APPLICABILITY OF THE RELIABLE EVALUATION INFRASTRUCTURE TOOLKIT FOR FACILITATING SELF-CARE RESEARCH

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ABSTRACT

State of the art healthcare devices currently used in the unsupervised setting holds several challenges with regard to the reliability of self-measured data. This affects the validity of the data and may lead to ineffective or unnecessary treatments. Pervasive healthcare concepts and context-aware technology appears promising as a way of mitigating these challenges and delivering a higher data quality. Carrying out relevant feasibility studies for addressing these challenges implies overcoming considerable technical barriers. System developers often have to rely on overly complex, error-prone, and time consuming platforms and technologies. Therefore, tools and technologies for facilitating rapid prototyping of self-care solutions are needed. The Reliable Evaluation Infrastructure (RELEI) is a toolkit for facilitating research into patient self-care activities in the unsupervised setting. It is based on rapid prototyping systems engineering methods and technologies. It supplies a range of relevant pervasive enabling hardware and software components for this purpose. The aim of this study was to evaluate the applicability of RELEI for facilitating self-care research projects. First, we present the RELEI toolkit and illustrate typical usage in two self-care case studies. Following this, RELEI is evaluated through 11 case studies. In conclusion, the RELEI toolkit was shown to be applicable for facilitating self-care related research projects in a wide spectrum of self-care projects.

Keywords: Self-care, reliability, telemonitoring, eHealth architecture, pervasive healthcare, context-aware.

1. INTRODUCTION

Healthcare systems are challenged by the demographic changes of the coming decades (1). Many studies have investigated the potential of moving patient care out of the hospitals and clinics, and into the home setting, or allowing patients to self-measure at the clinic, increasing patient-empowerment and self-care as one of several potential remedies to these challenges (2). Research within the telemedicine field has suggested addressing these challenges by improving treatment efficiency using both traditional and novel communication technology for remote care and consultations. This includes remote monitoring of patient parameters such as heart rate, blood pressure, weight, oxygen-saturation, medical adherence, and other parameters (3). This allows for monitoring patients in their homes or other unsupervised settings remotely from the treating physician's office facilitating increased patient-empowerment, self-care, and autonomy (4). In recent years, the pervasive healthcare community has proposed supporting such patient empowerment through the use of pervasive healthcare devices and platforms, relying on context-aware technology to support a novel paradigm of self-caring patients, less dependent on healthcare professionals, and freed from time and place constraints (5). However, this alternative paradigm presents several challenges with present day technology. When a patient is sent home or left unsupervised with a biomedical device to self-measure. He is no longer personally guided and monitored by a treating physician or nurse, but is left on his own to perform the measurements or take the prescribed medication. As a consequence, the quality of the measurement is no longer guaranteed by a healthcare professional, but relies on the patients training and abilities, and on the level of technology support provided. Healthcare professionals thus have to rely on the patient's ability to follow the prescribed treatment plan and guidelines. Medical research has identified that patients to a large extent do not follow such guidelines (6). This may result in erroneous and misleading readings, and may lead to the healthcare professional providing unnecessary or suboptimal treatment due to the low quality of the data obtained (7).

In order to investigate these challenges, we need methods and tools that will allow us to gain a better understanding of how the patient is acting in situ in the home or unsupervised setting while using pervasive healthcare equipment. For example, we would like to understand to which extent a patient correctly follows the guidelines on how to perform valid home blood pressure measurements: whether the patient was sufficiently rested, seated correctly, and in a low-noise environment, as well as whether the data was even measured on the right person. Other examples include whether the patient is taking the prescribed medication, at the correct time and dose, or remembering to self-measure weight before breakfast, after morning toilet visit, and without clothes as instructed. In other words, contextual factors that may affect patient adherence and bias measurement data.

