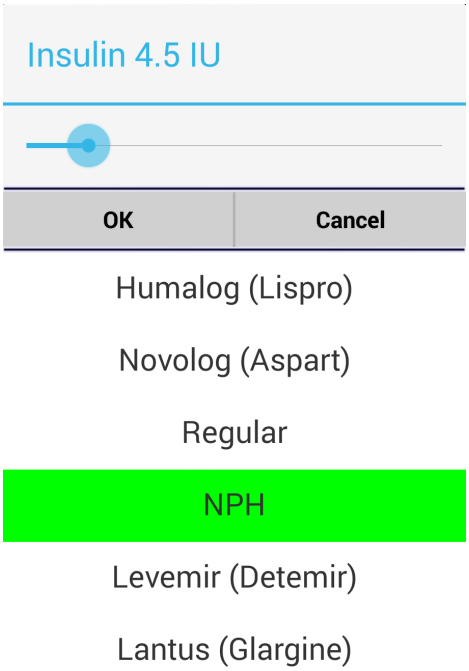

Figure 14 - Make a new insulin registration during simulation

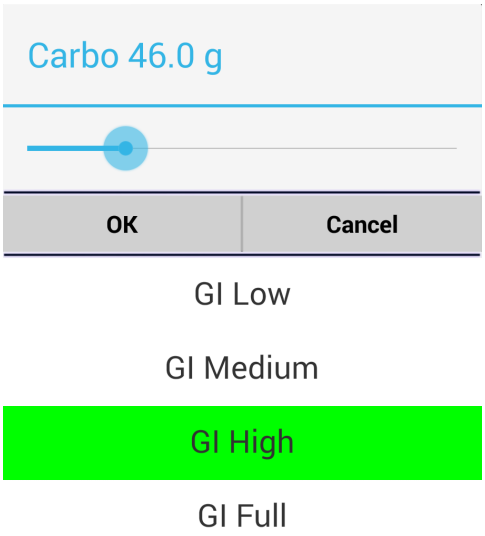

Figure 15 - Make a new carbohydrate registration during sim-ulation

Conclusion

We have developed Diabetes Automata, a software engine that offers the opportunity to run blood glucose simulation at user-defined time-speed.

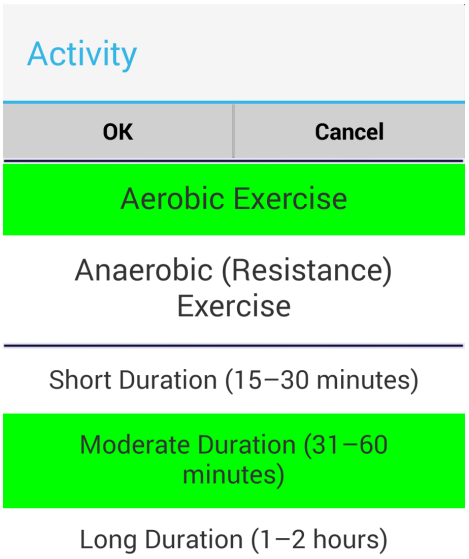

Figure 16 - Make a new activity registration during simulation

The main challenge with the simulator is to make it as realistic as possible. The Diabetes Automata aims to emulate the body's metabolism. We expect that our simulator can be used as part of serious games and contribute through this to a better understanding of the interplay between insulin, carbohydrates, physical activity, and blood glucose levels. This could make games closer to reality and, therefore, more motivational.

The system is not yet evaluated or tested, and is currently under development.

Acknowledgments

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Do mobile medical apps need to follow European and US regulations or not: decisions exemplified by diabetes management app

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Abstract

Rapid development of medical and health-related mobile applications (apps) has caught the attention of the regulatory institutions. Despite the fact that we have valid sources of information regarding related legislative issues, it is not easy for developers to interpret specific laws, directives and definitions. To clarify this situation, we summarize the main points of EU and US medical device directives and regulations for developers of mobile medical-oriented applications. To help developers decide whether their app should be considered under these regulations or not, we describe the process of evaluating the mobile phone app called Diabetes Diary (Diabetesdagboka) for classification as a medical device. In addition, we also highlight some serious issues the developers and regulatory bodies should keep in mind when inventing or encountering a new product.

Keywords:

Mobile Medical Application, mHealth regulations, classification of stand-alone software, diabetes.

Introduction

Mobile medical apps have become more and more useful and desired not only within the general population, but also as part of medical diagnosis and treatment within healthcare systems around the world [1][2]. Nowadays, smartphones are capable of communicating to sensors and medical devices to track users' physiological parameters such as motion, heart rate, blood pressure, blood glucose, oxygen saturation, and even ECG signals [1][3]. Moreover, integrated MEMS (Micro-Electro-Mechanical Systems) [3] based sensors are possible to be used for fitness and health tracking. These integrated technologies, which are cost-effective for healthcare systems and more affordable to the common population, have begun to play a dominant role in personalized medicine [4][5]. The rapid development of fitness and medical app functionalities, which include inter-communication between devices, enables the user to transfer and store all tracking data from multiple sensors into one central app. Individuals as well as health care authorities have recognized the potential for these integrated tools to benefit individuals with chronic diseases, enabling them to better self-manage.

In the case of diabetes care, integrated data from multiple devices can significantly ease data interpretation, and thus improve the lives of patients with diabetes. Instead of controlling and tracking each particular parameter, such as insulin doses, blood glucose or intensity of physical activity, via different devices, such as insulin pumps, glucose meters or activity trackers, it is highly desirable to let these devices communicate with each other and arrange all the necessary data in one place using one diabetes app. [6]

Another issue is on the one hand, the continuous increase of new non-medical apps, while on the other hand, much fewer medical certified apps, since approval often take a substantial amount of time and they are also often not thought of as necessary by the developers. Therefore, it is even more difficult for policy makers to find medical certified apps.

Institutions responsible for regulating medical devices are responding to this situation by preparing documentation describing which applications fall into these regulations and which do not. Although these institutions frequently issue new guidelines for developers, in attempts to adequately react to this rapid development of medical software, there are still some details for app classification which may be unclear.

Therefore, the aim of this article is to summarize and clearly explain the main points of medical device directives and regulations established in the EU and US for the developers of medical mobile apps. An example of a concrete mobile app, the Diabetes Diary (Norwegian name: Diabetesdagboka, developed at the Norwegian Centre for Integrated Care and Telemedicine (NST)), will be used to illustrate the process of classifying a mobile app as a medical device.

Regulations of mobile medical applications

Regulatory system in EU

Summary of relevant Medical Device directives

In the European area, the main organization responsible for medical device regulations is the European Commission. There are three Medical Device Directives in place, the Directive of Active Implantable Medical Devices (90/385/EEC), the Medical Devices Directive (93/42/EEC), and the Directive of In Vitro Diagnostic Medical Devices (98/79/EC) [7]. The document that specifically covers the European classification of medical devices and their accessories is the Medical Device Directive (MDD, Council Directive) 93/42/EEC [8].

This document describes the meaning of the terms "medical device" and "accessory", their classification, essential requirements, and other issues including their production. Fol-

lowing this directive, "accessories" are treated as "medical devices in their own rights" [8]. It means they are produced in order to be used together with a device to meet the requirements of use of such a device (e.g. electrodes for ECG monitors are considered to be an accessory) but they can also be marketed separately. A product can be considered an accessory if the manufacturer intends for it to be used "*in conjunction with one or several medical devices*" [9].

With respect to the classification of medical devices, the most pertinent section is *Article 9* (and its corresponding *Annex IX*), which dictates 4 classes in total – Class I, IIa, IIb and III, according to the risk of harm to the patient when using a certain medical device. The process of deciding whether a given device should be classified, and then in which class, is facilitated by rules defined according to the device's invasiveness (invasive, non-invasive), duration of contact with a body (transient, short term, long term), dependence on an electrical source (i.e. active medical devices) and others.

Regulations applied to mobile applications

With respect to regulations of mobile medical apps, EU is "*less centralized and more efficient*" [10] in comparison with the US. Most medical apps determined as a medical device are usually qualified as Class 1, which represents the lowest risk of potential patient's harm. This specific device class does not require so many legislative processes to be approved [11].

Unfortunately, the Medical Device Directive is not comprehensive enough for properly classifying health apps, or software in general. For this purpose, "Guidelines on the Qualification and Classification of Stand Alone Software Used in Healthcare within the Regulatory Framework of Medical Devices" (MEDDEV 2.1/6, last updated on January 2012) [12] has been issued separately. Here, we can find more detailed classification of stand-alone software used for medical purposes and also some decision steps that can help us to decide whether our software is or is not to be covered by MDD.

According to this document [12], a mobile medical app can meet both the definition of a "medical device" as well as an "accessory", depending on its intended use. In addition, if the app is not incorporated into a medical device, it is determined as "stand-alone software" which belongs to the group of "active medical devices". If categorized as a medical device, it has to have a medical purpose, but there are also some exceptions [12].

One of the main criterions for determining whether an app is classified by medical device regulations is a type of action performed on a medical data. Software that is simply a patient management system or a records storage system is not considered to be regulated [13]. To be more specific, it means that if the application is used only for storing, archiving, simple searching (similar to a library system, but not in case of identifying medical findings or medical images in health records), or it is used for communicational purposes, or if it enables lossless data compression, it is not considered to be a medical device [12][13]. Any design implementation used for embellishment purposes does not make the software to be classified as a medical device either, if its improvement is not made for medical purpose (i.e. better visualization of medical images used for a patient diagnosis) [12].

Whether the software is used to support patients or influence medical care and performs some action on data, it is necessary to check the Council Directive 93/42/EEC in Article 1(2)a,b, which describes the definition of medical devices and their accessories, and check whether its intended purpose of use appears there. Here, the medical device also means "*[software] whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease,...*" [8].

In case the definition of medical device does not fit to one in Article 1(2)a, but the software is an accessory to a medical device with a function of driving, monitoring performance of this device or influence the actions of medical device, it is covered by the MDD. In other cases, the software might not fall into the medical device directives. As an example, such software can be used for financial purposes, resource management and other non-medical purposes. [12]

When deciding which class the app should have, if it has already been evaluated as an active medical device, we have to follow the classification of medical devices (MEDDEV 2. 4/1 Rev. 9, June 2010), specifically Rules 9-12 describing active medical devices. If Rules 9, 10 or 11 that describe the functionality and purpose of the stand-alone software apply, then software is classified as IIa or IIb, according to the potential harm it may cause. Otherwise, Rule 12 classifies all other active medical devices as Class I, determined by their low risk or potential for harm to the patient. [14]

Steps for correct classification of the Diabetes Diary app

To illustrate this classification process, the mobile Diabetes Diary app has been used. This app is currently in the process of self-classification as a medical device, including gathering necessary documentation needed for CE-marking.

This app serves primarily as a logbook for diabetic patients. Users can make registrations about their daily food and insulin intake, blood glucose values and physical activity, including the possibility to enter notes regarding these registrations. The goal of the app is to encourage the patients to reflect upon their own entered data, thus learning how their lifestyle habits affect their blood glucose, or disease state. Due to its primary function as a logbook, this app would normally not be considered for regulation. However, there are other functions which change the classification of this app, including the ability to automatically transfer blood glucose values via Bluetooth from glucose meters, analyze input data and visualize it providing graphical feedback on a screen, approximation of BG values and calculations of blood glucose variations over a standard day. Furthermore, there is also a function that helps a user to decide insulin dosage. This function is based on simple searching in the history of the patient´s registrations within the app to find the most similar historic situation to their current situation based upon similar time, blood glucose before meal, dose of carbohydrates, and previous insulin taken. The results of this function presents the 20 most similar historic insulin dosages in the user's history.

There were also some clinical trials applied to this app, the latest one of which was related to its use by Type 1 diabetic patients [15].

Based upon these outlined functions and features, we will use the decision diagram, and the guidelines for stand-alone software (MEDDEV 2.1/6), to determine whether the Diabetes Diary app should be classified as a medical device and, therefore, covered by the MDD. If we conclude that the app should be considered as a medical device, then the next step is to determine the correct class for the app, according to the classification of medical devices document (MEDDEV 2. 4/1). An-

other useful guidance for mobile apps was published by Nictiz in November 2013 [16]. Nictiz is the "centre of expertise for standardization and eHealth" placed in Netherlands and financed by the government. This institution assists with implementation of IT standards in healthcare, and also publishes many practical overviews connected to standards, laws and regulation within this sector. [17]

Table 1 summarizes the main decision steps for classifying the Diabetes Diary app, based on combination of the float chart described by Nictiz [16] and one provided by the MEDDEV 2.1/6 [12].

Table 1 - Determination of the Diabetes Diary as a medical device and its subsequent classification [12][16]

Step	Question	Answer	Comments
Determination of Medical Device status			
1.	*Is the SW a computer program?*	Yes	A mobile health application is a computer program (according to ISO/IEC 2382-1: 1993)
2.	*Is the SW incorporated in a medical device?*	No	Since it is not incorporated, it falls under the definition of stand-alone software. If it was incorporated, the software would have to be classified according to the classification of the medical device it is part of.
3.	*Is the software performing an action on data different from storage, archival, lossless compression, communication or simple search?*	Yes	All these cases have already been explained above. However, it is important to make clear which types of actions are covered when altering the data. According to the MEDDEV 2.1/6 [12], "*...alterations may include reconstruction, lossy compression, filtering, pattern recognition, modelling, interpolation, transformation, classification, segmentation, registration (e.g. mapping a data set to a model or to another data set), calculations, quantification, qualification (e.g. comparison of data against references), rendering, visualisation, interpretation, etc.*. ". In our case, we uses some of these alterations. Thus, the software is performing an action on data.
4.	*Is the action for the benefit of individual patients?*	Yes	The app is used for gathering and evaluating the data, to help individuals manage their diabetes, with the potential to help healthcare providers make better clinical decision, if allowed, to browse through the patient's data stored in the app.
5.	*Is the action for the purposes defined in art 1.2a of MDD?*	Yes	The purpose of the app's functionalities include *"monitoring, treatment or alleviation of disease",* in this case of one's own diabetes, which fall under one of the categories defined by Article 1.2a of MDD [8]. These functionalities include monitoring the patient´s diabetes, helping the patient to manage necessary parameters (blood glucose, insulin doses, meal, and activity), and guiding an individual to make decisions regarding insulin or carbohydrates dosage.
6.	*Is it an accessory of a medical device?*	Yes	This step follows in case the previous question was answered "NO". While we did answer "YES" it is under discussion if our app could be considered as an accessory, since it is capable of transferring data from some blood glucose meters via Bluetooth. The decision depends on its intended use, since "*a product can only become an accessory to a medical device if the manufacturer of such a product establishes an intended use in conjunction with one or several medical devices*" (MEDDEV 2.1/1) [9]. Based upon either step 5 or 6, we still continue to step 7.
7.	***Result no.1: Medical device (stand-alone software) covered by MDD Annex IX as active medical device***		
Classification of the Diabetes Diary: active medical device			
8.	*Does the app contain a measurement function?*	No	For the actual state of our app, we do not use any measurement function. However, there might be some potential to use some sensors integrated into a smartphone, such as motion sensor, camera, etc. In this case we would have to verify this issue more properly. If we finally consider incorporating any measurement function into our app, we have to follow step 9.
9.	*Does the app have one of the following medical purposes:* *a. intended to administer, supply or exchange energy;* *b. intended to control, monitor or influence directly the performance of a class IIb active medical device;* *c. administer or remove medicine, energy or other substance to or from the body;* *d. intended for direct diagnosis or monitoring of vital physiological processes?*	No	As we can see, no one of the purposes described in step 9 fits to our app. However, if we decided to cover a function "*to obtain readings of vital physiological signals in routine check-ups and in self-monitoring of physiological parameters*" [14] (such as "*respiration, heart rate, cerebral functions, blood gases, blood pressure and body temperature*" [14]) it would have to be classified as Class IIa active medical device.
10.	***Result no. 2: Class 1 medical device, self-certification without intervention of notified body is allowed for CE-marking***		

After step 2 in Table 1, we can conclude that our health app is a stand-alone software falling within active medical device directives. At the end of the step 6, we have concluded that the app falls under the discretion of the MDD.

Then we can follow additional rules for active devices (9-12) of the classification of medical devices document (MEDDEV 2.4/1, Annex IX, section III.3). This part is also included in the Nictiz flowchart [16] (starting with the step no. 8) and where the most important part of the MDD´s rules applied on health apps is extracted.

Since the app does not have any measurement function, rules 9-11 of MEDDEV 2.4/1 do not apply, and we, therefore, must follow rule 12 which classifies this software as a Class I medical device. According to these observations we suggest that the app should be considered as a medical device with a low risk, which only requires self-certification [16].

If we consider incorporating a measurement function, during potential future development of the app, we would have to follow step 9, which would require the device to be validated by a notified body and assigned a CE mark [16].

Regulatory system in US

Summary of relevant Medical Device directives

In the US, the main organization responsible for medical devices regulations is The U.S. Food and Drug Administration (FDA). Nowadays, the regulation system distinguishes approximately 1,700 different types of devices separated into 16 specific groups called "panels" according to their intended use (e.g. General Hospital, Haematology, Neurology,...) [18].

The main document covering medical device regulations is the Federal Food Drug & Cosmetic (FD&C) Act [19].

This Act distinguishes three general classes of medical devices "*based on the level of control necessary to assure the safety and effectiveness of the device*" [20]. Class I requires only general controls; Class II requires, in addition to the general controls, specific controls that vary with the type of device. Class III devices require a Premarket Approval application (PMA), in addition to the general control.

General controls include e.g. device registration and listing, Premarket Notification 510(k), Good Manufacturing Practices, and others [21]. However, most of Class I and some of Class II devices are exempted from 510(k) requirements. [20]

The aim of the Premarket Notification is to compare a new medical product with one or more medical products that are already on the market. FDA then determine whether the devices are "substantially equivalent" or not [21].

Premarket Approval applies only for Class III devices and manufacturers of these devices have to prove, based on clinical data and scientific evidence, that their device is sufficiently safe. [22]

Regulations applied to medical applications

Compared with Europe, mHealth regulations in the US consider upcoming mobile technologies and stand-alone software used for health purposes in more detail.

To clarify the directives related to mobile medical apps, the FDA published the "Guidance for Industry and Food and Drug Administration Staff" [23] and updates this document regularly. The last version was issued in February 2015.

The regulatory status of a proposed product depends on its intended and indicated use. In addition, there are no flowcharts to aid a developer in the classification or regulation of their application. Instead, concrete examples of regulated applications and their features are listed within the Guidance [23] and sorted into 3 main categories of apps as a part of this Guidance (appendix A-C) [23] according to the FDA requirements. These are the "non-regulated" ones, those falling into "enforcement discretion", and those for which "regulatory oversight" is required. It is important to note that if an app falls within the scope of "enforcement discretion", it does not mean that such an app is not considered a medical device or does not need to be regulated. In this case, the FDA has the authority to decide, on a case-by-case basis, whether to place regulatory action on the product or not. However, at least for such medical apps that fall under "enforcement discretion", the FDA "*will not expect manufacturers to submit premarket review applications or to register and list their apps with the FDA*" [24].

The 2015 version of the Guidance [23], contains some noticeable changes when compared to the previous one [25], issued in 2013. The previous document dictates that mobile apps serving as an extension of a regulated medical device that "*display, store, or transfer medical device data in its original format*" are an issue for regulatory oversight. This means that if the app is used only as a display or storing place for medical data "in its original format", and does not control or alter the functions of the connected medical device, it is subject to Class I requirements, again which only require General Controls. However, in the 2015 Guidance, apps with this description are no longer mentioned within the category of "regulatory oversight". However, apps that meet the definition of Medical Device Data System (MDDS), which aim "*to transfer, store, convert format, and display medical device data in its original format from a medical device (as defined by MDDS regulation 880.6310 OUG)*" [23], are listed in the category of apps with "enforcement discretion". This category also applies to apps used for self-managing of diseases or conditions (e.g. cardiovascular disease, hypertension, diabetes or obesity) without providing any treatment, treatment suggestions or diagnosis, and, also, which enable patients to have easy access to their health information or interact with EHR. To simply remind patients to take their medication is possible, too. These apps are capable of allowing the patient to track their health information and share such data with their healthcare providers, without automatically recommending changes in their self-management or medication doses, etc. Under this classification, such apps are also allowed to perform simple and well-known calculations, e.g. Body Mass Index (BMI), mean blood pressure, and others [23][25]. Moreover, apart from the case of apps meeting the definition of an MDDS, "*mobile apps that allow a user to collect, log, track and trend data, such as blood glucose, blood pressure, heart rate, weight or other data from a device to eventually share with a heath care provider, or upload it to an online (cloud) database, personal or electronic health record*" [23] fall into "enforcement discretion", too.

To summarize, the FDA does not intend to strictly regulate apps for maintaining chronic health conditions that gather, store or share health information, as mentioned above, as long as they do not provide any treatment, diagnosis, or recommendations (e.g. in order to change prescribed medication). If an app did provide any of these, it would be a case for "regulatory oversight".

Apps considered to be regulated are, therefore, those that take the function of a medical device, e.g. using an integrated sensor (e.g. accelerometer, camera etc.) to measure physiological parameters for performing a treatment or diagnosis [23][25], or serving as the first display when collecting results of a measured value. This also applies to apps using an attachment for blood glucose measuring, which are classified as "Glucose test systems", for example the glucose meter iBGStar [26] or iHealth Align Glucometer [27]).

The impulse for lowering regulatory requirements for MDDS emerged from the growing need for inter-communication of several medical devices and health IT [28]. The MDDS were defined as Class III until 2011 and were afterward reclassified as Class I [28], yet still remained on the list of regulated systems (according to the guidance 2013 [25]). Gaining more experience with these systems, it has been demonstrated that "*MDDS devices, medical image storage devices, and medical image communication devices pose a low risk to the public*"[28]. Therefore, as it has already been mentioned above, with the arrival of the recent guidance 2015, apps being considered MDDS are under "enforcement discretion".

