PCARD Platform for mHealth Monitoring

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The introduction of information and communication technologies (ICT) into the integrated healthcare system could increase the self-management of health and therefore increase the efficacy and decrease the costs of overall health management. A personal mobile health monitoring system (PCARD) has been developed, which uses moderately-priced and user-friendly technological solutions, e.g. wireless body sensors for data acquisition, advanced algorithms for data analysis, widely available smart phones for visualization of measurements, and the existing communication infrastructure for data transfer. The solution is unobtrusive, works with existing devices, and provides useful information to both direct users and to the health care system. The PCARD system starts with measurement of ECG signal that incorporates significant information about the global health state. It then continues with display of the signal and its analysis on a personal terminal, such as smartphone and on Cloud-based storage, processing, and visualization software. Four pilot studies have been designed to validate to which extent the continuous measured ECG data could contribute to improved quality and efficiency of the healthcare. Also, the level of safety and reliability, the acceptance from users, and the potential for commercialization will be validated in the scope of the pilots.

Povzetek: Uvedba informacijskih in komunikacijskih tehnologij (IKT) v celostno zdravstveno oskrbo lahko poveča sposobnost samoupravljanja zdravja s čimer poveča učinkovitost ter zmanjša stroške zdravstvene oskrbe. Razvit je bil osebni mobilni sistem spremljanja zdravja (PCARD), ki privablja z zmerno ceno in uporabniku prijaznimi tehnološkimi rešitvami, kot so brezžične telesni senzorji za zajemanje podatkov, napredni algoritmi za analizo podatkov, vizualizacija meritev na široko dostopnih pametnih telefonih in uporaba obstoječe komunikacijske infrastrukture za prenos podatkov. Rešitev je nevsiljiva, deluje z obstoječimi napravami, ter nudi koristne informacije tako za neposredne uporabnike kot tudi za sistem zdravstvenega varstva. Sistem PCARD temelji na merjenju EKG-signala, ki vključuje pomembne informacije o svetovnem zdravstvenem stanju. Nato nadaljuje s prikazom signala in njegovo analizo na osebnem terminalu, ter končuje s skladiščenjem, obdelavo in vizualizacijo v oblaku. Štiri pilotne študije so bile zasnovane, da bi preverili, v kolikšni meri bi lahko neprestano merjenje EKG prispevajo k izboljšanju kakovosti in učinkovitosti zdravstvenega varstva. Poleg tega bodo študije prispevale tudi k večji stopnji varnosti in zanesljivosti, analizi nivoja uporabniškega sprejemanja mobilnega EKG merilnika, in potrditvi potenciala za komercializacijo PCARD sistema.

1 Introduction

Future mHealth solutions based on wearables for monitoring ECG, vital signs, and activity of subjects will provide an important means of healthcare. Although such wearables are also usable in clinical environments, they are most efficient when used in subjects' everyday activities. As such, they are perfect for discovering arrhythmias, measuring the impact of drugs on arrhythmias, documenting ischemia, following up on the adherence to drug therapies, checking up the results of ablation procedure, evaluating syncope and light-headedness [1], etc. Aided by the computer analysis of the provided rich set of measured data, the mHealth based monitoring could also tackle a large set of comorbidities (e.g. diabetes, cardio-oncology, cerebrovascular disease, and other neurological disorders affecting patient's mobility).

The PCARD mHealth solution could be applied in medicine (e.g. follow-ups of patients in tertiary level, or motoring of patients with palpitations in primary level), in wellness and health centers, at home for personal use, in protection of professionals during stressful and physically intensive tasks - for example firemen in action, and in sports, both amateur and professional. Although the mHealth solution could be usable almost entirely on its own, it should be integrated into the existing health care system for bigger impact.

Existing cloud-based mHealth solutions [2] are mostly aimed at gathering, storing, using, and sharing health information online. Most of them suggest various sensors to users but these sensors are all specialized to perform a single task. There is no integration of multiple sensors and no integration of these solutions with the modern electronic health records. The PCARD platform integrates users, caregivers, and medical community. It provides safe data transfer, secure data storage and manipulation, and application services for a completely integrated solution while it allows for manual interventions to the system if they prove to be necessary.