Traditional methods useful for this kind of research activities include observations in the home setting by researchers, either directly or through video capture (8). This requires the researchers to either be present during the experiment or manually transcribe and analyze audio or video recordings. This is time-consuming, error-prone, and potentially privacy-invading. Thus, we argue that this method is only feasible for limited qualitative studies. Also, there is the risk of inducing observer bias due to the presence of test facilitators. Video recordings are less intrusive, but still demand a fairly large technical setup as well as extensive reviewing work. The ability to correctly capture all context information might also be limited when using a single camera only. It might for example not be feasible to capture video for verifying both whether the user is correctly seated while also monitoring placement of the feet, and the handling of the blood pressure device at the same time. As an alternative to direct or indirect observations, it is possible to develop research prototypes that can discretely measure the desired use-context during a healthcare session. Rather than using direct observations or video-reviews, the researchers will gain a formalized and discrete data set of relevant user-behavior that can automatically be processed and correlated with the measurements. In this way, it may arguably be faster to perform longitudinal studies on a larger population, leading to a more comprehensive understanding than could be achieved with manual observations and data processing. However, creating such research prototypes is a non-trivial task. Depending on the problem under investigation, there is a need for a data acquisition platform, consisting of a computer with relevant processing capabilities, a sufficient communication infrastructure, relevant user interface hardware, video and audio recording, patient identification and other relevant features and components. We argue, that rather than having individual research projects design and build solutions from the ground up, a common toolkit would allow for reuse of frequently sought after hardware and software components. This include research projects exploring self-care activities such as medical adherence issues in the home setting, issues related to healthcare home measurements such as blood pressure, weight, blood sugar, oxygen saturation, as well as support for monitoring rehabilitation exercises.

To facilitate research into self-care activities in the unsupervised setting, we have created RELEI as a software and hardware toolkit for easy development and deployment of pervasive healthcare prototypes with a focus on studying adherence in the unsupervised setting using context-aware technology. RELEI is mainly intended for designing relevant research experiments and prototypes for studying patient adherence, but could also be used as a general purpose telemonitoring platform for pervasive healthcare and e-Health in the home setting, if adapted and matured as necessary. RELEI consists of an abstract ontology of relevant concepts, a software framework implementing the ontology, and finally a series of off-the-shelf devices and toolkits, as well as several custom-build context-aware sensors, such as chair, medication, and bed sensors, including software service wrappers for these hardware components.

The aim of this study was to evaluate the applicability of RELEI for facilitating self-care research projects into patient self-care activities in the unsupervised setting. Specifically, this paper presents the requirements on which RELEI is built, introduces the various components of the toolkit, demonstrates typical usage through two case studies, and presents the results of applying RELEI to a range of 11 self-care projects.

2. PRELIMINARIES

2.1 Requirements

We have recently surveyed the pervasive healthcare field and identified a range of requirements for an evaluation infrastructure toolkit for designing and evaluating self-care prototypes (9). The requirements identified were:

1. *Multi-featured Platform*: The evaluation infrastructure platform should be able to deliver sufficient computing power to cater to the needs of a wide range of self-care research projects – including: situation recognition of context, medical data analysis, user behavior monitoring, and other computational intensive tasks. Also, the platform should be able to support a wide range of communication standards for supporting relevant biomedical and context aware sensors and devices.
2. *Heterogeneous Execution Environment*: Support for multiple programming languages should be provided by the evaluation platform, allowing researchers to deploy different types of services and applications, and use external frameworks.
3. *Openness and Flexibility*: The evaluation infrastructure should allow for new frameworks and toolkits to be included, and allow for easy service composition.
4. *Ease-of-use*: The evaluation infrastructure should be easy to use and to extend with new features and services for research within reliable pervasive healthcare. Focus should be on the problem under investigation rather than getting the framework to work.
5. *Context Recording*: Features for audio and video recording of context triggered events should be available. Activating recording e.g. when a user is seated in a chair, a fall is detected, or a user is getting out of bed, etc., so that collected data can be compared to what actually took place for manual verification.
6. *User Identification*: Easy access to user identification, through both radio based and biometrical means.
7. *User-context Detection*: Programmatic access to common movement sensors, chair and bed occupancy sensors etc. should be available.
8. *Multi-application Support*: In order to support evaluating more than one project on the same platform, e.g. both evaluating for medical adherence, while also evaluating for reliable blood pressure measurement, the evaluation infrastructure platform should support running several evaluation applications concurrently.
9. *Reliable Execution Environment*: Applications and services running as separate processes should be controlled in a reliable fashion by a life cycle manager, so that services and research applications are kept running and automatically restarted if necessary. Also, the hardware platform should be made reliable, e.g. through redundancy of critical components, as to avoid single points of failure.