The FDA's "Product Code Classification Database" [29] is very useful source for developers who wish to determine whether their app should be regulated or not and, if so, which class the app falls under. One can search this database by accessing the official webpage of the FDA and search for devices similar to the one we need to classify, based on his/her inputs when filling a form on the front page of the database. Premarket notification summaries of already regulated medical devices are also accessible in official website. A particularly helpful part of these documents is a table illustrating which legally distributed and approved device is equivalent or most similar to the device being considered for approval, by displaying descriptions of existing apps with the ones needed to be approved.

It is also possible to contact the FDA Office of Compliance for determination of whether the app is a medical device or not. For classification and application decisions, the Office of Device Evaluation (ODE) is the authority which can be approached for these purposes. [30]

Steps for correct classification of the Diabetes Diary app

To determine if the Diabetes Diary app should be regulated by the FDA, and, if so, which class this app belongs to, we will compare our app with an existing one that has already been approved.

One of very few diabetes self-management apps which has received FDA clearance is the MySugr app. This app allows users to log their blood sugar values, insulin doses, meals (including the ability to take a picture of a food portion), activity and other notes [31]. It also enables the user to search in their data history, display data-analysis and graphical interpretations of the captured data, extract a printed version of report for a healthcare provider, set a blood sugar reminder, and share the information with other users, including family members. Apple Health integration and data synchronization with blood glucose meter are also possible [31]. In an interview of one of the co-founders, CEO, Frank Westermann, he declared that their app was classified as a Class I medical device in Europe and was registered with the FDA in US [32]. Here, he also mentions that "*this classification allows us to interpret treatment data and could mean that, for example, in the future we'd be able to communicate directly via a blood sugar measuring device*" [32].

We have observed that the features and purpose of the MySugr app are similar to the Diabetes Diary. Following the Guidance for mobile medical apps, we conclude that because the Diabetes Diary's purpose is to help patients with diabetes to self-manage their disease by enabling them to track, store, display and transfer medical data, in addition to enabling the individual to transfer blood glucose data from blood glucose meters, it would meet the definition of a Class I MDDS and fall under "enforcement discretion" [23].

The functionality of insulin dosage suggestions may, however, move the app into the scope of the "regulatory oversight" category, even though this tool is only based upon a simple search within the user's own history. Therefore, if the intended use is to recommend treatment, in this case medication dosage, it is indeed a case for regulatory oversight.

Discussion

It is evident that it is challenging to concretely define the boundaries between a "medical" and a "non-medical" mobile app, and to classify a medical device correctly based upon official documents.

Furthermore, the more functions the app has, the more complicated it is to make a clear decision. This is especially true if a developer decides, after receiving official approval, to further develop the app and add a function to adapt to market demands. It is not only necessary to evaluate each function separately when applying medical device regulations, but also to see the whole system and its impact on the final users and check it out when adding new functionalities.

Reading blood glucose values from an external blood glucose meter was one of the functions of the Diabetes Diary app, which made impact on how we examined the regulations. Whilst this case only deals with several finger-stick measurements captured during a day, the recent development of apps that display values from continuous glucose monitors (CGM) and share this data with other people, illustrate this foreseen challenge to both developers and authorities alike. Marketing of these apps have already been allowed by the FDA and classified as Class II, and are exempt from premarket submissions [33]. Such innovations represent a big step in diabetes self-management. Applications such as NightScout [34] or Dexcom´s app for Apple Watch [35], which allow remote monitoring of blood glucose readings using devices such as smartphones or smart watches [34], were struggling for regulatory approval. The FDA has finally approved the interoperability of Dexcom Share and Apple Watch, which should be available in US from April 2015 [36]. Thus, it is obvious that there will be more apps trying to share this type of data, which will impact their classification.

For both the EU Commission and FDA regulations, the more action performed on the data, the higher the probability of reaching the scope of medical device regulations.

Based on the directions mentioned above, developers of similar medical apps, usually serving as self-management systems, should be careful when specific alteration of captured data is performed, and/or when an app becomes a part of, or an accessory to, a regulated medical device.

Not only are added functions an issue, but the degree of sophistication and ability of singular functions, which blur the line between "simple" and "advanced". Different levels of complexity can be observed, for example, when implementing an insulin dosage calculator. Apps with this function can be

based on simple well-known calculations, where only a few parameters are needed, or more advanced calculations, where complex algorithms and more inputs are used. According to MEDDEV 2.1/6 [12] "insulin dosage planning stand-alone software" (such as bolus calculators) is clearly considered to be a medical device, and is moreover used as an example of Class IIb medical device when it influences a medical device of this Class. According to the FDA, mobile apps that perform simple calculations and that are used routinely in clinical practice are accepted to be under "enforcement discretion". However, the expression of "simple calculations" can mean different level of complexity to each individual. Nevertheless, if the intent of its use is a treatment recommendation, regulatory oversight is still required.

When searching for diabetes apps on iTunes or Google Play, there are several unregulated ones serving as an insulin dose calculator. These would, according to the directives, belong to the medical device descriptions (in both the US and the EU), whether this action was considered as a treatment recommendation. Although the developers often put warnings on their web page (if there exists any) about intended use of their app so that the product does not meet the definition of medical device, the potential risk of harm when using this app may not be sufficiently reduced by these announcements.

These examples illustrate additional concerns that we discovered during this process; who is authorized to determine what an "intended use" is for a device, i.e. individual users, developers, etc.? A product may be intended for use for one reason and effectively used for another purpose. Furthermore, based upon app descriptions on app stores or distributor websites, it can be unclear whether an app is reputable and who authorizes its use. The wording within official documents as well as advertised app descriptions can both be misleading to developers and users.

These apps displayed on Internet stores are often labelled as "medical", which may make somebody believe that it should be used for medical purposes [37]. Furthermore, there is often lack of information about whether the apps have been tested or not before being released to the market. Besides, developers often update their software based upon user or consumer desires, and not based upon medical necessity or medical regulation.

The purpose of the described regulations is not only to define and categorize a medical device, but also to ensure user´s safety and keep, or better, enhance the quality and usability of medical products. However, given the discussion presented, the evaluation and regulatory processes for the majority of the apps on the market still have many challenges regarding overall success of the rigorous application of the directives.

Conclusion

Rapid development of medical and health-related mobile apps has caught the attention of both EU and US regulatory institutions. Despite the fact that we have valid sources of information regarding related legislative issues, it is not easy for developers to interpret specific laws, directives and definitions, nor is their cooperation always enforceable, given the sheer volume of developers and apps. Therefore, the goal of this article was to provide simplified description of regulatory requirements related to mobile medical apps and also to highlight some serious issues the developers and regulatory bodies should keep in mind when inventing or designing a new product.

If a developer has some doubts about the correct classification of his/her product, or the app classified as a medical device or not, it is always better to consult the responsible organization.

Since the approaches to medical device classification and regulation of both the US and the EU systems are significantly different, it is difficult to directly compare them. As demonstrated, final steps of classification within the US system rely upon a comparison structure based upon apps which are already approved as medical devices. However, the EU system is based upon guidelines and defined rules illustrated through flow-charts which guide a developer's assessment. From a public perspective, identification of the correct classification of a regulated app often requires direct communication with its developer, because this information is not always publically available. This is especially the case for apps classified with respect to the EU regulations.

Although mobile medical apps are intended to help individuals improve their health and/or manage their disease, they all present different levels of potential risk of harm. Many of the apps that are currently available on the market and unregulated may present undetermined, or possibly higher, risk to the user, due to lack of understanding by the user or machine error.

While such classification processes present much additional work for app developers, these steps are essential to ensuring a device's quality, effectiveness, and above all, safety for end users.

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Study protocol: Health talk Norway

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Abstract

This paper is a study protocol. "Health talk Norway" is a one year project where we will pilot a new and increasingly popular international methodology for qualitative research on people's health experiences; the DIPEx methodology, developed by the Health Experiences Research Group (HERG) at the University of Oxford. This study will explore if Norwegian research and dissemination on health experiences can be improved using the DIPEx methodology. At the core of the DIPEx methodology is a web site disseminating people's accounts of their health experiences. DIPEx has been founded to promote the spread of well-researched data on personal experiences of illness and health for the benefit of patients, professionals (both clinical and academic), health services, health care providers and carers. The methodology has been developed in the UK and has so far been adapted to 9 other countries, in Europe, Australia, North America and Asia. Results from the pilot will be of importance for future development of a Norwegian health talk web site, and support research infrastructure for qualitative research on health experiences.

Keywords: health experiences, methodology, patients, qualitative, web science

Introduction

In "Health talk Norway" we will pilot the DIPEx methodology of health experiences research [1, 2], developed by the Health Experiences Research Group (HERG) at the University of Oxford and the DIPEx charity (which owns and publishes the website www.healthtalk.org). This is a methodology for developing, producing and systematizing qualitative research on people's health experiences. The methodology has been developed in the UK, but is also applied by researchers in 9 other countries: Germany, The Netherlands, Canada, Japan, Korea, Australia, Spain, Israel and USA. The 10 national research networks are joined in the organisation DIPEx International. If the pilot is successful it is our aim to apply for a large-scale project that confirms to the DIPEx International standards, but conforms to the specific Norwegian context (as identified in the pilot) and join the network.

The aim of the research study is to explore if Norwegian research and dissemination on people's health experiences can be improved using the DIPEx methodology.

Background

In research focused on people's health experiences and aimed at understanding how patients live with their illnesses and make treatment choices, the qualitative interview stands out with evident methodological advantages. Open-ended questions and the interview-researchers continuous work to remain un-biased allows for the informants to present in-depth stories [3]. In qualitative research interviews with patients, unexpected accounts and new angles that may differ from clinically centred understandings of illness can be revealed. Qualitative interview studies thus provide insights into how patients and the health-interested public actually reason; how they construct meaning around their everyday habits and health challenges. There is a growing body of interesting qualitative research on patient experiences, both internationally (for instance [4-6]) and in Norway [7-10]. However, small-scale qualitative research is met with challenges when it comes to dissemination and transferring applicable knowledge to general clinical practice, which is often case-based but maintains large-scale Randomized controlled trials (RCT's) as gold standard [3].

At the core of the DIPEx methodology is a web site in which extracts of patients and carers interviews (as text, audio, or video) data is systematically presented. The DIPEx database serves as research infrastructure, and the extracts presented on the web are easily accessible for both health personnel and the public.

The purpose of a more systematic, transparent and more broadly available presentation of people's health experiences is to reveal the potential of such data as well as being a direct source for patients and clinicians. An interest in patients' perspectives is necessary for the development of patient centred health care, which is underlined in contemporary health policies [11, 12].

The Internet is an important source for health purposes [13], and the use of online resources for peer-to-peer connection has been one of its most transformational features [14]. The inclusion of patients' experiences on health information websites is recommended because these are most likely to engage site users [15, 16]. Evidence suggests that patients use personal experiences in various ways to support their decision-making. A recent conceptual review concluded that patient experience is a key feature of e-health [14]. It identified 7 domains through which online patient experience could affect health; information, support, relationships, behaviour, experiencing health services, learning to tell a story and visualizing disease. France et al. [15] found participants' inclination to use personal experience information was moderated by assessments of personal relevance, the motives of information providers and the 'balance' of experiences presented. There is, however, a significant challenge that websites as well as other media sources using patient experiences, often present few anecdotal accounts, or focusing on heroic or exceptional testimonials.

In contrast, the DIPEx web sites are research based, and include excerpts from rigorously designed in-depth interviews with real patients and carers (cf. www.dipexinternational.org). The web sites are accessible by all, and a fully realized Health talk Norway will thus provide valuable input to fellow researchers, clinical workers, policy makers, carers and patients alike. If the experiences are collected as interviews, and analysed and presented as carefully selected illustrative clips (as in the Health talk/DIPEx model), they demonstrate the considerable and subtle variation in human response and can make information highly accessible to people with different levels of health literacy.

Methods and study design

Description of the DIPEx methodology

The website

Many health websites now include some patient experience data, but Health talk is a unique resource. On the UK site (www.healthtalk.org) there are over 80 sections, each of them based on a rigorous qualitative research study exploring the experiences of 40 or so people facing the specific condition, health or social care issue. Hence, each section within Health talk presents careful analysis of around 25 of the most important issues identified within these in-depth interviews, illustrated with around 250 video, audio and written extracts from the interviews. The site covers different conditions or health topics, including several major cancers, cardiovascular disease, mental health, epilepsy, rheumatoid arthritis, pregnancy, screening, sexual health and experiences of carers of people with dementia. The project aims ultimately to cover all major conditions and experiences of treatments [17].

Interviews, analysis and presentation of interviews on the website

In the UK, the interviews on the healthtalk.org are generated and analysed by experienced social science researchers most of whom are based in the HERG within the University of Oxford's Department of Primary Care Health Science. Interview transcripts are analysed by the qualitative researcher responsible for the data collection in collaboration with a research "buddy" or supervisor who have familiarised themselves with all the interview data. Attention is paid to emergent (i.e. unexpected) themes as well as those that were anticipated [1, 2] using the method of constant comparison. This approach ensures that the researchers write summaries on the issues that are important to the participants– not just the ones that health professionals and researchers may think are important. To ensure the quality and balance of the material included in the section, each summary is prepared by the researcher, checked against the interview data by a second researcher (the research buddy/supervisor) and reviewed by at least one suitably qualified member of an Advisory Group before final editing.

Evaluations of the methodology

The UK-website has been evaluated with patients and as a teaching resource. In 2012, the site received about 2 million visits and 55 million hits, representing growth of 37 per cent over 2011. The website has won several awards, and was highly commended, e.g. in the British Medical Journal (BMJ) Book Awards (2005) and the Health Service Journals Award (2005). Ann McPherson, the co-founder of Healthtalk (formerly DIPEx) was awarded the BMJ Health Communicator of the Year award in 2011.

The DIPEx methodology is thoroughly based in well-known quality standards for research interview techniques and dissemination. The DIPEx web site will thus be a valuable supplement to other Norwegian web sites built for and about patients, e.g web based hospital education courses for patients or www.helsenorge.no. A DIPEx site will provide information on everyday health experiences from the patients and carers, and to health care professionals or other patients, carers, researchers and policy makers.

Aim, research question and methods

Aim and research question

The aim of the pilot is threefold, in non-sequent order: First, to study, translate and if needed adapt the DIPEx methodology to a Norwegian health care context. Secondly, to assess the feasibility of a DIPEx web site in a Norwegian health care context, with emphasis on patient interests and ethical requirements, and thirdly to establish a network of qualified researchers in Norway, who already work in the field of people's health experiences. The overall objective can be operationalized into the following research question:

"Can Norwegian research and dissemination on health experiences be improved using the DIPEx methodology?"

Methods/Work procedures

As this project is a pilot of a methodology, we will describe our work procedures in this section. The section is structured according to the project aims:

Study and translate the DIPEx methodology

To be able to study and translate the DIPEx methodology, the project research team will attend courses in the DIPEx methodology at University of Oxford and participate in necessary translations of material using the dual focus approach to translation (18).

The DIPEx methodology will be tested in two series of interviews. Five patient interviews are already planned for in another research project at the host organisation Norwegian Centre for Integrated Care and Telemedicine (NST). These interviews will be oriented towards experiences from being a patient at a hospital surgical department. There will be three or more interviews with patients recruited through collaboration with other departments at the University Hospital of North Norway (UNN).

Assess the feasibility of a DIPEx web site in Norway

The feasibility report will include several sections. There will be a section reflecting on overall methodological considerations, comparing the DIPEx methodology with other qualitative work procedures. This also includes ethical considerations, based on the discussion that will then have taken place with the Norwegian regional ethical committee (REK). The feasibility report will also include assessment of required expertise, and technology assessment; i.e. of the web technology and of audio and videotaping equipment. The report will include advices for organisational anchoring of the research network and of editorial responsibility for the web site. There will be judicial assessment of lawfulness. We will also suggest a name for the Norwegian research network/web-site.

Building the network

The project research team consists of members whom are well established in Norwegian health sociology. The planned research network will be built successively, based in existing collaborations.

Discussion

The purpose of Health talk Norway is to contribute to the practical collaboration in health care. If successful, it will add valuable research based knowledge to be implemented in practical daily work in health care, and contribute to reach policy goals of patient centeredness and extended inter-institutional collaboration on patient treatment [11, 12].

Further, through gathering and systematizing qualitative research on people's health experiences and disseminating these, this project paves the ground for the social aspects of the doctor-patient encounter to be better grounded in existing (social) scientific knowledge, in line with the ideals of "kunnskapsbasert praksis" ("evidence based practice") in Norwegian health care work and education.

Through its ability to reach patients and the lay public via the web, the project also has an evident public health potential. At www.dipexinternational.org (downloaded 20.05.2015) we can read that: "DIPEx International's mission is to promote the spread of such research [rigorous research into people's experiences of major illness and health-related conditions] throughout the world for the benefit of all those dealing with health issues, including not only patients and carers but also health and social care professionals, providers and educators. Online, accessible publication of the results of robust qualitative studies provides a unique perspective on the very different ways that people deal with health issues. They educate those facing similar health challenges and remove the oft-felt sense of isolation. Clinicians and health service providers have increasingly recognised the importance of putting patient experience at the heart of service design and commissioning."

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Meeting Sickle Cell patients' unmet needs with eHealth tools: a preliminary study

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Abstract

***Background**: Sickle cell disease is the most prevalent inherited blood disorder in the world. It can lead to many life-threatening chronic issues and comorbidities. The prevalence of the disease is more important in developing countries. In developed countries, self-help solutions for chronic patients are rising and are increasingly used. E-Health tools become companions for self-managing patients.*

***Problem**: The use of mobile applications to support the self-management of chronic diseases has proved to improve the quality of life of patients. We try to identify the opportunities for people with Sickle Cell disease created by the use of such tools and investigate what are the patients' main concerns.*

***Method**: We have performed a literature review to under-stand the main challenges of the disease. Additionally, we sent a questionnaire to patients to identify their needs. Finally we researched how the potential use of eHealth tools and Information and Communication Technologies based solutions could resolve some issues.*

***Results**: The literature review has shown a low number of contributions but these studies had mainly positive outcomes. The results of the questionnaire have shown a significant dissatisfaction from patients about the health care system taking care of them. Patients' responses also showed their will to improve their general knowledge about the disease and their interest in using e-Health tools for improving their quality of life.*

Keywords:

Sickle cell disease, eHealth, mHealth, self-care, self-management, self-monitoring, self-help devices, wearable devices, quantified self, public health informatics, global health, uHealth

Introduction

Sickle cell disease (SCD) is a complex hereditary blood disorder affecting red blood cells. It is a chronic disease that touches approximately 200 million people in the world. Originally the disease was spread from southern Europe to central Africa and from India through the Arabic peninsula to Western Africa. This distribution is thought to be correlated with the spread of malaria. Nowadays, due to migrations [1], there are cases worldwide with a high prevalence in the United States, Central America, the Caribbean, and in the UK [2,3]. However, SCD remains a rare disease in the 25 member states of the European Union, with a prevalence of about 1-5/10'000 [4]. Africa is the most touched continent but worldwide, around 400'000 babies are born with the disease each year. Consequently, the number of patients with SCD is growing continuously [3].

Moreover, most of African countries lack of financial resources. Beliefs [7] and organizational issues decrease the capacity of rapid action and the acceptance of treatments [8,9]. On the other hand, Sickle Cell disease is a neglected global health issue, requiring more awareness and a public agenda [6,10–14].

How SCD affects patients:

The disease manifestations are essentially debilitating vaso-occlusive crises (VOC) causing acute and painful episodes lasting around seven days. Deformed red blood cells get stuck in capillaries, organs don't receive oxygen anymore, causing dysfunctions and organs failures. The crises lead in most cases to hospitalizations but can sometimes be managed at home [15,16]. Patients are treated urgently by a supply of oxygen, hyper hydration, blood transfusions, fever control and strong opioids administration. This has to be performed promptly in order to avoid life-threatening complications [17]. These acute and chronic complications can be, among others, strokes, acute chest syndrome, pulmonary hypertension, generalized organ damages, priapism, blindness and gallstones. They are the cause of a short life expectancy and a low quality of life [18]. In average, acute VOC occur once per year but patients report pain every two days [19].

Management of SCD:

In developed countries, until few years ago, people with SCD rarely survived after childhood. Nowadays, thanks to guidelines [20,21], new treatments, pain management, systematic cares and early screening, the life expectancy, the quality of life and the quality of care are improving [22]. Half of patients survive beyond 50 years [23]. Therefore the main challenge is to avoid VOC as much as possible. The more complications happen, the more organs will be damaged. Subsequently, the treatment will become more expensive, difficult to manage, painful for the patient and the risk of premature death will increase.

Patients can reduce the frequency of VOC by following certain habits. The United States Center for Disease Control and Prevention released a self-care toolkit [24] that provides advices and guidelines on the treatment of complications and the manifestations of the disease. The document provides tips on how patients can get healthy habits, track, manage their chronic pain or prevent infections [25]. Infections are known to be a trigger of VOC and to avoid that, it is recommended to get vaccines. Furthermore, patients are advised to drink a lot of water in order

to keep the red blood cells hydrated. It is suggested also to maintain a moderate body temperature and to avoid putting the body in hypoxia. Therefore, patients should avoid high altitudes, tiredness and exhaustion due to physical activity and optimizing their diet to keep a certain level of blood acidity. Indeed, acid pH induce the sickling of red blood cells [6].

Lately, no studies have been published regarding the use of ICTs to support the self-management needs of people with SCD. We will present later in this paper some of patients' issues that could be tackled by the use of mobile apps.