To evaluate PCARD, four pilot studies will be implemented. The resulting integrated health care model will advance the current health care system by providing additional links, data and knowledge pathways between the patients, their family and other informal care givers, and formal care givers.

This paper is based upon Kališnik et al. [3], extended with the following new contributions: (i) the personal computer software for ECG analysis has been added to PCARD, (ii) personal terminal software description has been expanded, (iii) the pilot studies performances have been expanded.

The rest of this article is as follows. First the method is explained – the PCARD platform for constant monitoring of vital ECG parameters. Next, the main constituents of the PCARD platform are described - the sensor device, personal terminal software, cloud-based software, and personal computer software. Then the pilot studies are presented, on which the PCARD platform will be evaluated. Finally, in Conclusion, the obtained results are summarized and the required future steps for PCARD implementation are listed.

2 Methods

We propose PCARD platform - a scheme of an mHealth system for mobile monitoring, which is schematically shown in Figure 1. The system comprises a small wearable device, Android application, protocols for data transfer, and software on the cloud.

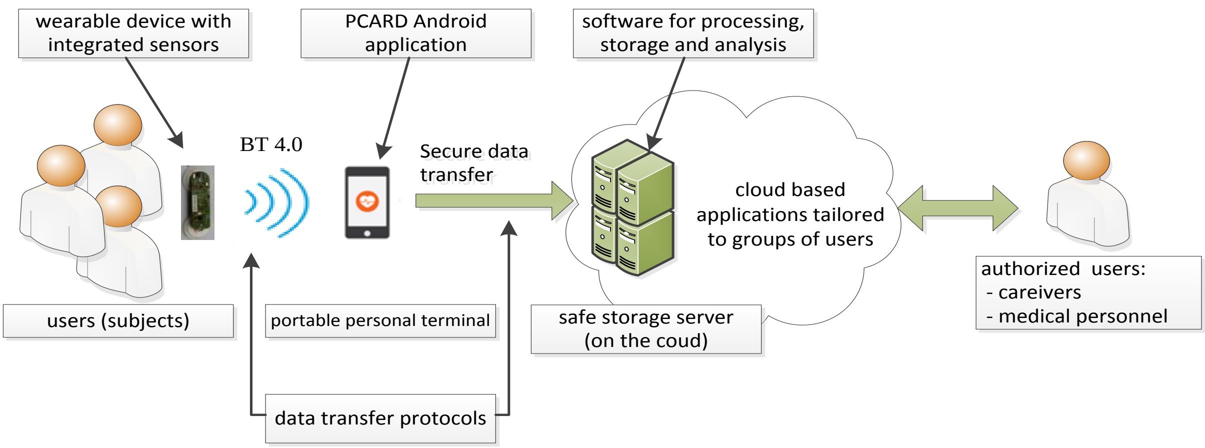

Figure 1: PCARD platform as adapted for the follow-up of cardiac patients.

The wearable device is a wireless ECG sensor, it has measuring and communicating capabilities, microcontroller, and software designed specifically for it. The application on ubiquitous Android based mobile devices (such as tablets and smartphones) has two functionalities: to act as a link between the wearable device and the cloud, and to display the measured data. The cloud software residing on secure computer servers takes care of the measurement storage, analysis, and interface for various cloud applications for all the intended PCARD users – subjects themselves, the authorized caregivers and authorized medical personnel. Standard technologies are used for the transmission of the measurements, e.g. Internet, Bluetooth Smart, Wi-Fi, SSL, and SOAP. Usage of cloud and standard communication building blocks offers an inexpensive implementation, as well as wide availability of the system.