2.2 Platform Overview

The RELEI toolkit was designed as a general purpose toolkit for facilitating the research of self-care applications and implementing the nine requirements defined in section 2.1. This involves both hardware and software components, as well as communication middleware. It is based on open source software and hardware rather than proprietary and closed solutions, as well as commercial off-the-shelf standard devices and sensors where relevant. This allows the research and commercial community to collaborate on the development of the platform, and ease the reproduction of research results that are based on the platform. Also, it allows platform developers to reuse existing frameworks and platforms. For example the Java Context Awareness Framework (JCAF) (10) have been used for context awareness purposes in one project, while the SPINE framework (11) has been used for user activity tracking in another. RELEI both represents the vision of a general purpose reliable pervasive healthcare and eHealth platform, as well as being an experimental toolkit for investigating topics related to patient adherence. Thus, the platform could both be useful for creating a complete smart home infrastructure (12) supporting ambient assisted living (13), or more special purpose portable telemonitoring health gateway platforms. This includes support for rapid and seamless deployment in the home of patients or at the outpatient clinic, as well as evaluation as part of a pilot study. It may also be used to inform the design of self-care solutions and create more reliable stand-alone biomedical devices, as illustrated in Figure 1.

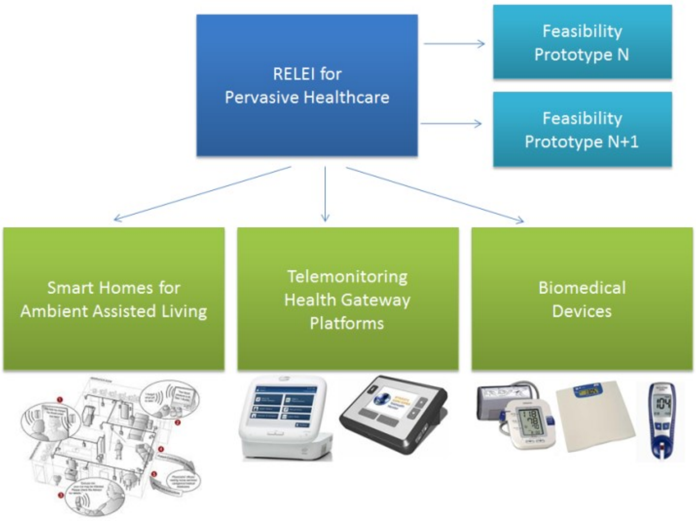

Figure 1: The RELEI platform can be used for assessing the reliability of pervasive healthcare systems used for self-caring patients. Experiences and components of RELEI may also be useful for improving stand-alone biomedical devices, telemonitoring gateway platforms, as well as smart home infrastructure. Reproduced from (9).