Quantified-self movement and SCD:

The Quantified-Self (QS) movement illustrates the engagement of individuals in self-tracking many parameters like physical activity and performance, diet, psychological changes, health status or by physiological data. Tracking mental and cognitive states like depression or mood, environment variables for example weather or noise or social variables like charisma is also popular [26]. These data allow the self-tracker to be more aware and to understand himself better, by seeing data and charts. Thus, the user can be the catalyzer of lifestyle changes. However, making sense of data by creating knowledge and information is complex. The general idea is to aggregate data from many people and to process them with data mining techniques [27] in order to find new evidences or hidden insights.

For example, people can use wearable devices to collect data and use a mobile application that analyzes them and shows them in a meaningful way. The community of QS is continuously growing and many start-ups, companies or researchers are helping to solve the various challenges. Consequently, questions are raising about how to use, evaluate, protect and trust data [28,29].

The Quantified-Self movement opened the door to the use of Information and Communication Technologies (ICTs) as a resource for patients to cope and track their chronic condition.

Predictive analysis and early detection of VOC:

Useful information can be created from collected health parameters like tiredness, low blood oxygen, fast heart rate, difficult breathing or dehydration. It can even lead to predictive analysis for the early detection of crises. For instance by analyzing the oxygen consumption and oxygen needs [30–34]. These data could be tied to an alert system. When an unusual event or measure is detected, such a system could advise the patient to contact his doctor or take an action. When a patient need very close surveillance data could be sent directly to the doctor and potentially avoid complications.

We can argue that early detection of VOC could be tackled soon since sensors are now able to track in real-time comprehensive physiological data [35–37]. Some tools already exist and can be applied to SCD. For instance to prevent dehydration with non-invasive electrolyte sensors [38] and adequate drugs [39].

Developing them, in an accessible way for patients can benefit their health outcomes. Automating the recognition of such symptoms can give the opportunity to treat patients in a timely way and a system could for instance, help to prevent the triggering of crises or provide advices for behavioral changes or for a healthier lifestyle.

The use of eHealth tools for a more effective management:

Self-monitoring has been done for years by people with diabetes to control their blood glucose level. Results showed clinical benefits and an improved treatment management [40]. Providing caregivers an updated view on their patients' health status can help them to make better health decisions. Specifically for Sickle Cell disease, high-income countries lack of coordinated care and the scarcity of the cases can decrease the quality of care. People with SCD, but also caregivers, often lack of knowledge about the disease [41,42]. Information, on the health status of the patient, that are collected during doctors' appointments, exams or checkups, could be acquired by other means. Patients could, with devices available on the market, handle the measurement of their blood pressure [43,44], oxygen saturation, heart-rate and fatigue level [45]. These measures could help patients and caregivers to have a better control and understanding of their condition, lead to a better management of the disease and potentially avoid some visits at the hospital [46,47]. The data could be transmitted remotely and improve caregivers' decisions. We have seen some examples of earlier interventions and better health outcomes with the use of home tele-monitoring solutions for the management of chronic illness and long-term conditions like for instance diabetes, chronic obstructive pulmonary disease, hypertension or cardiac diseases [48–50]. However there are some challenges. It requires patients to be educated about their disease, to have knowledge about their specific case and to understand how to manage their condition with such tools. Likewise, a good level of compliance is necessary to maintain a long-term management [51] and all contexts are not suitable [46,52].

Prevention and early diagnosis:

To prevent the burden of sickle cell disease, patients can, thanks to genetic counseling, determine if their conjoint is also carrier of the sickle-cell trait [53]. It can allow them to avoid a high-risk pregnancy. Furthermore, if the disease is detected during pregnancy, parents can, in some countries, request a therapeutic abortion [54,55]. However, when patients actually have the disease, in addition to medical care, they can seek support from medical specialists, patients groups and communities. They can look for advices on how and where to find good cares and share experiences on how to organize their everyday life [56].

Globally, main issues are the negligence of systematic screening and the late diagnoses [57]. Consequences are a lack of appropriate care such as children immunization. Yet, organizing such screenings can decrease the infant mortality rate drastically and accessible technologies, as exemplified with the use of mobile microscopes, coupled to the automated counting of sickle cells, can facilitate it [58]. The recent development of small, mobile, cheap and simple to use e-Health tools is encouraging.

Access to information:

Mobile platforms can be used by patients and caregivers to retrieve and show information. They can also allow to create a knowledge sharing global network. And this can be a great opportunity to gain knowledge from patients around the world and a step forward for a disease lacking of awareness [59].

Some patients organizations give patients the opportunity to become more informed about the on-going research, the existing treatments, the new potential treatments [60] or the alternative treatments [61]. Such organizations like the Global Sickle Cell Disease Network [62,63] or Orphanet [4, 64] can help patients to get informed of their existence. Here, ICTs can facilitate the access to educational content and provide a list of the organizations of interest. The information could be used as well by medical educators and by families [65,66].

Methods

We conducted a literature review in order to identify relevant papers about ICTs solutions for Sickle Cell disease. We included all the systems created to tackle at least one of Sickle Cell disease issues as well as the innovative systems including

those without any focus on self-management. The systems included must also have be meant to be patients-operated. We used the terms "sickle cell disease" in combination with the keywords "mobile", "electronic", "self-management", "system", "mHealth and "cellular" on PubMed, IEEE Xplore, Cochrane, Web of Science and PLOS ONE.

Afterwards, we sent a questionnaire to several patients associations around the world (n=19; mean age 31.9 years; 21% males; 79% females) in order to identify patients' main needs and wishes in term of mHealth or healthcare organization. For this study, we excluded non-adult patients because our preliminary literature review revealed a lack of studies aiming adult patients and because of the recent life expectancy increase. The questionnaire included a total of 47 questions, including mandatory closed-ended questions with the possibility of adding an additional answer in free text and non-mandatory open-ended questions at the end.

Results

Literature review:

We identified 25 relevant papers. This low number contrasts with the millions of patients worldwide. It perhaps illustrates a lack of interest and awareness about the disease. Nevertheless, the reviewed studies showed interesting outcomes with the use of eHealth projects. The majority of the reviewed studies showed how relevant and promising can be the use of ICTs for patients with SCD. For instance, a mobile app aiming to provide patients a tool to manage patients' symptoms demonstrated their great interest in the use of technologies, and this, regardless of their demographics [67]. A project about a smartphone-based microscope suggested the potential use of a cheap tool to screen sickle cell disease in developing countries. Imaging techniques could be applied to detect abnormal red blood cells [68–72].

Several papers aimed to enhance patient-provider communication, pain-management and management of the everyday life. Other teams have developed a system using text messages helping to conduct psychotherapy interventions or monitoring the pain remotely [73–75]. They showed that technologies can help to improve the physical and mental health-status of patients. A web-based diary and a text messaging service for youth provided services for monitoring pain symptoms [76–78]. We also found an example of a system monitoring the school attendance and the daily activities of teenagers with SCD. This projects aimed to understand the extent to which the disease make children miss days of school [79,80]. These different projects indicated that patients had a good level of compliance with ICTs tools helping them to manage their disease.

The earliest telemedicine applications for the disease have been done in the early 2000s. They have shown better clinical productivity, as well as a good patient satisfaction. Patients could gain better access to healthcare, especially in rural remote areas [81–83]. Such projects are subject to some limitations. A study concluded that establishing medical homes is not always interesting [84]. Indeed, the lack of specialized medical staff is often too high and the lack of personal cannot always answer the demands [85]. Self-management solutions combined to telemedicine applications, for instance for pain management, were preferable [86]. A recent paper revealed an interesting use of sensors on portable embedded systems for patients living in remote areas [87].

Questionnaire:

The results revealed many interesting indications. First of all, the question about patient satisfaction revealed that many respondents were moderately satisfied (N=19; 30%) with the way the healthcare system treats them but most of the patients (N=19; 45%) were satisfied with the healthcare system (scale of 0-4, from not satisfied to extremely satisfied). Those contrasting results underline the interest of improving self-management tools. Further analysis will be required in order to understand the correlation with demographical and geographical information.

Enhancing patients' health-literacy level:

Mobile applications can provide information to patients about the disease and on how to have a healthy lifestyle. As described previously, there are some important actions that patients can take in order to improve their quality of life and decrease the occurrence of crises. Apps can then have an educational role.

Main patients' wishes are the following:

- Patients (N=19; 75%) want to receive information about what are the best behaviors to opt for in their daily life.
- They (N=19; 70%) also want to increase their knowledge of the disease in order to learn how to detect early signs of flare-up.
- Results (N=19; 55%) point out that they want to have access to information about how to self-care and get support to follow a healthy lifestyle (N=19; 45%).
- Respondents (n= 19, 65%) reported the will of getting access to support groups or patients' communities. They (N=19; 65%) also stated the wish of learning more about the available medicine, the new treatments and the ongoing research projects in which they could be involved.
- Finally, a slightly less important demand for patients (N=19; 45%) is to learn about the causes of triggering of VOC.

Self-care and daily activity support:

SCD patients being exposed to a wide range of symptoms that affect their everyday life, mobile applications, eventually used together with other electronic devices, can help them to collect data on their current health status and on variables that can affect it. In this case, apps can have a tracking as well as a warning role. The respondents' wishes in term of self-care and daily activity support are shown by the following results:

- Returned surveys showed that the two major causes of daily life disturbances due to SCD are pain episodes (N=19; 95%) and fatigue (N=19; 74%). These findings are supported by studies showing correlations between fatigue, pain and quality of life among patients with SCD [88, 89].
- Most of the people suffer every day (N=19; 25%) or every 2-3 months (N=19; 30%).
- Patients have difficulty to practice the recommended by WHO amount of physical activity (N=19; 60%) and at the same time, they struggle to manage their medication and to perform other self-care related activities (N=19; 50%).
- Patients visit their doctor monthly (N=19; 35%) or every 2-3 months (N=19; 75%).
- They reported a moderate desire to get information about their current health status (N=19; 50%).
- Respondents seem to be interested in wearing a device collecting their health data (N=19; 60%) and particularly to gather data about their state of fatigue (N=19; 65%), their pain symptoms (N=19; 55%), their health

status (N=19; 55%), their vital signs (N=19; 45%) and factors that could have an influence on their health like pollution, altitude, weather, alcohol or tobacco consumption (N=19; 45%). The survey showed that (N=19; 70%) of the patients are willing to share their health data.

- They explained also that receiving alerts when they should take medication or when their health status is worsening (N=19; 90%) would be of great value.
- Most of patients (N=19; 80%) found very important to carry permanently on themselves, information on their health condition and information about the disease, especially in case of emergency.
- Finally, the biggest fear of patients, as seen in some of the remarks they wrote in the free text zone at the end of the questionnaire, is to not wake up the day after, because of a stroke or a deadly complication caused by a crisis.

Non-functional requirements:

Patients also described what would motivate them to use a system responding their needs in a regular basis. The simplicity of use and the design were not crucial criteria (N=19; 45%) but a stable system providing accurate and trustworthy information (N=19; 65%) was the most important requirement.

Discussion

The literature review showed that mobile technologies, from embedded systems, physiological sensors or smartphone apps can be used together to support patients. For instance, among the studies found during the literature review, the papers of Jacob E. et al. [75-78] address some of the psychosocial issues of youth with SCD by facilitating the communication with their care provider in pain situations. The results of the study has shown an effective way to remotely assess the seriousness of a crisis and this can contribute to answer patients' demands of learning when their health status is worsening and of getting help about how to self-care in a daily base and in case of emergency.

The questionnaire results are also promising and emphasize the capacity of ICTs to help people with SCD. Patients seem motivated by the use of such tools in their everyday life. Their interest is marked about the use of mobile applications as an information provider, about the best behaviors to adopt, the disease and the treatment. The demand is less important concerning information related to self-care or to the causes of triggering of VOC. Patients answers demonstrate the impact of the disease on the everyday life with all the limitations that implies on normal activities. Fears mentioned in the free text comments illustrate the importance of the psycho-social issues in SCD [95,96]. Patients tend to internalize their worries and can also be subject to supplementary stressors [97, 98]. Patients have also acknowledged the importance to carry information about themselves and the disease in case it would be needed.

Efforts have been done about this last point in some countries to improve the care of patients in situation of emergency. The French Minister of Health provides for patients, information cards with information on the disease and a summary of patient's main conditions. [90]. Patients can have access to those cards by contacting their doctors. The first card, which must be signed by the patient, provides information on the doctor's contact and information about the people to notify in case of emergency. It also gives information about the best practices and the recommended interventions in emergency situations. Additionally, the card informs about websites talking about the disease and gives telephone numbers of specialists. Additionally, the doctor can add personal medical information about the patient like the type of sickle cell disease, the basic level of hemoglobin, the special needs in terms of care, and the clinical antecedents. Finally, the doctor can write the complications that occurred frequently, the medicine regularly taken and the allergies. The last card is the information and advice leaflet. This document is meant to be used by the patient, his relatives and his entourage. It gives general information about the disease and practical advices about when to contact emergency services or how to prevent and manage early complications. Likewise, websites and contact information of the French patients associations are available. This kind of information can be helpful for patients and can be easily adapted to a mobile app or transferred on another device like an implantable chip readable by a caregiver [91]. This last point could raise other ethical issues and acceptance problems.

Rather than creating an entirely new system, it might be interesting to take into account the already existing solutions that solve some of the specific SCD issues. Some publicly available systems, for instance used in the diabetes self-management, can serve as a source of inspiration and could be used by people with SCD. Some mobile apps and wearable devices available on the market can track the sleeping patterns and the quality of the sleep, monitor the physical activity [92], symptoms of exhaustion, tiredness or fatigue, but also help to manage the medication, the dietary issues or the pain symptoms [93,94]. Results have shown that patients want to increase their knowledge of the disease, we can suggest that implementing evidence-based knowledge into a mobile app can potentially answer their needs. Furthermore, recent studies confirmed that systems developed using evidence-based knowledge could be more easily recommended by specialists and used by patients. [90].

As discussed, patients have multiple needs and wishes. Therefore, offer them systems with many functionalities that succeed to meet their needs while remaining simple to use and to understand is challenging. SCD patients have specific characteristics and face particular life situations that must be taken into account. For example during a VOC, pain can be so intense that any move is difficult and mobile tools could be designed to support patients in this moment by making emergency contacts easier. Needs are multiple and further study of the questionnaire answers will help to specify them in order to meet them accurately. At the same time, usability is one of the important factor able to keep patients motivated and invested. [99].

Future work

The next phase of our research will be to analyze in deep the results and to actively involve patients in the design of a solution that could fit their needs. We will also research the best devices that patient could use to track their health status. A participatory evaluation will help to assess the fulfilling of patients' requests. Previous studies have shown promising results when using such methods [100,101]. We will also investigate the specific characteristics of patients with Sickle Cell disease in order to identify which approaches are susceptible to keep patients motivated to use a system. Several games for health or apps using gamification items have reached a good level of compliance and popularity [102–104].

To illustrate our findings, we designed an early prototype of User Interface (UI) mockups. It is shown on Figures 1-4 The mobile app interface illustrated is meant to interpret some of the patients' main needs expressed in the results, for example their wish to get information about the best behaviors to opt for, their desire to get information about their current health status, the interest in collecting their health data, the demand of being reminded when to take medication or the need to get help in case of emergency. The UI design has been done by following the heuristic evaluation principles [105]. Thus, by using an iterative design process, we could increase the quality of the interface. Based on the proposed design, we will conduct focus groups with patients in order to get feedback, define their priority needs and the features they would like to use the most.

Figure 1 - First prototype of UI mockups proposed to patients

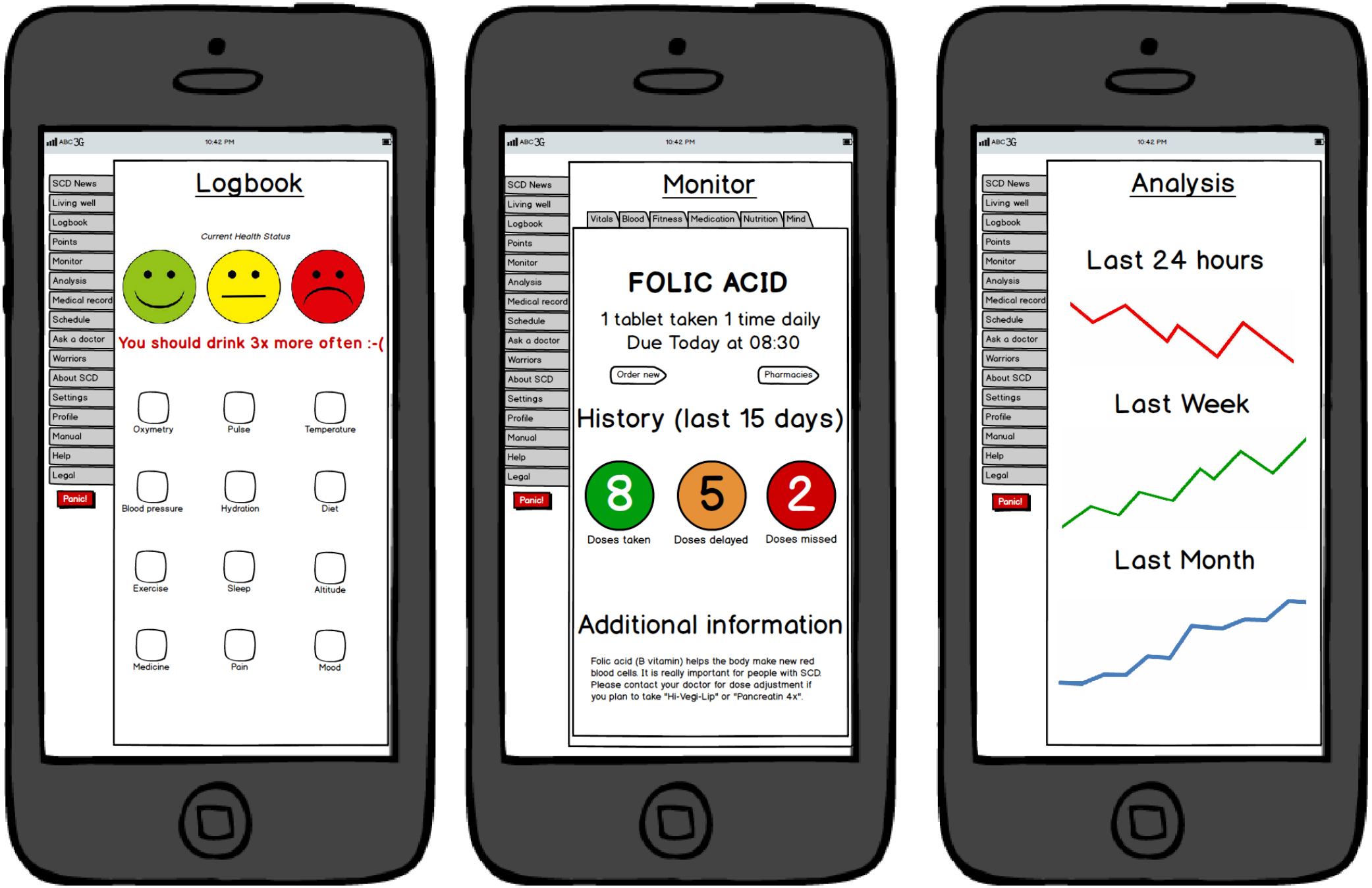

Figure 2 - First prototype of UI mockups proposed to patients

Figure 3 - First prototype of UI mockups proposed to patients

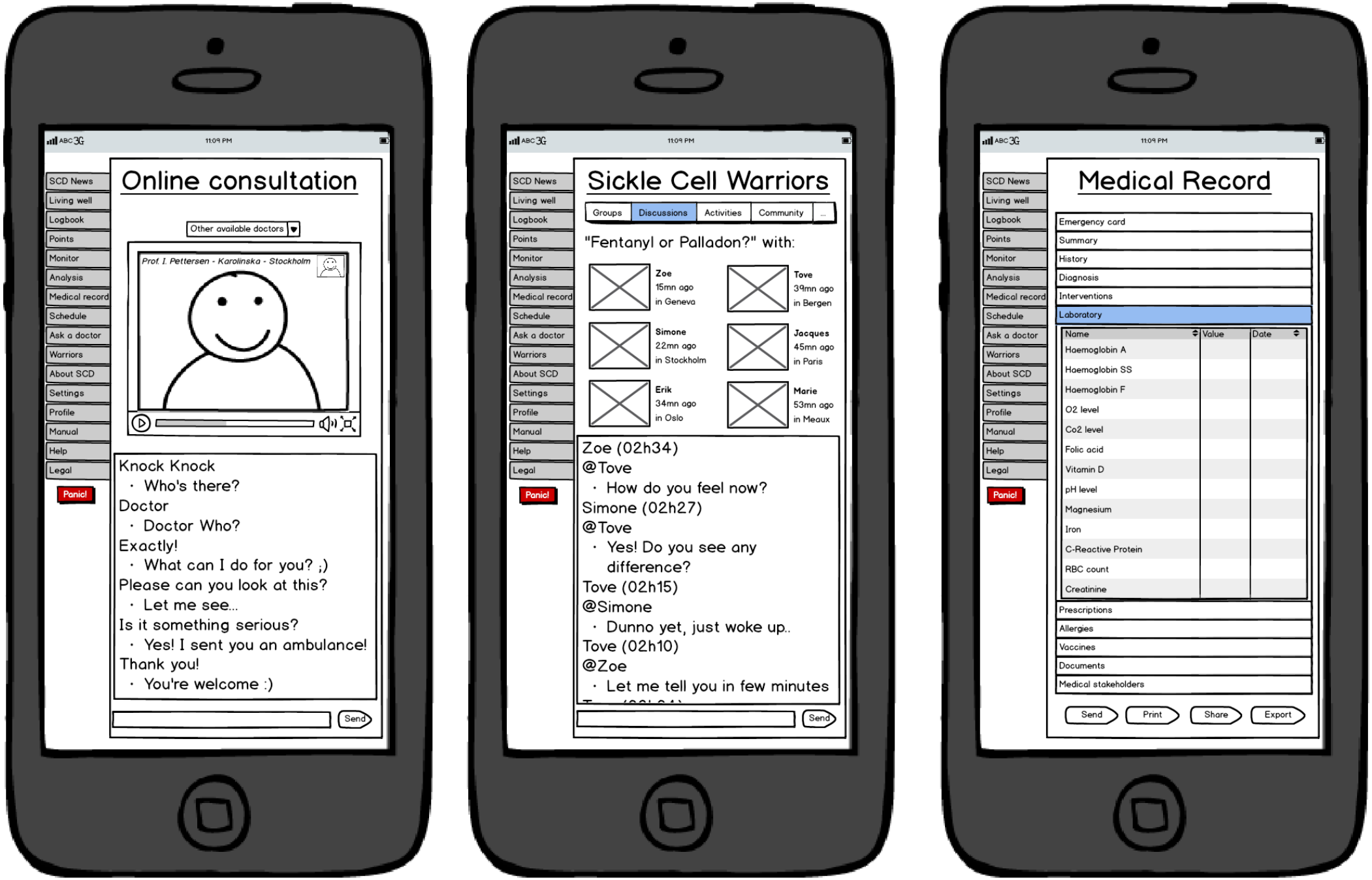

Figure 4 - First prototype of UI mockups proposed to patients

Conclusion

To summarize, patients suffer daily of pain symptoms and fatigue, they report seeing a doctor on a regular and relatively frequent basis. The majority of them is interested in wearing a device, and in collecting data about their symptoms but less about their vital signs or about the extern variables that could affect their health. Finally, patients show a strong interest about sharing experiences, by being in contact with patient groups or sharing their health data.