2.3 Technical Architecture

The current version of the RELEI platform allows researchers to utilize the individual components of the toolkit either as stand-alone components, which may easily be integrated into research prototypes as assembly components, or as a full service oriented architecture (SOA) platform deployment of the OpenCare platform (14). Also, developers may choose to only adapt the terminology of the conceptual ontology into their design. This usage flexibility is central to the toolkit design allowing for *openness and flexibility*. RELEI is designed to be *heterogeneous* and allow different applications and frameworks to co-exist and communicate. This is achieved by separating the individual services and applications into separate processes, relying on inter-process communication based on heterogeneous middleware technology. We have also wrapped several representative biomedical devices and context-aware sensors, as well as general purpose services such as notification, communication, persistence, and other relevant components. These components facilitate easy access to the most commonly used healthcare devices and context sensors. Furthermore, this has been wrapped into a middleware controlled service layer, governed by a life cycle manager to secure the continued operation of services and applications. In the following, we will detail the technical architecture of the platform. The OpenCare platform is used for life cycle management and service composition relying on middleware to separate processes controlled by the OpenCare Service Engine (OCSE) life cycle manager for improved reliability and stability (15). OCSE ensures that a process or service that is failing cannot cause the entire system to fail, and that the process is automatically restarted. This is achieved by separating services and user interface applications by a middleware layer, so that all inter-process communication is done using either socket or named pipes communication, passing through the OpenCare Service Engine, as illustrated in Figure 2. This also allows for deploying services on multiple distributed hardware nodes. Different versions of OCSE have employed different middleware frameworks. In the two most recent versions, the Internet Communication Engine middleware (ICE) (16) and Web services using the Windows Communication Foundation framework (17) were used respectively. ICE supports a high level of platform independence as it is available for most hardware platforms and operating systems. Also, language independence is high with support for most established programming and scripting languages. It has support for synchronous and asynchronous messaging, featuring object oriented semantics, threading support, built-in security and persistence services. Finally, ICE supports full source code availability and is released under the terms of GNU General Public License (GPL). Several alternative SOA-enabling technologies were considered instead of ICE, including CORBA, Java RMI, DDS, and Web services (18). However, ICE provided better characteristics in terms of footprint, ease of use, and support for heterogeneous middleware. Using heterogeneous middleware, such as ICE, supports a heterogeneous execution environment, as well as openness and flexibility allowing existing frameworks based on heterogeneous programming languages and libraries to be easily included into the framework. Previously we have integrated with the Java based SPINE (11) and JCAF frameworks (10), as well as to the Danish national healthcare infrastructure database project Net4Care (19), also written in Java. In total ICE supports more than 10 programming languages and 14 operating systems. In comparison, CORBA, DDS, and Web services supports a comparable number of platforms, but requires frameworks from multiple vendors, including non-open source and commercial licenses, to achieve the same breadth of supported platforms and programming languages (18).

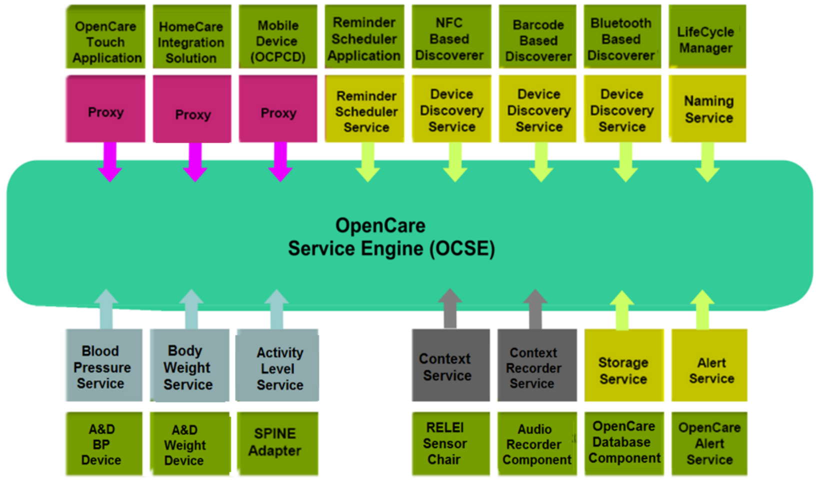

Figure 2. The OCSE service engine supporting the reliable execution of several heterogeneous components running on the same hardware platform in a service oriented architecture. All elements are services, communicating through the OCSE middleware layer. Replicated from (15)