Sickle Cell disease is the most common inherited disorder worldwide and provoke important symptoms that affect patients' quality of life significantly. However, it remains a mostly unknown and few documented health problem, as demonstrated by the low number of relevant papers found in the literature. The disease illustrates the inequalities in health faced by patients in different care settings, despite the fact that the medical knowledge about the malady is important and especially because it has been proved that simple treatments and specific habits can improve the life expectancy [106]. The differences in treatment of patients, whether they are in the same country or whether they are in low-income or high income countries have negative consequences on the health outcomes.

That's why, the current illiteracy and the lack of awareness in which the disease is still held is preoccupying. Health professionals remain inadequately trained and informed, as well as the family and the entourage. That could illustrate a lack of interest or an insufficient political will towards the implementation and the improvement of existing solutions susceptible to increase the quality of care.

Fortunately, the use of eHealth tools for patients with Sickle Cell disease, could constitute a progress in the support of the disease worldwide. By allowing patients to measure health parameters, such tools can help patients in the self-management of their disease. Likewise, reviewed papers have shown that ICTs can be of an important utility for the self-care and self-monitoring of people with SCD. Tele-monitoring applications have equally shown their usefulness in helping SCD patients with these concerns [73]. Such tools could contribute to reduce the number of crisis by improving the ability of the patient and his entourage to detect bad symptoms early and to react consequently but also by helping patients to adopt appropriate healthy habits. Also, and it is encouraging, patients expressed, through the questionnaire, a marked interest for these solutions. They want to improve their access to information, to educate their entourage and to raise the awareness on the disease. They also want tools allowing them to collect their health data and to receive a quick feedback and an appropriate treatment when necessary.

So, work remains to be done especially to improve the data collection required to know better the patients' needs and to assess which technologies are the most suitable. Finally, although fraught by many challenges, the use of eHealth tools for SCD patients has a potential of improving health outcomes by tackling main patients' concerns.

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CallMeSmart: Location tracking using BLE beacons

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Abstract

Mobile communication for health care workers are a critical part of today's hospital infrastructure. Unfortunately, many of these systems do not work together, leading to personnel having to carry several different devices during their shift, which often cause unnecessary interruptions for the staff. Newer context-sensitive systems aim to reduce these kinds of interruptions by being aware of the users' surroundings and context. CallMeSmart (CMS) is a context-sensitive system, which aims to help medical personnel by controlling their availability according to their situation. This is done by evaluating contextual data in real time; data about the user's work schedule, role, surroundings, etc. In this paper, we discuss the development and testing of a system that can adjust the users' availability by continuously tracking their location and adapting to it.

Keywords:

Tracking, context-sensitive, mobile communication, Bluetooth low energy, interruption management

Introduction

Interruptions are a frequent occurrence in hospitals today. These interruptions vary in importance; from critical patient alarm to a colleague wishing to discuss a non-critical issue, and they often result in both medical and administrative errors [1, 2]. We believe that many of these errors can be avoided using context-sensitive systems, which through knowledge of the users' surroundings can help to decide whether they are available for communication, or busy with a critical task that require their full attention. In an attempt to improve this, we present the idea of creating a tracking system for hospitals. This tracing system is then used to track the location of the users, and thereby adjust their availability. An idea that has been explored in several other systems [3-5]. The difference is that we combine the location together with other contextual data about the user's situation to decide the availability.

Mobile communication in a hospital setting

While becoming increasingly more popular in other parts of society, hospitals still hesitate to adopt the use of newer communication tools like smartphones. Pagers are still used actively within the health sector in Norway [6]; despite the fact that the national pager network was shut down in 2007[1] , hospitals run and maintain their own pager networks for internal use by hospital staff. The referenced paper is from 2007, but this is still the case for most Norwegian hospitals., even though some has started to use wireless Voice over Internet Protocol (VoIP) phones.

As some communication is role based, e.g. the staff on the current shift, the head nurse, etc., some staff will often end up carrying several communication devices while on call. This makes it easier to contact personnel, but it can also be very interruptive for the personnel that are contacted frequently. Personnel in key positions, or who are knowledgeable within a certain field, will often be consulted. For this group, frequent interruptions can have drastic consequences [7, 8]. The use of pagers can often also cause longer interruptions that intended, as the person being paged may have to spend time on locating a phone in order to contact the person sending the page. This does not get better by the fact that some systems are designed in such a way that a patient alarm will notify every nurse on a shift, instead of only those who are responsible for the given patient.

While there have been several attempts to streamline and improve communications in hospitals, technologically solid solutions are not sufficient for such improvement. The users and the organization need to be involved in the process. More than half of medical information systems end up failing as a result of user and staff resistance [9]. Since we cannot find any newer work that contradicts this, it is clear that future medical systems needs to be designed and developed including input from the users and organization, if they are to succeed.

Context-sensitive systems

Context-sensitive systems are systems that are able to use various contextual information in order to provide a better service to the end user. Context in this sense is often defined; as any kind of information that can be used to describe and act according to the surroundings of the system. This could be as simple as dimming the brightness of the screen if the surrounding area is dark, or a phone turning off sound when in an area where interruptive noise is frowned upon, e.g. in a cinema or a church. Other examples could include knowing the amount of people in the same room as the user, or the location of the user; e.g. if they are in their office or sitting in a cantina. These kinds of system can have huge potential benefits in both business level, as well as at a personal level. A lot of research has been done on the subject of context-sensitive systems [10-12].

[1] http://www.telenor.com/no/media/pressemeldinger/2001/telenor-legger-ned-personsokertjenesten-om-to-ar/

CallMeSmart

CallMeSmart (CMS) is a context-sensitive communication system designed for use in a hospital setting. The idea behind CMS is to allow for better communication between hospital staff while simultaneously reducing the number of interruptions that such systems often result in [1, 6]. To do this, CMS was designed to use contextual information about the user, such as personal commitments; e.g. meetings scheduled in their calendar, availability status, and location. If a surgeon is located in a surgical theatre, it implies that: he/she is scheduled for surgery, he/she is probably sterile dressed and cannot answer the phone/pager/message and thereby should probably not be interrupted.

Location tracking in CMS

CMS previously used a set of Windows XP based laptops, running a custom built C# application called Location App, in order to track the location of personnel using the system [13]. These machines would attempt to connect to any Bluetooth (BT) devices in range of the location station once every minute. If the software managed to connect to a CMS device, it would forward the information to the context-aware application using Web sockets. The reason that CMS did not use any form of lightweight beacons (i.e. BLE (Bluetooth Low Energy) beacons introduced in next section; Materials and Methods) from the start, is that when the CMS project started, there were not any lightweight beacons on the market. As such, we had to use what was available, which ended up being laptops with BT dongles. Ultrasounds was briefly considered, but deemed infeasible for several reasons, including cost, the level of accuracy was not needed, and that there was not an easy way to make the phone pick up the signal, which means that there might be need for a separate device to pick up the signal. It should be noted that the location tracking part of the CMS system has not yet been deployed in the pilot test system.

Moving to a system that use lightweight BLE beacons could greatly improve the current solution in terms of both cost and accuracy. Using laptops with BT dongles as beacons has a high cost associated with it, and requires access to a power outlet in order to keep the laptop running. As such, the number of "beacons" will be relatively low, which also means that the floor coverage, i.e. the amount of space that is covered by the beacons, will be limited. BLE beacons on the other hand are cheap, and can run for months on a single coin cell battery. These properties mean that they can be used to cover a large area for a relatively low price.

Related tracking technology

RFID: Radio-frequency identification (RFID) was initially considered as an alternative to using BLE for tracking personnel, but was quickly dismissed. This was mostly due to the fact that Android phones only support a subset of the RFID technology in the form of Near Field Communication (NFC). As NFC only works over very limited distance, i.e. a few centimetres, users would have to actively bring the phone up to the NFC antennas in order for the system to track them. This is obviously not something that is desirable, as the system should ideally handle this by itself. If larger range RFID were to be used to track the phones, additional devices would be needed together with large RFID antennas to be installed at the hospital. This should be avoided due to the CMS idea that everything should be available and controlled by one device, in order to avoid healthcare personnel to carry several communication devices.

Ultrasound: Ultrasound is another technology that was considered, but also quickly dismissed. While ultrasound would allow for accurate tracking of users, it would also force users to carry another device for this tracking, as the phones would not be able to pick up the signals. This would go against one of the things that CMS wants to do, which is to reduce the number of devices that health care personnel needs to carry with them during their shift.

Wi-Fi Triangulation: Wi-Fi triangulation is a system that uses the signal strength of nearby Wi-Fi access points, in an attempt to track the devices location. This works by having devices map nearby networks measuring the Received Signal Strength Indicator (RSSI) of the signals received from the access points. These values can then be mapped together with the access point's hardware address and possibly GPS coordinates provided by the device. This information can then be stored and used together with data from other access points in order to estimate the devices location. This is often the next choice considered when GPS tracking is no an option.

While this solution might work in some cases, it is important to consider the scenario in which it is used. The CMS system is currently deployed at an outpatient ward at a hospital in northern Norway. As such, there is going to be radiation shielding and radiation reflecting equipment operating within the same space as the tracking system. This makes Wi-Fi triangulation an impossible option to use for this project. However, Wi-Fi triangulation are already being used by hospitals for tracking. A recent example is from Miami Children's hospital that has launched a smartphone app to help patients and their families to navigate throughout the hospital[2].

Materials and Methods

BLE beacons

Circle

Circle[3] is a short range BLE beacon whose use is primarily targeted towards locational tracking of everyday items. It is similar to many other BLE beacons like StickNFind[4] and Estimote[5], in that it focuses on being lightweight and simplistic. The way it is marketed is primarily for sticking on various items, e.g. backpacks, key chains, and laptops. Users can download an application that can be used track the location of items in that it will notify the user when it can no longer detect the signal from any registered beacon. The technical specifications of the beacons can be found in table 1.

Table 1 - Technical specifications for Circle Beacons

Range	30 meters
Battery life	10 months
Battery type	CR2016
Dimensions	27 mm x 6 mm
Weight	21 g

[2] http://www.computerworld.com/article/2496201/mobile-apps/miami-hospital-turns-to-wi-fi-triangulation-for-smartphone-mapping-app.html
[3] http://circle.pmd.tw/en
[4] https://www.sticknfind.com/
[5] http://estimote.com/

Estimote

Estimote is a BLE beacon somewhat similar to Circle. It uses a larger coin-cell battery, and as such claims a higher battery life, claiming 3 years of battery life as the default. It also claims a higher broadcast range of up to 70 meters. For CMS this can be considered as a weakness in some cases as it can cause the system to pick up beacons that in reality are far away from the user. Estimote also supports firmware updates over the air, temperature sensors, as well as various other services and APIs. The beacons used in this project are pre-production versions of the commercially available Estimote beacons. As such, the exact specifications of the beacons are not known, but it seems fair to assume that they are close to the specifications of the commercial beacons.

Phones

Since the beginning of its development, CMS has been tested and runs on several Android-based smartphones over the course of its development, ranging from phones using Android 2.3 to Android 4.4.2. However, some testing and developing have been started towards working on Android 5. The Samsung Galaxy S4 is the primary phone used in the system at the time, but will use newer phones like the Samsung Galaxy S5/6 in the future. As the tracking system being developed for this project uses BLE beacons instead of regular BT beacons like the earlier versions of CMS, this would mean that if the system were to be integrated into CMS, some of these phones would no longer be viable according to older Android versions. This is because built-in support for BLE was first introduced in Android 4.3. For this BLT tracking project, testing was primarily done using a Samsung Galaxy SIII, running Android 4.3.

Design: floor coverage

The plan for the system was to place beacons in rooms and corridors where the users normally move around, in order for the devices to be in range of a beacon. This floor coverage, i.e. the amount of space covered by the beacons, would then allow the system to keep track of where users devices in order for the system to update the users availability settings, if needed. An example of how floor coverage might look like is presented in figure 1. Here we can see that walls block out signals from adjacent rooms and corridors. Hospitals often have radiation secured walls, but normally walls this rarely happens unless there are thick-armed walls made of a solid material like bricks or concrete.

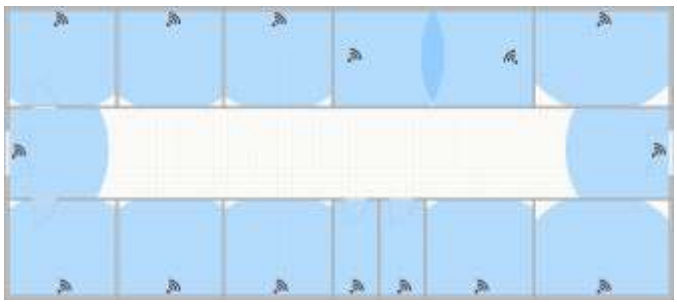

Figure 1 - An example of beacon network floor coverage

Beacon network

As the system is supposed to automatically adapt the availability of the user based on their location, beacons are divided into different list depending on where they are located and the availability associated with that location. As an example, beacons placed in meeting rooms would be considered to be in a medium availability zone, meaning that the availability of the user is reduced, while a cafeteria would be considered a high availability zone. Critical areas like, operating theatres, would be considered as a low availability zones, and thereby reducing the availability of the user. An example of dividing locations into different availability zones is illustrated in figure 2.

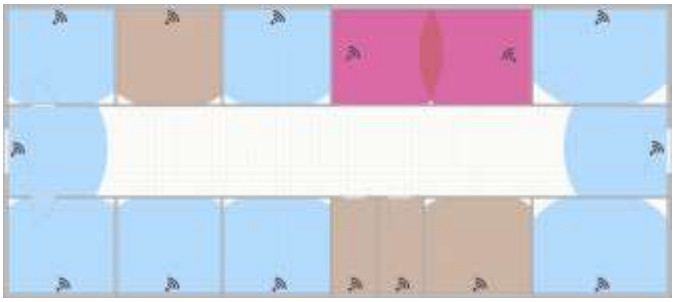

Figure 2 - An example of different availability zones

Program flow

When loading the system, it first schedules a new background thread that allows the system to keep running if the user leaves the application. This thread then starts a new scan. Once the scan is finished, the system contacts the server if it has any new information to be shared based on the beacons around it.

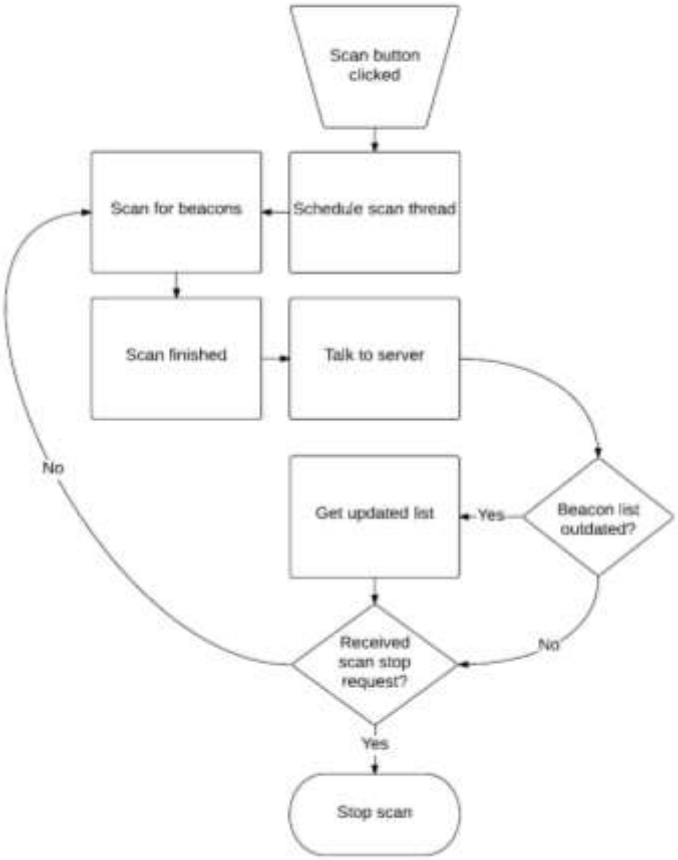

Figure 3- The flow of the tracking system

It should be noted that contacting the server after every scan, will in most cases be unnecessary, as most scan results would not result in a availability changes. As such, it would probably be better to adjust this so that the phone only contacts the server when a change in availability is made as a result of nearby beacons, or after a certain time has elapsed without any changes. When contacting the server, the system also sends a

hash of the current beacon list, which the server uses to ensure that the user always has the newest beacon list. If the current list of the user is out-dated, the server informs the system, which can then update the list. Unless the user has stopped the scan, the system then waits a pre-set time between each scan. The program flow is visualized in figure 3.

Results

Accuracy

In order to measure the accuracy of the system, a series of tests were performed. Primarily, two test cases were performed and measured. These test cases involved testing the phones ability to detect signals based on where the broadcasting beacons were in relation to the phone. The setup of the cases were defined as follows:

1. Two beacons on opposing walls in a room containing a phone. It was then measured how many beacons the system discovered when scanning.
2. Two beacons on opposing walls in a room adjacent to the room that the user is located. It was measured how often the signal from these beacons could be picked up.

Each case was tested with different combinations of scan time and scan intervals. For each test case the phone was placed in the pocket of the user, as this would be the primary location of the phone for actual use. The results of test case 1 can be found in table 2, and results for test case 2 in table 3. It should be noted that increasing the number of beacons in the vicinity of the scan increases the power consumption, as the phone needs to process more signals [14]. All tests in this setup used the Circle beacons.

Table 2 - Results from scanning tor beacons in the same room

Average beacons found	Scan interval	Scan duration
1.47	10 sec	2 sec
1.93	30 sec	5 sec
1.95	60 sec	10 sec

Table 3 - results from scanning for beacons in an adjacent room

Average beacons found	Scan interval	Scan duration
0.22	10 sec	2 sec
0.36	30 sec	5 sec
0.60	60 sec	10 sec

Power consumption

In addition to the tests performed to measure beacon detection, a set of tests was also conducted in order to measure how the phones battery was affected by repeated scanning. The results from these tests can be found in table 4. For this test, power consumption was measured as how much additional power was drained as a result of the scanning. Baseline consumption was estimated by observing how much battery power was drained when the phone was idling, i.e. doing nothing. Baseline consumption was measured to be roughly 1-2% per hour, leading to an average of 1.5% battery drain per hour. The percentages presented in the results are the averages of one-hour scans. As with the previous tests, these tests used Circle beacons.

Scenario

Scenarios are useful as they can be used in order to imitate behaviour that reflects the real world. In this project, we mainly wish to look at a specific scenario. As the focus of this project is on the development and study of a new tracking system, this should also be reflected in any represented scenarios. As such, the scenario imagined is one that imitates the movement patterns that users of the CMS system exhibit. Out of this, we wish to see how accurately the beacon network can be in order to track a users' location. More specifically, we define the scenario we wish to look at as follows:

- Personnel in hospitals often move around frequently during their workday. As such, there will be some areas in which their availability to others is going to be higher or lower than in other areas. By having a series of beacons that broadcast their presence, placed in various locations around the building, the CMS phones and systems can adjust user availability without the users having to manually interact. We wish to investigate this and get knowledge about how accurate the system can be used to track the users across rooms and hallways at the hospital.

We have introduced scenarios in which will allow us to see how well the system is able to track a user as they move around. In order to test this, a set of beacons was placed in different rooms, and a user moved between these rooms in a non-determined pattern. The results on witch beacons were detected where were logged by the phone. In these tests, we used both the Circle and the Estimote beacons. The layout of the floor, which the user moved around, is presented in figure 4. It should be noted that the beacon ranges shown in the figure are a theoretical illustration on how far the signals reaches roughly. The test results revealed that the signals did not reach as far, regarding through walls, as in hallways and open areas. Walls tend to impact signal range, though it does not completely block it. We discovered that the Circle beacons had a smaller coverage area than the Estimote beacons, and were more effectively blocked by the walls of the building. The estimate beacons were also affected by the walls, but not to the same degree.

Table 4 - Results from power consumptions, test one

Duty cycle	2 second	5 second	10 second
16.6%	3.04% (2/12)	5.00% (5/30)	3.00% (10/60)
20%	3.44% (2/10)	3.93% (5/25)	3.07% (10/50)
30%	6.66% (2/4)	8% (5/10)	3.50% (10/20)

Discussion

Accuracy

Initially, the idea was to use the RSSI from the beacons in order to estimate how far away the phone was located from the

given beacons when receiving the signal. However, as mentioned earlier[6] RSSI readings on Android fluctuate, something that was also verified during tests[7], though the observed results were not of such significance that it would invalidate usage. However, this makes it less ideal to rely on RSSI in order to determine more specific locating. Because of this fluctuation, less focus was put on using the RSSI and more focus was put on how reliable the phone was according to detect nearby beacons. The effect of this could probably be reduced by having a more aggressive duty cycle, where short but frequent scans were performed, and an average of the received RSSI results could be calculated.

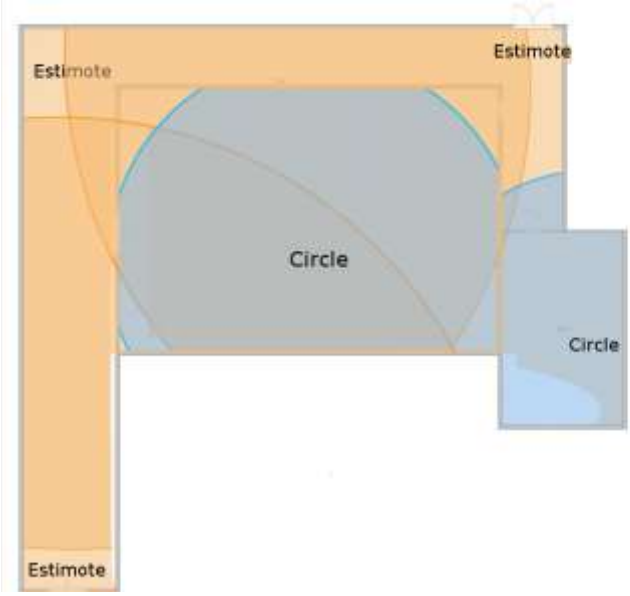

Figure 4 - The layout of the floor, on which the scenario testing was done, and the overlap of the beacon signals

As can be seen from the results presented in table 2, increasing the duration of the scan has a massive impact on how successful the phone is at discovering beacons. Part of the reason for this, is assumed to be caused by the broadcast frequency of the beacons. If scans last shorter than the beacon's broadcasting interval, there will be situations where the phones does not find any beacon signals. A contradicted reason could be that the phone gets more chances to pick up the signals broadcasted. The drawback is that; it is thereby easier to pick up signals from adjacent rooms or room that the user walks by, when passing through a hallway.

Looking at the results from table 3, we noticed that the number of beacons found remains low even when increasing the length of the scan duration. However, when increased, the discovery rate more than doubles. Increasing the scan duration too much is, however, not desirable as it makes it a lot easier to pick up signals which would not correctly indicate the position of the user. The low discovery rate observed is primarily because of two reasons, wall material and beacon positioning. While there are limitations as to what can be done in regards to walls, good positioning of beacons can probably have noticeable effects on the system. An example could be placing beacons on walls opposite the doors, in an attempt to reduce the chance that someone walking by the room detects the beacon. A small amount of testing and configuring seems necessary to indicate this, though the sample sizes used for this test were far too small to make any sort of valid conclusion.

In order to make the system realize that a beacon is not in the same room as the user, might be to have the system perform scans in different patterns. An example of this, might be having a scan interval of sixty seconds, but then scanning several times for one or two seconds. The system could then analyse the signals found and then make some assumptions according to stored experience. If one beacon was picked up four times and another just one, it would stand to reason that the first beacon was probably closer, or that the other beacon might not be in the same room.

Some short tests was also performed where the phone was held in the palm of the users' hand. While not tested extensively, the testing performed seemed to indicate that accuracy was improved, as there were fewer obstructions between the phone and the broadcasted signals.

Power consumptions

As mentioned several times already, power consumption is perhaps the most important things to keep in mind when discussing these kinds of systems. If the system demands too much power the phone will need to be charged frequently, which will be an annoyance to the user. As such, battery life should ideally be longer than the shift of the personnel that uses the system. An average shift for the personnel that currently use the CMS system last around 6 hours. As CMS phones have a battery life that hovers around 12-14 hours, the results of testing the new system seems to indicate that there should not be any need to worry about the phones running out of power during shifts.

Looking at the results presented in table 4, it is clear that increasing the scan duration does not increase the power consumption too much. Instead, increasing the frequency of the scans has a much higher impact, in some cases even doubling the amount of battery power drained.

Another thing worth noticing, is that the more that beacons broadcast themselves, a greater amount of power is consumed, both by the beacon itself, but also the phone. This is a result of the phone having to process more incoming signals, but at the same time, it can allow for more accurate location tracking. The amount of additional power consumed as a result of this, is minimal on newer devices.

Scenarios

While the result presented in table 2 and table 3 are useful in their own right, it is more interesting to see how the system manages to track a user as they move throughout a building. Something that was noted while moving around the floor was the fact the Estimote beacons used had a far stronger signal than the smaller Circle buttons, and as such were picked up from a far greater distance, which matches the stats presented on their website. This is illustrated in figure 2. Signals from the Estimote beacons were also much more frequently picked up through walls. While having strong signals is a good thing in most cases, it can also be a hindrance in this case, as the system ends up picking up signals from beacons that are far away. The primary takeaway from this scenario testing was that simply scanning for signals is too naive of an implementation if the system is to be as accurate as desired. The system needs to either use the strength of the received signal or some other scheme in order to find more accurately pinpoint the users location.

[6] https://community.estimote.com/hc/en-us/articles/202028913-Why-beacons-are-less-responsive-on-Android-than-on-iOS

[7] This was tested by placing a phone on a table with beacons on either side of it and then checking the received RSSI of the beacon signals.

Evaluation

The accuracy results show us that the system is accurate as long as the beacons are in the same room as the user, but the results drop significantly when beacons are placed in an adjacent room. While this testing was done only with the Circle beacons, the scenario testing showed that the Estimote beacons were much more reliably discovered through walls, and it stands to reason that the results of the accuracy testing would probably look different if also tested with the Estimote beacons.

As mention earlier, phones in the CMS system currently have a battery life ranging around 12-14 hours with heavy use. With an average shift lasting around six hours, and phones being charged between shifts, it wouldn't be a stretch to say that the additional power consumption that would result from implementing the new tracking system would not be a deal breaker in terms of power consumption. Considering that an improved system might reduce the frequency of scanning in favor of another scanning pattern and that future chip sets are though to become even more power efficient, battery consumption might be reduced even further, which is always desirable.

During the scenario testing we noticed that the signals broadcasted from the Estimote beacons were picked up from adjacent rooms more often than the circle beacons. Overall, the Estimote beacons showed better results in terms of signal strength as well as reach. This matches the numbers presented on the product websites[8]. As already mentioned, this is normally a good thing, but can be an annoyance for this kind of system. Reviewing the test results, it seems fair to say that the type of beacons used will have a massive impact on how well such a system will work.

Overall, the result gathered were within the range of what was expected. Estimote beacons were more easily picked up from a distance than the Circle beacons, walls block some signals but not everything, battery consumption increases with scan frequency, and simply scanning for beacons does not give accurate enough data to decisively find the users location.

Conclusion and future work

The developed system is still in an early stage, and there are several things that could be done to improve it. A deeper investigation at scan intervals and scan durations is things that could be interesting to look in too. This is a key component in two of the most important parts of the system; *accuracy* and *power consumption*. Being able to maintain the same level of accuracy while decreasing power consumption is always a desirable goal for such a system. This point could be explored by looking at scanning patterns, e.g. short scans with a constant interval, or longer intervals followed by several short scans. Another way of exploring the issue of accuracy build somewhat upon this, which is using rules in order to determine whether a discovered beacon should be considered in range, or ignored. Examples of this might be that if the system does four short scans in rapid succession, the user is assumed to be in the same room as the beacon if at least three of the scans received a signal from the beacon, and that each signal had an RSSI value higher than a certain threshold.

Another thing that could be interesting to look into is increasing the accuracy of the system by using several beacons in the same room in order to triangulate the position of the user in a similar way as Wi-Fi triangulation. This would be highly depending on the RSSI received from the beacons, and as mentioned earlier, the Android BT stack is still not accounting for signal interference. This could also be combined with the previously mentioned point of using rules in order to improve the accuracy of the system.

From an administration point, it would also be desirable if the phones also occasionally could poll the discovered beacons reading their current battery status. Having the phones do this job, would make the maintaining of the beacon network a lot easier. As this would allow the administrators to know which beacons were starting to run low on battery and might need to be replaced, it is easier to keep a flawless BT tracking network running. The fact that phone logs discovered beacons, could also be used in a similar way. As an example, if no phones have logged a beacon in a high traffic area, then there might be something wrong. Maybe the beacon ran out of battery, had a technical malfunction, or was unintentionally moved. In either case, having the system discovering these things might be helpful in reducing the amount of time needed in order to maintain the system.

Conclusion

A system for tracking users using a series of BLE beacons that sends signals to the users' smartphones in order to track the devices location has been developed. We conclude that the system is still in an early stage and there are still many improvements that can be made. We still think that tracking systems like this can be of great benefit for systems like CMS and other systems that benefits from knowing the location of its users or equipment, as long as the accuracy in locating the devices is not dependent on a very precise locating. These systems hold no value if they consistently track users to the wrong location.

It is worth mentioning, due to privacy and ethical reasons; tracking data within CMS is only available for the system itself. The location data is logged into the system for security reasons, i.e. what really happen if something went wrong, but is not available for the hospitals employees or managers.

While the system that was developed in this project might not be accurate enough to be considered to be integrated into the CMS system in its current state, it has demonstrated that using BLE beacons as a utility in tracking systems is assuredly possible, and a simpler easier to implement solution than the current solutions tested. We note that the type of beacons used can have a massive impact on the system, and simply scanning for nearby signals is probably too naive to achieve the desired accuracy.

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The Role of Research Institutions in Health IT:

Health IT Research Institutions vs. Health IT Companies

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Abstract

Health information technology is often presented as a solution to increase the efficiency and cost-effectiveness of health care providers. However, health IT is still far from meeting the stakeholders' expectations. The aim of this paper is to discuss the role of research, in particular of research institutions, in the field of health IT. The differences in the roles of health IT research institutions and health IT companies is discussed according to a framework on the determinants of successful health IT implementations. It is argued that it is necessary to understand that health IT research institutions and health IT companies are two different players with different focus. As health IT companies have their focus on the product, the production of new knowledge should be the main focus of health IT research. In this sense, the two should not be evaluated in the same manner.

Keywords:

Health Information Technology, Research, Successful Implementations

Introduction

Global trends, as the progressive increase in the proportion of elderly people in the society, often with a high prevalence of chronical conditions, and the decrease in the number of health care personnel, call for changes in the way health care is delivered [1-3]. Hence, healthcare providers are pressured to become more efficient and cost-effective. In this context, health information technology (IT) is often presented as a problem solver [4, 5].

Despite being considered as a solution for the problems in the health care sector, health IT is still far from meeting the stakeholders' expectations [6-18]. Why do promising research projects continue to fail to be turned into current practice? The aim of this paper is to discuss the role of research, in particular of research institutions, in the field of health IT. It is argued the necessity to understand that health IT research institutions and health IT companies are two different players with different focus. Therefore, their production should not be evaluated in the same manner, as their goals and scale of deployment are disparate.

This paper is divided into three sections. In the first section, the problem is introduced, and a brief literature review is provided. In the second section, the demand on health IT research is described, and a framework on the determinants of successful health IT implementations is presented. In the last section the role of research in health IT development is discussed.

Background

In the preface of a recent, large scale reform in the Norwegian health care, 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*" [19]. 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*" [19]. A clear goal on the use of IT in the Reform, as stated on page 135, is that "*electronic communication should be the standard way of communicating*" [19]. In line with this vision, an extensive IT investment is currently taking place in Norwegian health care. In the northern health region of Norway, 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 [20]. This is the largest IT investment in the region ever.

In an attempt to answer this eagerness from the government to improve the public health services, more research on health IT has been called for [21, 22]. However, as mentioned in the Introduction section, a substantial amount of the literature in the field of health IT, reports on unsuccessful implementation projects, challenges and unforeseen consequences of IT in health care [6-18]. Health IT has been failing to fulfill in real production settings the expectations drawn during research. This leads to the question: What is a successful implementation project, and what is a successful implementation in a research project?

Broens et al. [22] have identified the determinants of successful health IT implementations. These determinants are classified in five major categories: (1) *Technology*; this category encompasses four sub-categories, namely support, training, usability and quality. These sub-categories refer to the robustness of the health IT solution and its adequacy to the users' needs. It also highlighted the necessity to train the user in the handling of the health IT solution and support him/her in problem situations that might occur during its operation; (2) *Acceptance*; this category describes the key factors for health IT to have a persistent usage in everyday practice. This concept is described in three sub-categories: attitude and usability, evidence-based medicine and, diffusion and dissemination. (3) *Financial*; this category evidences the cost-effectiveness need of the health IT solution and the importance of such studies to ensure future financing structures; (4) *Organization*; emphasizes the lack of working protocols for health IT. The implementation of health IT often

requires changes in the existing organizational structure (intramural) and/or how institutions relate to each other (extramural); (5) *Policy and Legislation*; this category consists of three subcategories: legislation and policy, standardization, and security. The three topics describe, respectively, the health IT solution conformance to the existing legislation and policy, the use of standards to ensure uniform practice and interoperability, and the patients' physical safety and patient information security.

The following section will discuss the role of research institutions in this setting.

Discussion and Conclusions

It is the authors' opinion, that health IT research institutions and health IT companies are two different players with very different focus. However, the trend nowadays is for health IT research institutions and health IT companies to aim for the same handovers (i.e. full-scale deployment solutions). Additionally, they are also being evaluated in the same manner. This being said, in what ways are they different?

Health IT companies do not have the obligation to generate new knowledge, their focus is to generate a new product. On the other hand, the focus of research institutions should be on generating new knowledge and not on delivering a solution in the full-scale deployment state. However, the duration of a research project does not allow researchers to approach all the determinants identified in the framework presented in the Background, with the same depth. When the team involved in the research project is interdisciplinary, as argued in [23], it is possible to approach all the topics referred to in the framework during research. That being said, the question arises as to which depth can, or should, this topics be approached in research?

Hereafter, the differences in the roles of health IT research institutions and health IT companies will be discussed according to the framework by Broen et al. [22] on the determinants of successful health IT implementations, and summarized in Table 1.

In the *Technology* category, research institutions are often a step ahead of health IT companies. Researchers tend to monitor *in loco* the pilot phase of the project. By doing so, they interact in a larger extent with the health workers in their daily work than developing teams in companies. Hence, researchers are in a better position to provide personalized training and support to the user. Even though research institutions, due to their multidisciplinarity, are in a privileged position to provide this type of service as part of multi-faceted implementation projects, this strategy is seldom applied. Projects using multi-faceted implementation strategies, i.e. that provide a pluralistic research approach that does not focus in one particularity but instead aims to provide an overview of the research case, are extremely complex and costly. Companies aim for multi-faceted implementation strategies, which often fall short in meeting the needs of the organization due to the lack of relevant knowledge, as discussed below. Another issue is the health IT solution adequacy to the users' needs. Research project applications are funded according to how well they fit the topics of grant calls, which in principle meet users' necessities. However, health IT companies have an extensive knowledge of the market they operate in. This doesn't mean that research projects are more suitable than corporate projects. Again, this strengthens the claim that each player has a different focus.

Acceptance is probably the determinant in which research has contributed more in the last years. An increasing number of research projects are devoted to study the effects of health IT in the environment it is integrated. Research projects focusing on patients' experiences, impact on the organization, slow diffusion and dissemination, have contributed with great knowledge to this field. On the other hand, health IT companies develop new solutions upon request, or based on market opportunities. Their focus on having a product on the market leaves very little space for extensive contribution of new knowledge in this field.

The cost-effectiveness of a health IT solution is of great importance. Either coming from research or from a company, a solution will not survive in daily practice if it is too costly for the health care provider. A number of research projects fail in the *Financial* category. This happens for two main reasons: (1) the subject is not approached; and this may occur because the researchers' vision is out of the scope of the project, or, even if the researchers acknowledge the need of a financial study in the project, the limited time of the project leads for this study to be one of the first parts to be left out; (2) the study is not carried out with sufficient depth; this may also happen as a result of limited time, that might not allow for the required data to be collected. A company project has a different nature. Companies finance themselves, therefore a project will not survive, even before deployment, if it is not cost-effective. They are ready and willing to adopt strategies that make them more competitive.

In the authors' opinion, the *Organization* category is closely related to the *Acceptance*. The lack of working protocols that have been comprehensively described to support the development of health IT often leads to the need to perform changes in the organization. To change an organizational structure requires an extensive knowledge of the organization and the people that work in it. Health care organizations are recognized to have a high level of resistance to change [24]. Therefore, to make the changes required for health IT implementation it is necessary for the organization to accept the solution and recognize its usefulness. For the reasons already outlined above, research has provided the biggest part of the knowledge required to accomplish this work.

Policy and Legislation might be the most controversial category. Considering the scale of deployment of the final solution, in principle, research projects should not have the necessity to approach this category to the same depth as companies. However, to ensure a possible implementation for pilot purposes, research often diverges from its aim in an attempt to tackle the problem in the policy level described in the framework. One of the reasons for this may be found by the inexistence of research platforms provided by the healthcare provider and the involved health institutions [25]. The inexistence of platforms capable to support research pilots means that research implementations have to take place in production settings. As much as it is wanted, this process is extremely time-consuming for research projects. In companies, most of the required platforms and IT infrastructures already exist, and/or the connections and networks required to have them in place are already established.

It has been shown that health IT research institutions and health IT companies have different roles in the field of health IT. As health IT companies have their focus on the product, the production of new knowledge should be the main focus of health IT research. In this sense, the two should not be evaluated in the same manner. For research, consideration of what is a successful research project, and the successful implementation of a pilot, should be separated. Even if a research project does not reach the deployment phase, the knowledge generated might be of great importance, and a major contribution to the field of health IT.

Table 1 – Role of Health IT research institutions and Health IT companies applied to the determinants of successful health IT implementations in Broen et al. framework

Category	Health IT research institutions	Health IT companies
Technology	• Extended interaction with health workers - *In loco* monitoring of the project - Personalized training and support to the user • Adjusted to the topics of grant calls	• Extensive knowledge on the market • Reasons for development - Customer request - Market opportunity
Acceptance	• Contribution with new knowledge to the field - Studies on the effects of health IT, patients' experiences impact on the organization, slow diffusion and dissemination	• Focus on the product - Very little space for extensive contribution of new knowledge to the field
Financial	• Most project fail to approach the solution cost-effectiveness, because: - The subject is not approached either because it is considered to be out of the project scope or, the limited time of the project leads for this subject to be one of the first parts to be left out - The subject is not approached with the sufficient depth; this may be due to the project limited time and lack of data	• Self-financing - Projects do not survive, even before deployment, if they're not cost effective • Ready and willing to adopt strategies that make them more competitive
Organization	• Extensive knowledge on the organization needed to - Accomplish the organizational changes required for health IT implementation - Accept the solution and recognize its usefulness	• Customer focus - Constrain the problem with tailored solutions in continuous adaption to the user
Policy and Legislation	• Deployment: Pilot • Attempt to tackle the research subject in the policy level aiming a possible implementation - Inexistence of research platforms - Extremely costly and time consuming for research projects	• Deployment: Full-scale • Most IT infrastructures and platforms already exist • Established connection network

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The Living Challenge of Ambient Assisted Living – a literature review

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Abstract

Ambient Assisted Living (AAL) is a rapidly evolving research and development area propelled by scarcity of health resources caused by an aging workforce and increase of citizens in need of health care and health assistance on a regular basis. This paper presents a literature review of the current state-of-the-art of AAL. The objective is to point towards methodological actions to be taken into account in AAL research on this basis. Searches were conducted in five research databases. The search identified 86 papers. 10 of these papers were review papers chosen for analysis. The analysis presents an overview of the current status of AAL within the following categories: technology, users, application domains, rationales, successes and challenges of AAL. The paper concludes that the living part, i.e. the everyday practice of people living with Assistive Technology, is the primary challenge to the field due to its complexity of people and practices challenging the technological development and use. This calls for methods that support research carried out in close co-operations with the living environment and facilitate the complexity of stakeholders within the use-domain in a constructive and innovative manner. Living Lab is discussed as a general example on such methods.

Keywords:

Ambient Assisted Living, Literature review, Assisted technology, Living Lab

Introduction

Ambient Assisted Living (AAL) is a rapidly evolving research and development area. This is due to shortage of resource in most Western countries facing an aging workforce and an increase in the number of citizens in need of health care and health assistance on a regular basis. AAL is increasingly influencing health care and health informatics and it is generally assumed that supportive technologies will be required to maintain an effective health care delivery in the future. This is reflected in international and national initiatives, e.g. the European Unions joint Programme in Ambient Assisted Living, ICT for Aging Well, and support to development and implementation of welfare technology. AAL is also addressed in the recommendation of the International Medical Informatics Association (IMIA) on education in biomedical and health informatics [1] as a necessary learning outcome for health informatics specialist just as e.g. usability engineering and cognitive aspects of information processing.