The .NET platform (17) was chosen as the main development platform for RELEI, as this platform can run on several operating systems, including the Windows family: Windows CE, Windows Mobile, Windows Phone 8, .NET Micro (embedded framework), as well as Linux and Android (via Mono). The choice of middleware has allowed a heterogeneous focus, where external frameworks, toolkits, and applications can easily integrate via the middleware layer using multiple programming languages. Furthermore, in case special purpose platforms are needed, it is possible to use virtualization, as the middleware allows for inter process communication across virtual machines as well. For hardware platform, we have relied on several Intel Atom-based embedded Windows touch screen computers, which provide adequate processing power for most types of intended self-care case studies, including for situation recognition of context, medical data analysis, user behavior monitoring, and other computational intensive tasks. Furthermore, this has allowed us to support several communication standards for supporting relevant biomedical and context aware sensors and devices. As the wireless IEEE 11073 standard (20) for healthcare devices is not currently supported on the Windows platform, this has been achieved through virtualization of Linux. We have created components and OCSE service implementations for several commonly used pervasive healthcare and telemonitoring devices, including from A&D, Omron, Nonin, Corscience, and Beyer. A total of five different commercial blood pressure devices both wired and wireless, two wireless single-lead electrocardiography (ECG) devices, three weight-scale devices, two blood sugar devices, and two wireless oximetry devices are supported. These software components allow researchers easy access to relevant biomedical devices for experimental purposes. Also, context-aware sensors for specialized projects have been developed which are generally applicable in reliable pervasive healthcare research, including: a bed occupancy sensor, a movement sensor, door sensor, mobile activity sensor node, noise level sensor, as well as several prototypes of an intelligent chair and a mobile context-aware chair seat, for measuring whether a patient is correctly seated, e.g. during blood pressure measurement. A medication sensor for adding support for tracking medication adherence was likewise implemented. In addition to this, RELEI features video and audio recording components for supporting context recording. These components can be triggered by relevant contextual events. Besides video and audio recordings, the platform can also record context-sensor data during a healthcare session, allowing for a precise and discrete quantification of user behavior during measurements that can be coupled with the video or audio capture and used for verification. Also, support for several home automation standard sensors has been implemented, based on Z-Wave and ZigBee. These include movement, temperature, and humidity sensors. For supporting user identification, RELEI provides support for Near Field Communication (NFC), Radio Frequency Identification (RFID), and barcode components for identification of users and equipment. Furthermore, face recognition and voice recognition have been integrated for user identification based on a commercial product. For monitoring user activity levels in the home setting, RELEI has been interfaced with the SPINE framework (11). SPINE provides support for Wireless Body Sensor Nodes (WBSN), which can be used to support scenarios such as fall detection and patient activity tracking, including for rehabilitation purposes. Several other frameworks have been considered for use in RELEI, including a framework for capturing basic movements in mobile gaming, which appears useful for supporting research into mobile systems for reliable monitoring of rehabilitation efforts in the unsupervised home setting (21), with a specific focus on chronic obstructive pulmonary disease (COPD) patients. This would also support using persuasive technologies for rehabilitation (22). Also, automatic context tagging could be supported by the "Generic Activity Framework" as presented in (23). This framework decouples the "observation subsystem" from the rest of the activity model and allows for easier developer access to activity recognition technology and programming.

2.4 Case studies

In the following we present two case studies showcasing different uses of RELEI in the home environment of a patient, as well as in the hospital outpatient clinic.