Despite the attention on AAL, it is difficult to define such domain due to its continuous technological development. Recent roadmaps from the European Union Commission concludes that "there is no common view about the precise definition of Ambient Assisted Living (AAL)" [2]. The scope of AAL is broad including a variety of Assistive Technologies (AT), users and application domains. Thus the roadmap identifies three broad application domains (ALL for persons, ALL in the community, AAL at work) and five types of enabling technologies (Sensing, Reasoning, Acting, Interacting, Communication). A general description of AAL is that it encompasses "information and communication technology based products, services and systems to provide older and vulnerable people with a secure environment, improve their quality of life and reduce the costs of health and social care" [3]. The "living" perspective in AAL is broad and includes, according to the EU roadmap, AAL for people with different kind of living locations (family home, supported or sheltered housing/apartments, nursing home etc.), and on the move (mobile); AAL in the community: and AAL at work [2].

The purpose of this literature review is to present an overview of the current state-of-the-art of this broad field. The review serves as a basis for considering the methodological consequences of the challenges identified in the review. Furthermore, the summary of published research in this literature review provides a resource for other researchers and professionals working with AAL. The literature review is based on peer-reviewed literature.

Materials and Methods

The literature review was carried out via structured search in five research databases: ACM digital library, IEEE Explore, Google Scholar, ScienceDirect, and Scopus. These databases contain research in Information and Communication Technology (ICT), eHealth and electronic engineering. The search in the databases was structured via search strings of "AAL" OR "Ambient Assisted Living" OR "Assistive Technology" OR "AT" OR "Welfare Technology". Since the ambition is to present an overview of current AAL research, the search was limited to papers published within the recent six years period 2008 – 2013.

86 publications were identified. Among these we selected review papers for analysis. This included 10 papers reviewing a large amount of AAL literature.

The reviews used for analysis cover a variety of perspectives. Some of the review papers focus exclusively on video based technology [3], [4], a majority of the reviews focused on AAL in the home of elderly [5], [6], [7], [8], [9], [10], [11] and one review focused specifically on ethics [12]. One of the reviews aim at presenting concrete projects from around the world within the AAL area [5], others focus specifically on presenting the technologies involved [10] [11] and developing a taxonomy of different levels of operation [4], and others again focus on explaining different types of service categories [6].

In our review, being a review of reviews, we focused on revealing the main methodological points to be learned from current studies.

The analysis was carried out by readings of the selected papers and organizing findings within the following categories:

- Users (who are the users presented in the literature?)
- Use environments (what are the use environment studied in the literature?)
- Technology (what is the primary AAL technology in the literature?)
- Rationale (what is the expressed rationale for AAL in the literature?)
- Current status (how does the literature present the current state of AAL searched for in presented successes and challenges?).

Results

In general, the literature review reveals a series of minor studies, technological trials, and descriptive studies. Consequently, the literature does not present contours of theoretical frameworks or conceptual models for AAL. As such the literature resemble the broad field of AAL characterized by a lack of common view of AAL [2]. However, the literature does reveal current priorities, trends and general challenges of AAL. These are summarized below and elaborated in the subsequent sections:

- A primary focus on elderly citizens as users
- A primary focus on the home of elderly citizens as use environment of AAL
- A primary focus on monitoring technologies
- A primary economic rationale of AAL
- It is a success when technology works as intended in the research setup.
- The overall challenge is the "living" part of AAL, which is characterized by unpredictable and complex application environments, users and technologies to be integrated in an ambient assistive manner

Users

Primary users are elderly people as the main target group of AAL and "vulnerable people" [3], "cognitive impaired people [4], and "disabled" [5] as additional potential target groups.

A complexity of many stakeholders is presented in two of the reviewed papers including family caregivers, designers, health care professionals, decision makers all with different needs when it comes to technology and information [6], [7]

Use environment

The use environment of all the reviewed papers is the home of the elderly – term often coined "smart home". Thus, the literature presents a more narrow perspective on AAL than the one defied by the EU commissions including on the one hand different types of living locations such as the family home, home for seniors, supported apartments, nursing homes and on the other hand community- and work environments [2].

Technology

The primary technology under development and studied in AAL literature is monitoring technology in a span from video cameras and computer vision systems [3], [4] wearable technologies and assistive robots [5] and an overweight of sensor based technologies [6], [7], [8], [9], [10]. Also this is a narrower picture of AAL then the one defined by the EU commissions roadmap [2]. Some of the review papers address this narrowness and call for technology that prioritize social connections, assistive communities, and human participation [9].

Rationale

A primary rationale of AAL presented in the literature is economic with the ambition of reducing care costs [3], [4], [5], [7], [9].

Another rationale presented in the literature is improved health via technology that can "keep elderly people from the negative consequences of an emergency or potentially dangerous situation" [6]. This prevention of emergencies is presented together with rationales of "improving the quality of life" [8], safety, wellness and social connectedness [10], independence and self-determination [12].

Successes

In correlation with the economic rationale of AAL, a central success is a decrease of hospital admissions 5, [7], [9]. This economic success is a vision of AAL. However, none of the studies present evidence of the effects of AAL on health outcomes [8].

In correlation with the exploring character of the field of AAL, it is a field characterized by a series of minor studies and technology trials [7]. Success is estimated on the basis of the lack of failure on the technical device level [4], [10]. Also technological reliability is a vision, not a reality of AAL. As presented by [4] "there is still a long way to go to achieve off-the-shelf products".

Challenges

The literature identify a series of challenges from technical maturity and lack of standards [3], [4], [9], complex technical networks, usefulness and acceptance of Assistive Technologies by users [6], [7], [8], [12]. It is a general conclusion in the literature that the overall challenge is the technology's ability to meet the complexity of the real life of use – the "living" part of AAL. The complexity of AAL is presented as "beyond pure technical development" [6]. There is a need for understanding the living part of AT and move beyond assumptions that users will accept and adopt AAL without hesitation or training [5], [6] [8]. Consequently, several papers call attention to the need to focus on "interdisciplinary work between all stakeholders and the service engineers" [6]. The complexity of stakeholders is emphasized as important and stakeholder participation is presented as a current missing link in AAL research and development [7], [8], [12]

Discussion

The above mentioned challenges as well as the roadmap from the European union points to a need for methodological considerations on how to design and implement AAL: "All stakeholders should be aware that user involvement is the key for a technological, innovative and business success in AAL – from the initial concept through systems design and integration to the prototypes and business models" [2] However, user involvement is not a straight forward issue in this context. As mentioned above the main users can be identified as "elderly

people", but this is a very broad group that might very well include more differences than similarities in the requirements to AAL. Besides, there are also the surrounding people (relatives and professional caregivers) with their specific needs and requirements to AAL. Most of the papers reviewed have as a basic premise that AAT in general will make a positive improvement in the life of the elderly people. AAL is thus supposed to increase the personal autonomy and quality of life [4] allow people to live independently at home [3] [8] assist people with reduced physical functioning and also resolve social isolation [5] [10] by extending the time older people can live in their own home [9] help detect signs of illness [10] and so on. Whereas knowledge on actual users, use situations and use environments more belongs to the challenges that need to be addressed in the future [5] [8] [9].

A general issue related to acceptability of AAL and mentioned in several of the papers [3] [5] [8] [12] is the tension between privacy and security. As mentioned in [3]: "The dilemmas arise from the impossibility of weighing up the benefit of surveillance systems and the potential loss of privacy". Part of the dilemma might be handled as a question of different kinds of data protections, but there is no general true answer to this dilemma and the issue has to be solved as specific solutions for specific users in specific environments.

The overall challenge is as mentioned before the technology's ability to meet the complexity and multiplicity of real life. One methodological approach aimed at handling this need for cooperation among relevant stakeholders is Living Laboratories [2]. Living laboratories, Living lab from now on, refers to a setting that allows for innovation and cooperation between the various participants (different types of users, designers, researchers etc.) involved in development of e.g. AAL. The purpose of livings labs is thus to "enhance innovation, inclusion, usefulness and usability of ICT and its application in society" [13]. The concept of a living lab refer both to an environment that has different types of technology installed and a methodology that aims at supporting the cooperation and co-creation among the different participants involved [14]. Thus living labs support research in context and co-creation with users and are at the same time a test bed for different types of technologies [15] Different forms of Living lab exist, sometimes a natural setting is turned into a lab like a whole city or a real home and sometimes a lab is turned into a natural setting like when people move to a smart house. Living labs does not provide a formula for how to design for the complexity of life but represent an ambition to embrace the complexity of the real life when developing new technologies.

Conclusion

AAL is a broad field challenged by the complexity of problems involved in assisted living with technology. The current trend within AAL focus primarily on technology designed for elderly people living at home with monitoring technology. However, European Roadmaps and the literature highlight that AAL has a wider scope and include a variety of people interacting in complex networks including communities and work on a daily basis. Thus, AAL has the potential to expand beyond monitoring technologies. The literature call for expanding the current trend of AAL toward a focus on the power of human beings and their ability to support each other through technological cooperation's.

AAL is driven by visions about costs and health improvements. There is no evidence of the cost effectiveness and health improvements of AT. The field AAL is characterized by test of novel technologies where reliability challenges research and development.

Research implications from this literature review call attention to several aspects:

- the maturity of AAL and its importance for research and development, i.e. preparing AAL to reach a maturity that makes it possible to be tested in living environments is an important research focus. This includes the functionality of AALs but also the integration of multiple applications in AAL networks.
- methods that can facilitate research and development in the complex living of AAL. The complexity is a challenge to knowledge and resources of research and development and call for methods that can provide understandings of complex everyday living and innovative development of new practices for assistive living in a resource wise manner.
- A need to clarify the role of AAL stakeholders. It is a central challenge to engage stakeholders in AAL research and development. Methodological development on stakeholder participation should include a clarification of how best to set a team for AAL research and development.

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Diabetes Group Education versus Individual Counselling: Review of Conflicting Evidence

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Abstract

Current guidelines for diabetes self-management such as from the National Institute for Health and Care Excellence (NICE) do not mention group education or use of electronic applications as part of their recommendations. Perhaps this is partially because there is lack of quality evidence supporting use of either intervention. This review examines what appears to be conflicting evidence regarding clinical outcomes of group education and individual counselling strategies for people with diabetes. A final set of 14 studies was included, with a total number of 30977 participants. More than half of the studies found no significant difference between group education and individual counselling or motivational interviews. Two studies favoured group education, while two favoured individual counselling. Understanding the merits of the different approaches is important for informing health education strategies, but so far the evidence remains conflicting for clinical outcomes.

Keywords:

Diabetes, group education, tailored care.

Introduction

Type 2 diabetes remains a huge health concern and the problem is projected to worsen. Therefore, clinically effective care regimes that are also cost effective may reduce the burden on the health care service and society in general. In search of cost-effective measures, patient organizations in Norway and abroad organise group motivation and education programs, with substantial financial commitment into such programs.

However, current evidence-based recommendations suggest only individual education and counselling as essential parts of diabetes management. Guidelines, such as NICE, have not considered the more cost effective group programs or electronic and mobile self-help applications as part of their recommendations. Perhaps this is partially because there is lack of quality evidence supporting use of either intervention.

Current evidence is clear about the benefits of group education programs in contrast to usual care [1][2]. However, the literature has also consistently shown that the benefits are often in the short term only [3] while in other longer-term studies, the benefits have been shown to rescind [4].

More recently, studies report individual education as more efficacious than group education programs [3][5]. Despite these new findings, group programs seem to continue to be attractive, perhaps primarily for their affordability and social aspects. This area of inquiry has nonetheless gained much attention, as researchers seek to replicate earlier findings or build newer quality evidence.

Much of our knowledge regarding education approaches for diabetes comes from literature that is almost two decades old [6-8]. Since then, developments in education techniques, research methods, and information and communication technology have warranted an updated review of the subject matter.

For example, the advent of user-friendly mobile phones and mobile applications [9][10] , as well as the growing popularity of Internet social groups for diabetes [11], have changed the way individuals educate themselves, and manage and cope with diabetes.

The objective of this review was to name and qualitatively describe salient characteristics of studies that compare group education with individual care for people with diabetes. The synthesized information helps building evidence for cost-effective care that is also clinically effective.

Materials and Methods

The methodology is loosely based on the PRISMA recommendation for reporting items in systematic reviews [12]. The overall goal was to assess high quality evidence within the subject matter.

Eligibility Criteria

The eligibility criteria can be partitioned into the inclusion and exclusion criteria. We have used "Participants, Intervention, Comparator and Outcome" (PICO) [13], an evidence-based practice that aids conducting reviews for answering clinical questions. We only included randomised controlled studies (RCT), and studies without proper control were excluded.

Inclusion Criteria

Participants – RCTs with diabetes patients, regardless of the diabetes type, ethnicity, age group or location.

Intervention – the studies must be about education or counselling.

Comparison – the studies must compare at least two types of interventions; group education or therapy, and individual or tailored care or counselling.

Outcome – the studies must report at least the HbA1c or Blood Glucose levels as the primary outcome.

Additional criteria were that the studies must have been published within the last 5 years (i.e. since 2010). The follow-up period required for each study is at least 6 months, and studies published in other European languages other than English were not considered. We excluded unpublished literature (grey) in order to focus on higher quality evidence that is formally published.

The time constraint ensures we only consider recent advances, since seminal reports have become out of synch with recent advances. In addition, choosing a longer follow-up period was necessary to assess diabetes outcomes since HbA1c, a key outcomes for diabetes, is a long-term measure of blood glucose levels, reflecting health status approximately 3 months back in time.

Information Sources and Search Strategy

We searched biomedical literature databases; PubMed, EMBASE and Google search engine. We used "Diabetes", "Group", "Individual", "Education" and "Counselling" as the key search terms, and constructed search strings using logic operators.

Study Selection and Data Collection

From the initial search hits in databases, we examined the title for relevance. In iteration, we also considered the abstracts for relevance. From the semi-final set, full text was assessed for eligibility. No independent assessment was done by co-authors at this stage.

The data collection process involved going through the full-text and identifying the data items that were relevant for our case. The following data items were are developed from the authors' own experience with the subject matter, as well as from previous reviews:

1. Year of study
2. Length of follow-up
3. Number of participants
4. HbA1c
5. Key conclusion

Results

Current results appear to suggest a general disagreement within the research community as to whether group education is more efficacious than individual education or counselling.

Study Selection

As shown in Figure 1, the final set of included papers had 14 papers related to 13 controlled trials. We started off with a set of 89 papers based on search in the literature databases. We initially excluded 62 of these papers due to irrelevant title or abstract. After inspecting the full text, we further excluded 13 of the remaining 27 papers because they did not have sufficient basis for comparison, or the reporting was insufficient or poor.

Study Characteristics

All the included studies had some comparison of at least two different approaches to diabetes patient education and counselling, as shown in Table 1. There were no clinically significant differences between group education and individual counselling in 10/14 (~70%), and this represents studies that account for 17784/30977 or 57% of all the informants.

On the one hand, we have Hwee et al. [14] and Merakou et al. [15] who concluded that group education was better than individual counselling, while on the other hand, Sperl-Hillen et al. [5] and Vadstrup et al. found individual counselling more clinically effective. Studies by Sperl-Hillen et al. [5] and Merakou et al. [15] were both based on USA-developed and recommended "Conversation Maps" for individual counselling. The two studies focused on type 2 diabetes, and both had a follow-up period between 6 and 12 months. Despite the similarities in the two studies, they reported conflicting findings.

The nature of the interventions varied widely within the classifications of either group or individual. Studies varied from 6-hour group sessions to monthly group session run over several months.

Synthesis of results

Studies that had a follow-up period of more than 12 months were thrice more likely to find no significant differences in the two approaches, than did studies with 12 months or less follow-up (odds ratio = 46, p=0.0156). Further, all the studies that found significance differences had a follow-up period of 12 months or less. There does not seem to be any relation between the year of the study and the key conclusion.

In terms of recommendations, two studies, Vadstrup et al. [16] and Smith et al. [17], recommended that group education programs or peer education schemes should not be widely implemented, citing an unjustified waste of resources. One study cited how group education schemes had been very costly to maintain.

Of the five studies that reported blood pressure as a secondary measure, three found significant improvements in-group education, especially the systolic blood pressure.

Discussion

The evidence supporting either approach as more efficacious than the other is more unclear today than it was a decade ago. The main finding emerging from this review is that no significant differences between the two approaches were found. This finding may seem strange and in direct conflict with seminal work, but plausible explanations may lie in the way electronic applications are used ubiquitously by participants.

There exist today a number of electronic applications that patients use, even though such applications have not been sanctioned by their general practitioner or the health authorities. Patients who use electronic applications likely benefit from the advantages of both group (through online social networks) and individual counselling (through tracking personal health information), thus blurring the line between the two intervention types.

While researchers agree that education is an important element of a self-management regime for people with diabetes, the best delivery method for such education remains contentious. What is surprising, however, is that the majority of the included studies reported no significant differences between the two main approaches.

There are a number of potential explanations for the current findings. The first explanation may be that there does not exist any reporting standard, and as a result studies have not consistently or clearly reported data such as the ethnicity of participants, their location and geopolitical circumstances, their socioeconomic status, their education level, their age or the time since they were diagnosed with the disease. Second, except for the USA-developed Conversation Map, education interventions also lack reporting standards regarding, type of education material, the delivery methods or teaching style.

Except for one study reporting higher costs associated with their group education strategy, all the other included studies did not report economic figures. It is conceivable that these studies assume group education is more cost effective, and this may be the only major advantage area over individual counselling.

One study reported that over 80% of the participants preferred individual counselling to group education, when given the choice. This underscores a metric that is over and above the cost-benefits or health outcomes of group education – user preferences – that is often ignored in this debate.

Table 1 – Studies included in the analysis

	Reference	Year	Follow-up (months)	Sample Size	Diabetes Type	Main Conclusion
1	Sperl-Hillen et al.[5]	2011	6.8	623	2	Individual is better, using US conversation map
2	Hwee et al.[14]	2014	12	12234	1&2	Group is better, has less adverse incidences
3	Endevelt et al. [18]	2014	24	223	Pre-t2	No significant difference
4	Merakou et al.[15]	2015	6	193	2	Group is better, using conversation map
5	Khunti et al.[19]	2012	36	731	2	No significant difference
6	Mash et al. [20]	2014	12	1570	2	No significant difference
7	Vadstrup et al. [16]	2010	6	143	2	Individual is better
8	Dinneen et al. [21]	2013	18	437	1	No significant difference
9	Vadstrup et al. [22]	2011	6	143	2	No significant difference
10	Simmons et al. [23]	2015	12	1299	2	No significant difference
11	Smith et al. [17]	2011	24	395	2	No significant difference
12	Rautio et al. [24]	2012	12	8584	2	No significant difference
13	Minet et al. [25]	2011	24	349	1&2	No significant difference
14	Lau et al. [26]	2011	60	4053	-	No significant difference

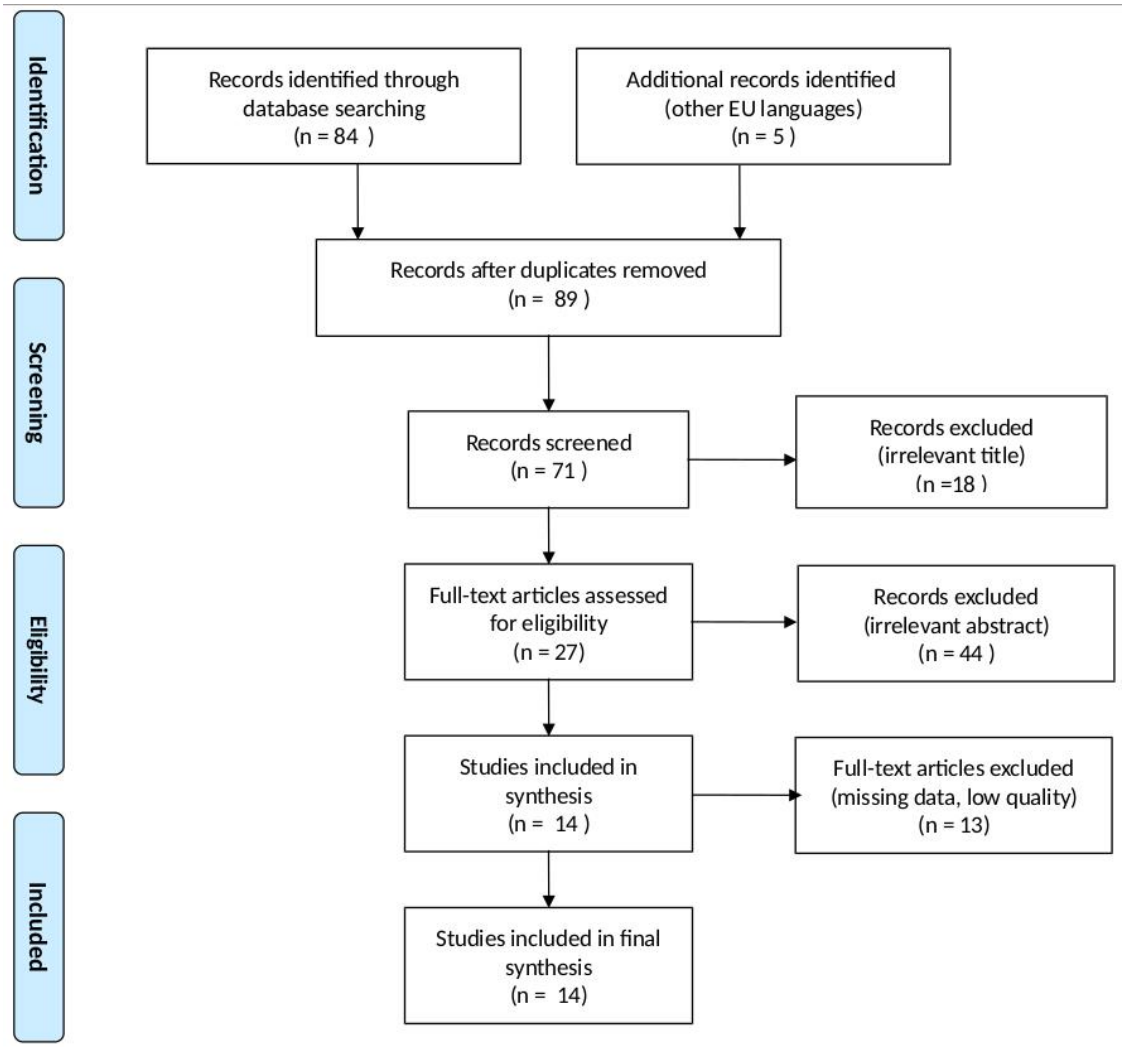

Figure 1- Study selection flow diagram

Risk of Bias

There are a number of local initiatives that are only published in local EU languages other than English, and our search did not expand to these databases. It is possible that expanding the search may reveal important cultural differences that could help us better explain current findings.