2.4.1 Case Study I: Calm Medication Reminder System

This case study aimed at improving patient medication adherence levels by using context-aware technology to remind hypertensive patients to take their medication on time. This is done without needlessly intruding on the patients by observing personal preferences and context of the user, as investigated using the Context-Aware Medication Reminder System (CAMS). CAMS has been used as part of a participatory design process as a proof-of-concept for exploring calm guidance as a design concept (24). The aim of this study was to design a system that adapts its medication reminding facility to only remind a patient to take the prescribed morning medication if it is not taken within a fixed time interval after rising from bed. Also, it should only alert the user if needed, and does so using the relevant communication media in the given user context. Such a system could be used for future investigations as to whether patients become more compliant in taking their medications when they have a reminder system that is not unnecessarily intruding into their lives, except when actually relevant for patient safety.

The case study employed the RELEI platform for user interface and reliable execution environment. The RELEI bed sensor and medication adherence sensor components were used as two separate processes, and a third process contained the user interface application and business logic. Studying patient adherence to medication involves both registering the acceptance (willingness to start), compliance (timeliness of taking the medication), and persistence (adherence over time) of the patient. Furthermore, in order to study the effect of an intervention, in this case an audio alert in case medication is not taken on time, it was important that the prototype could autonomously turn the reminder service on and off, in order for the patient to serve as self-control.

2.4.2 Case Study II: Unsupervised BPSM in the Department of Renal Medicine

This case study revolved around patients with hypertension or receiving BP lowering treatment who are required to self-measure their BP in a dedicated self-measurement room before consultation at the Department of Renal Medicine. Current praxis does not guarantee valid measurements, frequently leading to misdiagnoses or inappropriate antihypertensive medication.

The aim of case study II was to investigate patient ability to correctly self-report and follow recommendations (25). The case study used the RELEI platform as user interface and reliable execution environment. The standard RELEI sensor chair and A&D blood pressure device sensor components were used as two separate processes. A third process ran an audio context classification service, using the audio recording component of RELEI, and an audio classification service component was used for classifying whether the patient had talked during measurement. The recorded audio was later used to evaluate the accuracy of the audio classification results. A fifth process contained the user interface application and business logic.

A context-aware system was designed based on RELEI in order to gather information on BP measurements and relevant context parameters. Patients were not informed that the system automatically collected behavior-data, and were instructed to self-report their measurements on a paper sheet as usual. The study then compared the automatically registered data with the self-reported in order to detect any non-adherent reporting behavior. Also, the study investigated the participants' ability to adhere to the measurement recommendations. The study found that a third of all 113 participating patients failed to self-report measured BP data correctly and none of the 642 measurements obtained adhered fully to the recommendations. Results indicate that context-aware technology may be useful to accurately model aspects of non-adherent patient behavior. This may be used to inform staff of the validity of the measurement and pinpoint patients in need of additional training, or to design better aids to assist the patients.

3. METHODS AND MATERIALS

We evaluated the applicability of RELEI in 11 self-care case study projects where either the complete RELEI toolkit or components hereof were used in the analysis, design, and/or evaluation phases of the individual case study project. The case studies included both laboratory and clinical-proof-of-concept prototypes (4). We compared how the case studies used RELEI, and to which extent. Also, we evaluated whether RELEI provided sufficient support for the individual case studies or whether more components were needed.

4. RESULTS

All 11 case studies used RELEI in the design, implementation, and/or evaluation phases. Seven of these case studies were laboratory-based experimental proof-of-concept studies; three were clinical proof-of-concept feasibility prototypes; while one was a pilot study as a part of a planned clinical trial. A total of 321 test subjects participated in the 11 studies, of which 264 were hospital patients participating in the four clinical evaluation studies, while the remaining were focus group members, with a mix of patients, senior citizens, students, and other volunteers. The 11 case studies were carried out by six different research groups. In Table 1, an overview of how the 11 self-care studies used RELEI, including which components, the type of project, and patient group, is presented. Patient groups included hypertensive patients, diabetics, heart disease, kidney disease, chronic obstructive pulmonary disease (COPD), anticoagulation therapy patients (INR), as well as healthy pregnant women as part of a screening program. Clinical projects were performed at three outpatient clinics, as well as in a care facility, and in the private homes of four diabetes patients.

Table 1. Overview of self-care case studies using RELEI

	Case study	Patient Group	Project Type	Components Used	Setting	Evaluation	TS
1.	Home BPSM	Hypertensive	US, MAV	OCSEB, BP, CS	Laboratory	Lab PoC	22
2.	Ambulatory BPSM	Diabetics	-	LAOP, REWS, AR	-	Lab PoC	20
3.	Calm Medication Reminder System	Hypertensive	US, MAV, MAA	BP, CS, BS, MAS, RFID, VR, AR	-	Lab PoC	1
4.	Automatic Weight Measuremen System	Heart disease	US, MAA	OCSEB, MWS, FRC	Laboratory	Lab PoC	6
5.	Morning BPSM prior to taking Medication	Kidney disease	US, MAV, MAA	BP, BS, MS	Laboratory	Lab PoC	1
6.	Lung Function Rehabilitation	COPD	-	OM, RFID	Laboratory	Lab PoC	2
7.	INR Medication Reminder Syst	INR	-	MS, BS	Laboratory	Lab PoC	1
8.	Mobile Home BPSM	Diabetics	-	LAOP, BP, MSB	Clinic	Clinic PoC	4
9.	Obstetric outpatient clinic BPSM	Pregnant diabetics	US, MAV	OCSEB, BP, SS, AR	Clinic	Clinic PoC	41
10.	Nephrology outpatient BPSM	Hypertensive/ Kidney disease	-	OCSEB, BP, CS, AR	Clinic	Clinic PoC	189
11.	Obstetric BPSM screening	Healthy pregnant women	US, MAV, MAA	OCSEF, BP, CS, MSB, IS, AR	Clinic	CT	34

Abbreviations used in Table 1. MAV: Measurement adherence verification project, MAA: measurement adherence aid project US: unsupervised setting project, OCSEB: open care service engine platform used in a basic single application setup, OCSEF: full usage of the OCSE framework, LAOP: the Light Android OCSE Platform - a very basic implementation of OCSE on Android, REWS: RELEI web service framework - extending existing RELEI services for distributed use, BP: blood pressure device, CS: chair sensor, BS: bed occupancy sensor, MAS: medication adherence sensor, MWS: medical weight scale sensor SS: sensor seat, RFID: radio frequency identification service, FRC: face recognition service, AR: audio recording service, VR: video recording service, Lab PoC: Laboratory feasibility experiment using proof-of-concept prototype, Clinic PoC: Clinical proof-of-concept prototype, CT: Clinical Trial.

5. DISCUSSION

In all 11 investigated case studies we found RELEI to be relevant and applicable for supporting rapid prototyping and evaluation of self-care research projects. Although, several of the self-care research prototypes needed to adapt existing context-sensors, RELEI was able to support all research and evaluation objectives and activities. To exemplify, as presented in case study II, the audio recording service (AR) was used to automatically start recording audio data when a patient was seated in the chair sensor during the BPSM process. Data was later used to compare automatically classified results, e.g. whether the patient had talked during measurement, with what actually occurred during the measurement (25).