By excluding unpublished literature and localized reports available on the Internet, we may have reduced reporting bias. Since many countries continue to pour money into group education and motivation programs, even without any scientific evidence of effectiveness, many of these patient associations report mostly the positives of social interactions.

Limitations

One limitation is that we could not perform meta-analysis because of the non-standard reporting, which makes comparing effect or outcomes between studies problematic. For example, some studies reported only the relative differences between groups, and not the actual baseline and follow-up HbA1c.

"Usual Care" is a popular phrase for control groups in many studies, but the nature of this usual care is unclear. It may in fact include elements of individual counselling and education as recommended by evidence-based guidelines, but we generally excluded studies that were not explicit, and we may have missed some evidence. These limitations, however, do not undermine the value of our main findings.

Conclusions

This review confirms the conflict in the literature and reveals that there are no significant differences between group-based education and individual counselling approaches. This directly contrasts with key seminal evidence, and therefore requires further investigation, to enhance our understanding of the factors that foster the best outcomes.

Acknowledgments

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Telemedicine Services in Arctic Environments – Challenges for Successful Implementation

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Abstract

The growing interest in Arctic areas, both from professionals and tourists, is a challenge for the health care system in areas suffering from extreme weather conditions, long distances and poor communication network coverage. Offering adequate health care services for people who live in these Arctic areas might be very difficult in part of the year. Access to medical services, in particular specialist services, is limited. In cases of emergency such as a large-scale accident, the system is further challenged. This paper discusses major challenges for successful implementation of telemedicine services in Arctic environments, with a special focus on handling accidents. Lessons learned from less challenging regions will be addressed in order to recommend a common set of critical success factors for implementing telemedicine service.

Keywords:

Telehealth, arctic, search and rescue, emergency response, telemedicine, critical success factors for telemedicine.

Introduction

With an increased focus on severe weather conditions and climate changes like erosion and storm surge, availability of medical care has become important for sustainable societies in Arctic regions. Telemedicine plays an important role as a tool for offering health care to people in remote areas, and is used in all circumpolar areas [1-9]. Telemedicine in North Norway is widely known for early adoption of telemedicine services to serve the population living in rural and remote areas in the Arctic [10-12]. Visionary politicians, health administrators, doctors and researchers who saw the possibilities to offer high quality healthcare to everybody regardless of where they live, initiated the development of telemedicine services.

Since the first telemedicine services were established twenty-five years ago, telemedicine has enabled specialist health care services to people living above the Arctic circle in North Norway, one of Europe's most remote and exposed regions.

After its foundation in 1993, The Department of Telemedicine at the University Hospital of North Norway (UNN) in short time became one of the most recognized telemedicine centres worldwide, mainly due to the centre's capability to launch operative telemedicine services. In 1999, the department was renamed to Norwegian Centre for Telemedicine (NST) and was given extended responsibility in Norway. From 2002, NST has been a World Health Organization (WHO) Collaborating Centre for Telemedicine [10]. At the recognition ceremony, Dr. Gro Harlem Brundtland, Director-General of WHO (in 2002), argued in her opening speech that telemedicine would have an important role in the development of health systems [10] by saying:

> *"Information and communications technologies (ICTs), as a whole, have introduced profound opportunity and potential for the worldwide advancement of medicine and health care. Telehealth, electronic health records, computer-prescription entry systems, and e-health, hold great promise for the future."*

To realize the full potential of telemedicine, Dr. Brundtland argued that several challenges had to be met within [10]:

- Security, privacy and confidentiality
- Legal and ethical aspects
- Organizational aspects
- Technical know-how
- Funding

Telemedicine services in Northern Norway include: teleoto-rhinolaryngology (ENT), teleophthalmology, telecardiology, telenephrology (teledialysis), teleobstetrics/prenatal telemedicine services, teleemergency service, teledermatology, teleoncology, telecare, teleendocrinology, telesurgery, telepsychiatry, telepathology, teleradiology, telemedicine solutions for patient empowerment, maritime telemedicine, e-learning, e-messages, electronic communication in telemedicine services and use of videoconference for various purposes. In recent years, also mHealth solutions are being used to serve the population in remote areas.

This position paper discusses critical success factors for deploying telemedicine services in general, and in a specific search-and-rescue scenario in the Arctic. The paper will be extended with a thorough literature review for arctic telemedicine in 2016.

What is so special with the Arctic?

The most obvious difference between the Arctic and "normal environments" is the harsh weather conditions. Snow, wind and low temperatures have a strong influence on the way telemedicine services can be provided.

The SARINOR project[1] conducted a GAP-analysis on search and rescue (SAR) capacities in the Norwegian SAR zone around Spitsbergen/Svalbard [13]. Figure 1 shows a map with the Norwegian SAR zone.

[1]http://www.sarinor.no

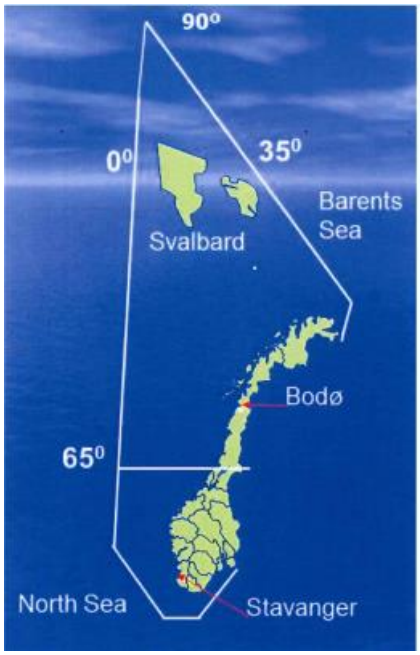

Figure 1 - Norwegian Search and Rescue zone

Personnel from all actors involved in SAR participated in a 2-day workshop to discuss how to handle a cruise-ship accident with 1900 passengers 400 km from Svalbard. The report clearly concludes that there is insufficient capacity outside mainland Norway to handle such a scenario. The main challenges identified are [13]:

1. *Long distances: even though the rescue helicopter can reach the destination 400 km from its base, there is not much time left to located and pick up people.*
2. *Time: transport takes time, and the harsh climate limits the chances for passengers to survive in the sea or on the ice.*
3. *Collaboration with nearby ships, and the Coastguard, is essential to find and rescue a large number of passengers.*
4. *Requirements to on-board rescue equipment should be reviewed.*
5. *Data communication capacity has low reliability and low bandwidth.*

The SARINOR GAP analysis concludes that the effect of telemedicine in a large-scale accident is unclear and should be investigated ([13], page 19), and that new technological solutions for SAR should be evaluated.

Critical success factors for deploying telemedicine

Over the years, much effort has been made to identify the critical success factors for implementation of telemedicine services. The most recent initiative is the EU-funded project MOMENTUM, which is a thematic network for sharing of knowledge and experience in deploying telemedicine services into routine care.

One of the deliverables from MOMENTUM is 18 critical success factors for deploying telemedicine [14]:

"The context:

1. *Ensure that there is cultural readiness for the telemedicine service.*
2. *Come to a consensus on the advantages of telemedicine in meeting compelling need(s).*

People:

3. *Ensure leadership through a champion.*
4. *Involve healthcare professionals and decision-makers.*
5. *Put the patient at the centre of the service.*
6. *Ensure that the technology is user-friendly.*

Plan:

7. *Pull together the resources needed for deployment.*
8. *Address the needs of the primary client(s).*
9. *Prepare and implement a business plan.*
10. *Prepare and implement a change management plan.*
11. *Assess the conditions under which the service is legal*
12. *Guarantee that the technology has the potential for scale-up.*

Run:

13. *Identify and apply relevant legal and security guidelines.*
14. *Involve legal and security experts.*
15. *Ensure that telemedicine doers and users are privacy aware.*
16. *Ensure that the appropriate information technology infrastructure and eHealth infrastructure are available.*
17. *Put in place the technology and processes needed to monitor the service.*
18. *Establish and maintain good procurement processes.*

In June 2005, Northern Norway Regional Health Authority (Helse Nord RHF) established a working group of senior doctors that should perform a systematic evaluation of telemedicine services in North Norway, and suggest which of the tested should be selected for large-scale implementation. In addition, the expert committee also discussed how to motivate health care workers to use telemedicine services. A number of actions were discussed. They argue that the equipment should be simple, user friendly and functional and that the reimbursement rates are in proportion to the total use of resources. In total, eight different actions were discussed. These are [15]:

- *Support team / super users:* To avoid technical errors or user errors "super users" of telemedicine systems and a support team that quickly respond to problem calls and alarms must be connected to the departments.
- *Training and codetermination:* All clinicians must get adequate training. The training must focus on the user's needs. A more comprehensive training must be offered to the "super users". Codetermination in processes is important factor for a good work environment and motivation.
- *Customer-oriented:* Patients should get access to and copies of their medical data.
- *Continuous operation must be ensured*: Only solutions that have proved to be reliable should be chosen.
- *Participations in development projects in the industry:* Hospitals should enable cooperation between contractors/developers of telemedicine equipment and groups of clinical specialists.
- *"Up-to-date" solutions:* A plan for continuous upgrade and replacement must be made.
- *Identifiable profits - tariffs (reimbursement):* The reimbursement system must reward the hospitals that

invest in the most prioritized areas of telemedicine services.

- Goal-oriented research: We must ensure that research recourses are allocated to the fields that are most relevant for telemedicine research.

In their report, Normann et al. [16] present five recommendations for bringing telemedicine into routine service:

1. *Increased use of videoconferencing for clinical, educational and administrative purposes.*
2. *Strengthen the national initiative on electronic messages.*
3. *Focus on dynamic solutions to support complete and standardized patient paths.*
4. *Initiate a national effort to develop a methodology for the implementation of telemedicine.*
5. *Clarify roles and responsibilities for operation and maintenance of telemedical solutions.*

The next chapter will discuss these general success factors in terms of special aspects for providing telemedicine services in the Arctic.

Challenges for successful implementation of telemedicine in the Arctic

Even though the Artic environment puts restrictions to the use of telemedicine services, some challenges of telemedicine are universal. According to Nesbitt et al.[17], the main goal for telemedicine (telehealth) services is:

> *"... to achieve a tight synergy between the fields of telehealth, mHealth, electronic health informatics, informatics and Health Information Exchange – with an overarching vision to improve access and quality in a cost effective environment."*

In 2000, the Arctic Council published the "Arctic Telemedicine Project Final Report" [9]. Telemedicine specialists from the member countries in the Arctic Council developed the report: Canada, Denmark (including Greenland, Faraoe Islands), Iceland, USA (including Alaska), Sweden and Norway. The report concludes that telemedicine can play an important role in providing adequate healthcare to people in the Arctic. However, it was identified that telemedicine is "work in progress" and effort should be focused on:

- Telecommunication should be in place in Arctic areas to support telemedicine services. Affordable and reliable communication is the cornerstone for implementation of telemedicine services.
- Health professionals in the Arctic must receive adequate training in order to fully utilize the telemedicine tools.
- When implementing new telemedicine services in the Arctic, priority should be given to front end users in the most remote and under-served communities.
- People living in Arctic should be informed about telemedicine programs and services in order to get "greater acceptance for the values of quality distance delivered health care".
- Health care managers and administrators shall be notified about availability of different telemedicine tools that can be used to meet identified health service needs.
- Arctic telemedicine systems should be spatially and temporally interoperable.
- Implementation of telemedicine service should be based on international guidelines.
- Close collaboration with Emergency Prevention, Preparedness and Response (EPPR) Working Group of the Arctic Council.

Even though a number of telemedicine services have been successfully implemented in the Arctic part of Norway, still many regions in the Arctic have not yet fully exploited the potential of telehealth services. Basic challenges include:

- *Telemedicine services:* Identify and prioritize potential services.
- *Standards:* Recognize appropriate health ICT standards.
- *Interoperability:* Investigate most appropriate solutions for clinical ICT systems' interoperability.
- *Funding:* Provide sufficient funding for implementation and operation of adequate telemedicine services.
- *Privacy:* Implement appropriate mechanisms for privacy and confidentiality.

The goal is to offer improved access to care as well as improved quality of care for people living in Arctic areas.

Telemedicine services to support search and rescue in the Arctic

In a review paper from 2014, Amadi-Obi et al. [18] present the results from a structured literature review of telemedicine applications in the pre-hospital environment. The initial search gave 1279 studies, of which only 39 were accepted for further analysis. Studies that did not address cost-effectiveness, feasibility or clinical outcome were excluded.

The overall results from the review show that there are very few studies that report on the effectiveness of telemedicine in emergency medicine. However, the authors conclude that:

> *"Telemedicine could enhance emergency medical services by helping expedite urgent patient transfer, improve remote consultation, and enhance supervision of paramedics and nurses."*

In a study from 2009, Reddy et al. [19] identify three major challenges to effective crisis management:

- Ineffectiveness of current information and communication technologies.
- Lack of common ground: shared understanding of the situation and the procedures to be carried out.
- Breakdowns in information flow: information is lost somewhere between sender and received, often in the "coordination centre".

Even though Amdadi-Obi et al. [18] conclude that telemedicine can play an important role in emergency response, the challenges identified by Reddy et al. [19] may be even more emphasized in an arctic environment. Given the special factors in the Arctic as described in the introduction, and the uncertainty of telemedicine effects identified by both Amadi-Obi and the SARINOR GAP analysis, it is clear that more research is needed on arctic telemedicine.

Future work

The work presented in this position paper is a high-level view on telemedicine services in general and how special conditions in the Arctic may limit the effect of the services. Extreme scenarios such as a large-scale accident may emphasize existing challenges with telemedicine in emergency response.

This paper has identified a set of focus areas, major challenges to deployment, and some promising evaluations. The next step is to conduct a thorough literature review of telemedicine in the Arctic, to clearly identify proven solutions for search and rescue, which support general and more specific services.

Conclusion

In order to successfully implement telemedicine services in Arctic areas, we need to:

- Understand the role of telemedicine in Arctic environments, both in primary and secondary health care.
- Understand the role and impact of information technology in implementation of sustainable telemedicine services in the Arctic.
- Realize the influence of telemedicine on clinical outcomes, patient empowerment, safety and quality of life in Artic areas with basic health services only.
- Recognize design and implementation challenges associated with telemedicine systems in the Arctic.
  Identify and investigate issues related to standardization between on-board equipment on ships and SAR-team infrastructure.
- Carry out sound studies that measure effectiveness of telemedicine in arctic environments.

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Exploring implementations of electronic nurse and care messaging at municipality level

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Abstract

Electronic exchange of nurse- and care-related information between hospitals, nursing homes, and home nursing care has been included for a number of years in national strategies for the Norwegian health and care sector. This focus has increased over the last year, and according to the Norwegian Health Network (NHN), most municipalities are now beginning to use so-called "e-messaging." The aim of this abstract is to investigate efforts to improve these kinds of implementations. The abstract compares experiences from first-line leaders (FLLs)[1] and "their" nurses in three municipalities. Data were collected through two surveys: one for leaders, and one for nurses. The study findings indicate that both leaders and project organizations underestimate the implementation challenges at nurse level and the need for implementation plans adjusted to local resources and work environment.

Keywords:
electronic messages, leadership, training

Introduction

Because of substantial problems with automatic exchange of patient information across different electronic patient record (EPR) systems, the Norwegian government launched the national e-messaging program "Nasjonalt meldingsløft" in 2008 [1]. The aim was to develop an e-message system (EMS) that could be integrated into different EPR systems and make selected patient information available for all partners in the health and care sector within their own EPR system. In addition, one overall goal was to improve collaboration and continuity of care [2]. As this project has been delayed, the Norwegian Office of the Auditor General last year requested faster development of technical solutions and a greater use of political and administrative instruments [3]. A new deadline has been set: from the end of 2015, e-messaging is expected to be the norm for exchange of patient information between municipalities, general practitioners, and hospitals [4]. Recent research shows that there are still many challenges related to the exchange of patient information; for example, at the interface between hospitals, nursing homes, and home care services [5, 6, 7]. In addition, and with respect to e-messaging in particular, there are many factors affecting dissemination [8]. The National Health Network (NHN) groups these by 1) the municipality, 2) the regional resource organizations ("kompetanseorganisasjoner") and/or 3) external circumstances. At the municipal level, the largest risk factors so far have been lack of anchoring, national standards, collaboration, delivery, priorities of collaborating actors, and internal priorities in the municipalities. This makes it relevant to study the implementation of e-messaging between hospitals and nursing homes/home nursing care as a holistic approach[2]. This abstract refers to a project in which e-messages were implemented in hospitals, nursing homes, and home nursing care throughout one Norwegian county. Space limitations restrict this report to an account of the implementations at the municipal level, in nursing homes, and home nursing care, focusing on how the first-line leaders (FLLs) contributed to the implementation processes. Three research questions were investigated: RQ1) In what ways and to what extent did the FLLs prepare for the implementation; RQ2) What challenges emerged during/after the introduction; and RQ3) How were the emerging challenges explained?

Materials and Methods

To answer the research questions, a quantitative study was carried out [9]. Because of potential differences in the integration between the EMS and the three EPR systems used in the county, three municipalities with different EPR systems were selected. One of these served as a county pilot, which began at the end of 2013. The other two municipalities joined the project in spring 2014. Two Questback online surveys were developed, one for the FLLs (N = 12) and one for their nursing staff (N = 64). Because nurses are mainly responsible for the exchange of patient information, they were also responsible for the e-messages. The questions were based on previous research on implementations of information and communications technology-based Information Systems (in Health- and Care Organizations as well as in others), public reports on e-messaging, and theories of change management. The surveys included the following topics: use of e-messages, characteristics of the introduction process, leader focus on quality and change, experienced internal and external challenges (as well as their underlying causes) during and after the introduction[3], deviations and errors, satisfaction with the e-message implementation and the e-messaging system, and suggestions for improvement. In addition, leaders were asked how they had prepared staff for development and change, whether they had experienced changes in roles and responsibilities, and their own contribution to success. While a six-point Likert scale (1 = to a very large extent; 6 = to a very small extent) was used for most of the questions, some questions permitted a binary choice and a few required free responses. Scale responses were placed into three categories: "To a large extent" (1 and 2), "To a medium extent" (3 and 4), and "To a small extent" (5 and 6). The written responses were first coded according to the questions and the above concepts. Thereafter, the meaning was condensed [10].

[1]First-line leaders lead colleagues who carry out work or services near the end of the production chain.

[2]Implementation is used here to describe an organizational effort directed toward diffusing appropriate information technology throughout a user community.

[3]Internal challenges are challenges related to their own institution; external challenges are those related to their collaborating hospital.

Results

FLLs' preparation efforts (RQ1)

In response to the sixteen specified preparation efforts, FLLs indicated that they had prepared their staff for the implementation as follows: 1) "To a large extent": Clear information about leader expectations (75%), available for dialogues (75%), motivate to work in new ways (64.6%), information about the implementation (58.3%), motivate staff to change current ways of working (58.3%), provide for sufficient time for testing (50%), and relevant training (49%); and 2) "To a medium extent": Sufficient training (64.6%), new internal routines (58%), new routines and ways of working to achieve error-free message exchange (58.3%), quality assurance of new routines and ways of working (64.6%), control routines for message exchange (58.4%), exchange of experiences between staff and external collaborators (50%), and provide for sufficient economic resources to the unit (64.6%).

Challenges and explanations (RQ2 & RQ3)

All participants were asked in the surveys about the two biggest challenges that they had experienced during and after the introduction, both internally (related to their own organization) and externally (related to their collaborating hospital). Table 1 shows differences in group responses. The greatest differences were related to the assessment of technical challenges, the EMS, and message control.

Table 1 - Two biggest challenges (I = internal; E = external)

Challenges (%)	Leaders N = 12		Nurses N = 64	
	I	E	I	E
Technical	16.7	8.3	40.6	29.7
Security	25	16.7	9.4	9.4
The EMS	33.3	16.7	45.3	31.3
Message control	41.7	41.7	31.3	28.1
Lack of collaboration	8.3	16.3	7.8	18.8
Unclear responsibilities	25	25	26.6	37.5
Weak FLL leadership	0	0	1.6	4.7
Other organization challenges	33.3	41.7	34.4	32.8

Both surveys also asked about the underlying causes of these challenges. The FLLs referred mainly to unsatisfactory internal routines (41.7%). Rated second were poor training, insufficient message control, insufficient leader involvement (themselves), and lack of meeting places for exchange of experiences between hospital and municipality (all 25%). Insufficient routines/procedures for external collaboration, errors in the EMS, and system downtime were cited by 16.7% of leaders, while poor end user support and too few staff were cited by 8.3%. No FLLs chose lack of anchoring at the municipal level. Most nurses explained the challenges were because of poor training (46.4%). Insufficient routines/procedures and lack of internal meeting places for exchange of experiences were both rated next (25%), followed by too little information (21.9%), lack of meeting places for experience exchange between municipalities and hospitals and insufficient message control (both 20.3%), and too few staff (17.2%). Too little support, difficulty using EMS, and system downtime were all cited by 12.5% of nurses. There were four additional causes, but these were cited by fewer than 10% of the nurses.

Discussion and Conclusion

Transfer of care information within and between departments and across organizations is demanding. Research highlights that even today many of the challenges related to patient safety in public health services are linked to mistakes related solely to this type of communication [11]. The present findings indicate that these problems remain after the introduction of e-messaging. This comparison of leader and nurse experiences illustrates both similarities and differences in the two groups' explanations of the challenges. For both groups, the most frequent explanations were poor training and insufficient internal and external routines (though the order differed between groups). Training was also frequently mentioned by nurses in the free response questions; for example, more time for compulsory, better, and more detailed training; hands-on testing/trials before and during the implementation; and more extensive exchange of EMS practices and extended follow-up. This comprehensive need for training and extended user support is so far not reflected in national and regional project implementation guides and evaluation reports [2, 8]. We suggest that insufficient training and a strong demand for improved internal and external routines, together with concerns about lack of meeting places, might indicate that organizational preparation tends to be insufficient and its need underestimated. Our findings show that this kind of organizational preparation was only assessed "To a medium extent" by leaders, despite the fact that previous research emphasizes the importance of involving leaders, not least FLLs [12, 13], to successfully implement organizational development and changes.

Also of interest are the differences between groups in responses to the two biggest internal and external challenges. Although more than 40% of the nurses cited the EMS and technical issues as the largest internal challenges, a similar proportion of responses by FLLs was found only for message control, and they rated technical challenges as the second lowest. This might indicate that there is little discussion of internal challenges between leaders and nurses. Regarding external challenges, the nurses identified mainly unclear responsibilities and other organizational challenges; the latter was frequently cited by FLLs. This suggests that external organizational challenges need further investigation and could be an area for improvement. This finding is in contrast to the findings in the final report from the Norwegian e-message project [3], which claims that the important factors for dissemination and use are related to the municipality and not to external conditions and circumstances.

As mentioned above, further work on this issue is needed. For instance, it would be interesting to interview some of the FLLs and nurses about the issues they identified as organizational challenges and examine in more detail the type of training nurses received. Finally, one weakness of this study should be mentioned. The Likert scale did not allow participants to choose "Not at all" as a response; this might have led to biased responses.

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A Cardiac Web Prototype for Semantic Interoperability and Decision Support

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Abstract

Clinical decision support systems can be improved if data exchange among different organizations with full and understandable clinical meaning is achieved. Towards this end, the development of new methodologies of information management is necessary. Among them, CEN/ISO EN13606 (archetypes) is the most promising approach.

According to World Health Organization, cardiovascular diseases are the leading causes of death worldwide. A good number of risk indices from electrocardiogram signal processing have been proposed for cardiovascular risk stratification. We have considered here the Heart Rate Turbulence (HRT) due to its clear and concise guidelines.
Based on previously built HRT ontology and archetype, a web prototype was created to achieve semantic interoperability among heterogeneous hospital systems; and to avoid technical limitations when different commercial tools are used. The web prototype was able to provide the user with the following functionalities: (1) binding the HRT ontology concepts to the HRT archetype nodes by using a designed archetype-ontology binding system; (2) compiling and maintaining database HRT records; and (3) exporting these records, while enabling semantic interoperability to allow data exchange among different systems.

Keywords: Semantic interoperability, SNOMED-CT, archetypes, web technologies, clinical decision support, cardiovascular risk stratification.

Introduction

Health care providers require rapid and reliable decision-making processes in patient diagnosis, treatment, and follow-up. In recent decades, it is undergoing a change from traditional medical approaches based on clinicians' experiences to innovative methods, which use signal and image processing for decision-making. In this context, the called Clinical Decision Support (CDS) systems have been widely studied in the literature [1,2,3]. Medical informatics provides a large variety of resources to healthcare community to improve many issues of their clinical daily practice [4]. In this setting, Electronic Health Record (EHR), a longitudinal record with patient health information, can be very useful to provide access to the vast amount of clinical information and to share data among heterogeneous Hospital Information Systems (HIS). However, the ability to exchange data and to understand clinical information from EHR with independence on the system (semantic interoperability) is a major challenge in this field, specifically in public health systems [4].

The aim of this work was to design an architecture for exchanging EHR data among heterogeneous HIS. To account for the technical requirements of different systems, a web prototype called *HRT Archetype Proto* was created. In order to get semantic interoperability, the CEN/ISO EN13606 standard was used to build the archetype (knowledge). We focused on the Heart Rate Turbulence (HRT) domain due to its concise guidelines and clear indices calculation procedures for cardiovascular risk stratification. Archetypes were saved as *ADL* files.

Materials and Methods

Semantic interoperability is an essential factor in achieving the benefits of EHR to improve the quality and safety of patient care, public health, clinical research, and health service management. European Commission encourages the use of standards to represent the relevant health information for a particular application using data structures (such as archetypes and templates), terminology systems and ontologies [6].

On the one hand, SNOMED-CT is the most comprehensive, multilingual clinical healthcare terminology in the world [8]. Following this terminology, this work considers the HRT ontology presented in [9].

On the other hand, we used CEN/ISO EN13606 to define a rigorous and stable information architecture [10]. CEN/ISO EN13606 follows Dual Model architecture, i.e., an architecture model that defines a clear separation between information and knowledge. The information is supported by a Reference Model (RM), which contains the basic entities for representing any information of a specific domain. The knowledge is based on archetypes, i.e., formal definitions of clinical concepts as a structured and constrained combination of RM entities. The RM is used to collect data, whereas the Archetype Model (knowledge) describes those data structures semantically. Hence, the main capability of this Dual Model is that knowledge could be modified in the future, whereas data will remain unaltered. Clinicians from different hospitals agreed the nodes and constraints of the HRT archetype developed in [7], providing an adequate knowledge representation from a clinical viewpoint.

A web prototype based on the HRT ontology/archetype was built to overcome the limitations of technical implementations among heterogeneous HIS. The prototype is a proof of concept of the schema shown in Figure 1. The HRT archetype nodes obtained from the *ADL* file were considered as fields in

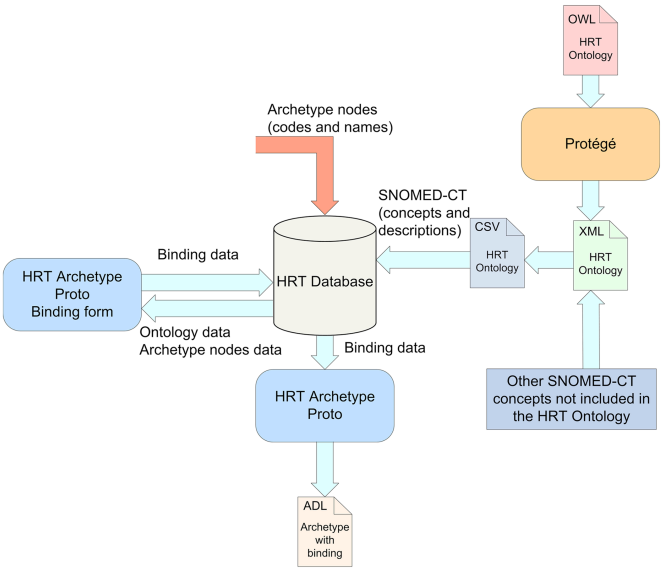

Figure 1- Schema for HRT web prototype.

a MySQL HRT database to collect data (information) from differet HIS exactly in the same way. Thus, the archetype constraints such as ranges of allowed values and coded text options were also assessed.

Furthermore, a simple system to bind SNOMED-CT concepts from the HRT ontology with the nodes of the HRT archetype was developed following the schema shown in Figure 1. As the first step, Protégé software tool was used to export the HRT ontology into an xml file. This file was converted to csv format to be able to include more SNOMED-CT concepts potentially useful but not considered in the HRT ontology. The obtained *csv* file was imported into the HRT database. As a second step, the archetype nodes (codes and names) were also imported into the HRT database. With the mappings stored in the HRT database, the terminology section in the *ADL* file is completed, and it can be now readily shared among different systems.

Results

The web prototype, called *HRT Archetype Proto,* generates xml files in the form of EHR extracts, by combining data from the nodes of the archetype and the EHR data entered by the clinicians, both stored in the HRT database. These extracts have the same structure and constraints as the developed archetypes, so they provide the same advantages, i.e. semantic interoperability.

As a result, the prototype provides with: (1) a simple and helpful system for binding archetypes to the HRT ontology, and (2) a clinical data export approach based on semantic interoperability. Therefore, our web prototype supports the use of clinical standards for CDS, and the development of a structured database to scientifically assess and improve the knowledge of the HRT domain for wider and subsequent cardiac domain expansion.

Conclusions

The present work has demonstrated a web prototype for achieving semantic interoperability among heterogeneous EHRs by using ontologies and archetypes. *HRT Archetype Proto* provides the user with the following functionalities. First, the creation and maintenance of EHR extracts from the knowledge of the HRT archetype; and second, the export of these extracts in *xml* files, hence allowing their exchange with fully semantic meaning among different systems, since these extracts are generated from archetypes.

Overall, *HRT Archetype Proto* enables building a new web system for HRT decision support based on clinical data standards and SNOMED-CT conceptual model. The proposed prototype provides a multi-centric system to access to EHR information. Oncoming work is devoted to apply the web prototype in the daily practice for automating and streamlining the clinicians' workflow for cardiovascular risk stratification. Specifically, our short-term research is focused on the extension of the prototype to take into account more indices for cardiovascular risk stratification (e.g., heart rate variability indices). It will allow the long-term ability to generate a complete patient record using information from different EHRs.

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Innovation through Design game- A development process

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Abstract

This study examines the development of an mHealth solution to help avoid non-adherence amongst users of prescription medication. The most frequent cause to non-adherence in medical treatments is neglect. With the increasing use of smartphones, this solution model based on a smartphone application is believed to have the potential to offer an appropriate solution to this problem. The design phase was designed around an User Innovation Management approach which included one workshop. This workshop consisted of a design game session alongside a Wizard of Oz inspired sketch session. These sessions provided insight into the necessary functions and requirements for the application. The users expressed their wishes for alarm and calendar functions to organize their prescription plans, and an automatically updated medication list of their prescriptions through the Shared Medication Record. Despite the potential lack of informants, it was reported that the chosen approach helped discover a new way of establishing contact between the primary and secondary sectors to the users which in the end is supposed to prevent the non-adherence in the treatment plans.

Keywords: mHealth, medication, medical adherence, Community Based Participatory Research

Introduction

In the Danish healthcare system, one third of all patients are considered non-adherent in medical treatment[1]. Pubmed defines the term medication adherence as: "*Voluntary cooperation of the patient in taking drugs or medicine as prescribed. This includes timing, dosage, and frequency*". The lack of medical adherence can affect the treatment outcome [1]. This has the potential to incur longer sick leaves, as the treatment will not work as intended. In addition, it is difficult for the health professional to assess the patients' health conditions. This can lead to cancellation or modification of the treatment, which may end up harming the patient further [2]. In order to overcome this problem the Danish government introduced, the Shared Medication Record as one of the primary solutions [7]. The Shared Medication Record is responsible for the communication between all sectors with important information regarding the user's medication and treatments. The program is currently designed to focus on the healthcare professionals and their internal communications. The only public entry to the system is through a webpage login that at best is cumbersome and at worst impossible to use on mobile devices. Combined with smartphones and their capabilities becoming a greater part of our daily lives, we choose to focus on developing a solution within the mHealth paradigm [3]. Through using the User Innovation Management (Hereafter: UIM) approach as the backbone of the project, we intend to engage prescription medication users in a design game to gather the relevant insight to make the necessary requirement specifications, and finally, to construct a working high-fidelity prototype[4].

Materials and Methods

Recruitment Strategy:
Participants were recruited from a voxpop conducted in one of the downtown pharmacies in Aalborg. The questions used in the voxpop were based upon what literature indicated were the main issues [1]. The voxpop consisted of twelve clients who reported problems regarding their medical treatment and how they structured their intake. Of the twelve respondents approached, four yielded suitable and had the desire to participate in the timeframe we would be working under. The participants were all women and ranged in the age between 20 and f40 years old. The requirement for participation was that they had to be under treatment with three to four prescriptions. There would be no other requirements to the participants, since the goal of our intended application is for a wide range of people in different treatments and situations.

Process:
To support the development process we chose to include the project planning and management method UIM.
UIM is a method for cooperating with users at the early stages in design processes, that helps discover innovation grounded in users needs and values. This user-driven innovation process was divided into three phases: co-operation, context and conceptualize [4]. In the co-operation phase, the focus was on selecting users alongside creating a plan for the innovation process. The context phase is focused on generating insight into the current problems and needs and generating visions for possible futures. In this project, the context phase had its fulcrum around voxpop sessions and a design-game that was established early on. The voxpop sessions helped generate insight into the current problems and helped construct scenarios which were part of the design game. As the perspective is shifting in approach from designing for users, to one of designing with users, there is a need for new ways of thinking and working [8]. Since the early 1990s, authors have suggested games as guiding metaphors for the interplay between designers and users [8]. The aim of design games is to help facilitate a cross-disciplinary design process. To frame design activities in a game format improved the idea generation and communication between participants [5]. Traditional games in general are frequently based on strength and skill, but in design games the players seldom compete in order to win. Design games within a participatory design setting often have participants with different interests and preferences [5]. Design games are, however, good at downplaying power relations amongst the participants, and factors that might otherwise have had an impact on the idea generation [8]. Lastly, in the concept phase, the objective is to manifest design ideas with

the data gathered from the previous phases. In this phase, a Wizard of Oz inspired workshop was conducted, where the goal was to create a high-fidelity prototype along with the users [6].

Results

In the first phase, we established cooperation with users alongside structuring the next phases of data gathering. Through several voxpop interviews, we managed to get an insight into the user's daily life and their daily problems with medication intake. These insights and problems were used to develop scenarios that were part of the design game. These scenarios were obligatory in the completion of the game since they managed to stimulate innovative thinking [4]. To create a good atmosphere amongst the participants, the use of icebreakers in form of funny questions, where they had the opportunity to win rewards if successful in completing the course there was set out for them [4]. Through the design game, we managed to identify three patient-centered functions: an alarm function, a calender function and a search function.
Alarm function: It was important to several of the users to be able to organize their day. They proposed to incorporate an alarm function, which can be used to alarm the user with predefined timestamps for medication intake.
Calendar function: The need to incorporate a calendar was high among most of the users since they often forgot when to buy new pills. The calendar should have the option for users to write small notes, and therefore work as their main calendar, because having separate calendars - one for medication and one for everyday life, would be irksome.

The search function: The shared medication record which is the Danish healthcare information system where patients have the option to check their current ordinations, was something the patients had little to no knowledge about. To help the users gather information about their ordinations, the search function was implemented. This function should be split up in two parts, where one gave the option to search in current prescription by connecting to the Shared Medication Record. This way it automatically updates as soon as the practitioners prescribe or update medication ordinations. The other part of the functions gives the users the option look up on other forms of medication.

Discussion

The use of a design game with scenarios resembling daily life situations has given us the opportunity to understand the users' values and needs. Based on the collected data, it is now possible to establish system requirements, which reflects the users' solution models. We anticipate that this approach can be implemented in other development situations in the mHealth paradigm. The users, regardless of prior knowledge, were important actors in identifying key functions and needs.

Therefore, it is important not to underestimate the potential User Innovation Management and design games, has to offer to new innovation projects in the future. The Design game contributed to an environment, where the users had the opportunity to be innovative in a fun and creative way. It is important to create a safe environment where the users are not afraid of being innovative and to think aloud. In order to do this, we experienced that icebreakers had an effective way of making the users feel comfortable.
To conclude on our innovation process, our next step will be creating a high fidelity prototype, to be the focus of a usability test with another set of informants and an expert in usability design.

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ICT Supported Communication Between Patients and Staff at Radiology Departments

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Introduction

Digital Post is a secure web application for written digital communication between citizens and authorities in Denmark. Since November 2014, it has been mandatory for individuals above the age of 15 registered with a Danish civil registration number (CPR number), to receive messages from public authorities as *Digital Post* including referrals from public hospitals. By the end of 2015 80% of the written communication between citizens and the health care system will be carried out by digital means in order to make workflow more effective and reduce costs for paper and stamps [1].

In governmental strategies for digitalization emphasis is on digital distribution of information from authorities to citizens [1]. However, *Digital Post* can be used as means of two way communication between citizens and authorities, and thus be a tool for involving the patient in decision making and planning of his/her care pathway, which is a policy goal for both politicians, healthcare professionals and patient organisations [2]–[4].

The *Digital Post* user interface is similar to that of an email system. When health care systems provide for email consultations, patients appreciate the possibility for communication with healthcare professionals concerning non-acute conditions, appointment scheduling, flexibility in when to write, read, and respond, etc. Healthcare professionals acknowledge the advantages of flexibility and possibilities of greater continuity in the treatment, but are also concerned about the use of time, and risk of compromising the patients sensitive personal data [5]–[8]. The use of *Digital Post* for communication between patients and healthcare professionals affords the benefits of email communication, and thus the possibilities for involving the patient in decision making and planning of his/her care pathway, with no risk of compromising the patients sensitive personal data[1]. However, the use of time for written communication will still be a concern.

Patients undergoing X-ray examinations and scannings communicate with healthcare professionals at the radiology department for a relatively short period of time compared to the care pathway in total. Outpatients receive a Digital Post message comprised of the scheduled time, information on how the examination is performed and how the patient can prepare for the examination. If the patient wants to alter the scheduled time, or need some more information on the examination, or scanning the traditional means of communication is a telephone call in opening hours. Digital Post offers itself as an alternative means of communication between patients and healthcare professionals at radiology departments.

How Digital Post can be a tool for involving the patient in decision making and planning of X-ray examinations and scannings is being investigated in an Action Research project.

This abstract describes the results of the initial actions focusing on exploring potentials for using Digital Post for dialogue between patients and healthcare professionals at radiology departments.

Materials and Methods

The project is carried out in cooperation with representatives for patients and staff at the Department of Radiology, Diagnostic Centre, Regional Hospital Silkeborg, Central Denmark Region. Approximately 80,000 patients undergo X-ray examinations and scannings at the department every year [10].

A dialogue conference initiated the project in the spring 2014. The purpose was to explore visions and ideas in relation to Digital Post dialogue. The dialogue conference was conducted according to principles for Action Research dialogue conferences [11] combined with participatory design methods for designing learning processes supported by information and communication technology [12]. The 17 participants represented patients, secretaries, radiographers, radiologists, communication workers, staff manager, ICT managers at all levels (department, hospital and region) and an ICT developer from a company providing Digital Post solutions.

Visions and ideas from the dialogue conference formed the basis of 5 subsequent workshops performing iterative processes on developing and testing designs for using Digital Post as means for dialogue. The workshops was conducted according to principles of participatory design and usability testing [13]–[15]. Workshop participants represented patients, secretaries, radiographers and communication employees depending on the objective of the specific workshop.

In total 6 representatives for patients, 2 secretaries, 4 radiographers, 1 communication employee and 1 local ICT manager participated in the workshops. One representative for the patients and all of the representatives for the staff participated in the initiating dialogue conference.

The project has been assessed by the Danish Scientific Ethical Committee in Region North. The Committee found that as the project is not a Health Science Research project, consequently it shall not be reported according to the Law on Scientific Ethical Consideration of Health Science Research Projects (no. 593, 14/6/2011).

Every participant signed an informed consent statement at the dialogue conference and at each workshop.

[1] Messages from authorities to citizens are send by Secure/Multipurpose Internet Mail Extensions (S/MIME) protocols through an Electronic Document Management System or an email client (i.e. Microsoft Outlook). This provides authentication of origin by digital signatures, and data confidentiality by encryption.

Citizens access Digital Post by a twostep autentification called *NemID* consisting of username and password, followed by a one-time password from a code card. Messages send by citizens via *Digital Post* are encrypted by the certificate indicated for the recieving adress by the authority [9].

Results

The dialogue conference disclosed the participants' visions and ideas on using Digital Post for communication as means for enhancing cooperation, coordination of information and shared decision making by patient and staff. The secure written communication can provide for including patients knowledge and preferences in scheduling, preparing and following up on X-ray examinations and scannings.

At the workshops, participants designed and tested prototypes of tools to support the use of Digital Post for communication as means for cooperation, coordination and shared decision making. The protypes are:

Patients guide for Digital Post dialogue. The guide consists of illustrations and a short text (190 words).

Staff guide for Digital Post dialogue. The guide consists of:

- Guidelines for conducting Digital Post dialogue to ensure both patient care and patient data protection.
- Drafts for answering Digital Post messages from patients. The drafts comprise wording suggestions for answering common questions asked by patients.
- Manual for using and producing new drafts for answering Digital Post messages from patients.

The templates for information are written in Microsoft Office Word and will be applied to the relevant communication systems as part of the implementation process:

- The patients' guide will be published on the department home-page. A link and brief information will be included in the Digital Post referrals.
- The staff guidelines and manual will be created in e-Dok, the document management system in the Central Denmark Region. e-Dok is open to the public.
- The staff guide drafts will be created as email message templates and signatures in Microsoft Office Outlook, which is the mail system used by staff for recieving and sending Digital Post.

Discussion

This project has pointed out possibilities for expanding the utility of the common public ICT system Digital Post. Patients and healthcare professionals have designed and tested tools for using existing technology for communication in order to enhance cooperation, coordination and shared decision making in relation to X-ray examinations and scannings. The design of the tools take into consideration coherence in Digital Post correspondence, efficiency in working processes and protection of patients personal data.

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