In order to allow for experimenting with advanced pervasive user interaction and sensor support, an infrastructure platform is needed. Several infrastructure platforms for pervasive healthcare, telemedicine, and ambient assisted living (AAL) projects have been proposed (12). Such platforms aim at enabling the patients to monitor themselves at home, employing a range of healthcare devices, and freeing the patients from having to visit a physician. They focus on interoperability of devices, as well as procuring the data transport from sensors to hospitals. Well-known AAL platforms include the Smart and Aware Pervasive Healthcare Environments (SAPHE) project (26), the UniversAAL project (27), and the Hydra platform (28). More recently, u-Health was developed for applying service governance of service oriented architectures in order to make pervasive healthcare services more secure, reusable, interoperable, and available (29). Also, several commercial platforms, such as the Intel Health Guide (30), Bosch HealthBuddy (31), and Tunstall mymedic (32) are available. As such, it could be argued, that there is no need to introduce new platforms. However, while research platforms such as Hydra and UniversAAL are partly open for extension, they have limited hardware component support out of the box, requiring users to expand the framework with the needed components manually. SAPHE has several biomedical devices supported, but is not available as open source. Although Hydra and UniversAAL are based on Java, they remain partly open to integrate with non-Java applications, due to their reliance on web services as middleware. In comparison, the OCSE framework currently used by RELEI uses either the ICE middleware or W3C Web services, allowing all frameworks supported by either of these two technologies to integrate. This includes C++, Java, .NET, Python and most other contemporary programming languages. Furthermore, all RELEI components can also be used as stand-alone components, by linking them directly into evaluation software, independently of the OpenCare platform. The commercial platforms have a wide range of standardized biomedical devices supported, including weight scales, blood pressure devices, oxygen saturation and blood sugar devices. However, it is not possible to integrate these with novel context-aware sensors, in order to investigate aspects of reliability, as needed in the case studies presented previously. Also, the ability to add external frameworks, such as the SPINE framework or JCAF is not possible in the commercial platforms. The Intel Health Guide is able to integrate with all biomedical drivers that conform to the Continua Alliance standards (33). This is however not targeting user-context tracking sensors and similar devices, which have not yet been standardized. We argue that it is highly relevant to keep solutions open for modification and integration, rather than closed and inaccessible. This is especially relevant for platforms that should be used for research projects. Furthermore, keeping interfaces open, flexible, and simple appears highly relevant if we want to make it easy for researches to use the platform. If the available application programming interfaces require excessive cognitive and engineering competencies to master, it might be easier to build a solution from the bottom rather than relying on existing frameworks. However, openness and flexibility comes at the price of increased hardware cost and higher power consumption, which should be taken into consideration before employing RELEI and related toolkits. Initial experiences with RELEI appears promising and research solutions based on OpenCare and RELEI have been deployed to several hospital outpatient clinics, nursing homes, and other care facilities, as well as in the home of patients. Furthermore, elements of OpenCare are actively being used as part of a commercial product, and have been deployed to several Danish care facilities and nursing homes.

6. CONCLUSION

Based on the identified nine requirements for an evaluation infrastructure toolkit for designing and evaluating self-care prototypes, RELEI have been designed and implemented. This study evaluated the RELEI toolkit through use in a range of 11 self-care research projects concerned with constructing and evaluating clinical proof-of-concept feasibility prototypes. Results illustrate the breadth of how RELEI can be used to support self-care research projects in different contexts and patient groups.

Previous work identified the need for a platform for evaluating reliability aspects of self-care research projects in the unsupervised setting and the specific challenges emerging from them. While several eHealth and pervasive healthcare platforms and toolkits exist, none of them focuses specifically on facilitating self-care research on reliability issues. Thus, RELEI was suggested as a dedicated toolkit for facilitating the research community to address these specific challenges and investigate the potential for change. It is not possible to conclude whether RELEI is more effective or relevant than such related platforms and toolkits. Thus, RELEI should not be regarded as an alternative, but rather as a supplement to be used in combination with other toolkits, platforms, and frameworks for supporting pervasive healthcare, eHealth, and ambient assisted living research in the unsupervised setting.

In conclusion, the RELEI toolkit has shown to be relevant and applicable for facilitating self-care related research projects in a wide spectrum of self-care research studies. The concepts and technologies framed by the RELEI toolkit could be considered a step toward achieving more reliable healthcare systems in the unsupervised setting, facilitating the delivery of higher data-quality, possibly leading to increased patient and physician confidence in pervasive healthcare technologies for telemonitoring, eHealth, and ambient assisted living solutions. This could lead to improved diagnostics and treatment outcomes, and reduced healthcare expenditures across the spectrum of the most prevalent diseases and conditions.

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