The design of the system takes into account the existing technical standards, allowing easy connection of various wearables and their immediate replacement if an improved version becomes available. Besides the ECG sensor, the system architecture allows the inclusion of additional sensors on the same wearable or the additional wearables, which could help improve the monitoring of the patient's condition, for example, sensors for remote monitoring of respiratory acoustic phenomena (cough, obstruction), or sensors for activity detection, etc. Some of the measurements are already feasible with our custom sensors [4].

Based on the graphic presentation of a critical vital parameter and its recent changes, it is possible to evaluate the effectiveness of a treatment and to foresee a possible deterioration. An alarm can be implemented to alert the medical personnel on the high possibility of deterioration before the monitored vital parameter reaches a critical value. Based on the simultaneous evaluation of multiple variables, the automatic analysis can provide the threat level and its trend (MEWS) [5]. The analysis of vital functions in a longer time period allows for the implementation of cognitive methods, for example, analysis of a cardiogram over longer time period contributes to the personalized patient’s threat level[6][7][8].

2.1 ECG body sensor

The heart of the PCARD system is its small and lightweight wearable device, which is fixed to the subject’s skin using standard self-adhesive electrodes. The device measures ECG with high resolution, which is suitable for both personal and clinical use. In addition to the ECG, the device also senses its environment, including position and movement of the subject [4][9], and subject’s skin temperature, thus providing information about the measurement conditions. This device is also suitable for inclusion of other features, such as: EEG, vascular pressure, skin resistance and respiratory rate measurements. Such an electrode represents an important worldwide technological breakthrough.

With a single charge of the built-in battery, the device can operate continuously for more than three days. The device itself is extremely simple to use, to maintain and clean, as it requires no setup, it exposes no cables or switches, and is enclosed in smooth biocompatible plastics. With no movable parts it is extremely robust, can be made watertight, and by itself poses no absolutely risk to the users. It is intended for wide individual use, is affordable and is the basic building block of the mHealth technological network.

With an appropriate placement of the device on the chest, good visibility of all electrocardiographic waves (P, QRS and T) can be achieved with the quality sufficient for medical analysis. Therefore, PCARD can be used to help identifying arrhythmias and other cardiac conditions [5]. In contrast, the measurements from implanted ECG recorders (Implantable Loop Recorders [10]), often record P waves that are poorly visible or not visible at all. With an ECG sensor fixed by standard electrodes on the chest as is case with PCARD, the placement of electrodes can be easily modified and fine-tuned to maximize the recording quality of the desired electrocardiographic waves, and allows for a better quality ECG recording.

To maximize their potential, wearable devices should be non-disruptive to their users; to this end, PCARD device is made small, multifunctional and wireless. It can be worn under any kind of garments. We have already successfully prototyped a differential wireless sensor for measuring body surface potential on short distances. One of the prototypes is shown in Figure 2 with the raw measured ECG signal displayed on the Android based smartphone.

Figure 1: Prototype personal equipment of PCARD system: small body sensor and Smartphone.

2.2 Personal terminal

The necessary link between the ECG sensor and the ECG analysis available to appropriate experts is a personal terminal – a device with computing and interconnection capabilities that the user carries around at all times. Ubiquitous smart phones can readily fulfill this role [12] and the PCARD makes extensive use of Android powered smart phones.

Personal terminal connects to the ECG sensor via Bluetooth Smart protocol and records everything that the ECG sensor measures. This protocol offers sufficient bandwidth, data encryption and is low-power, meaning it conserves well the ECG sensor's and the personal terminal's batteries, which are the limiting factor for autonomy length.

For an integrated care solution, the measured data should be available to the patient herself as well as to the medical personnel. Therefore, the personal terminal analyses and displays the data to the user in real-time and in a user-friendly fashion on the personal terminal display, while it also forwards the un-processed data to the cloud via Internet connection. The data can be sent either in near real-time (with only several seconds of delay) or in larger packets, for example once a day, depending on the monitoring purpose. It can also be processed before sending to lower the data size and to provide only the pre-defined statistics to the cloud.

Software running on the personal terminal could be extended to provide alerting in case it detected life-threatening heart conditions. The alerting could be directed either to the user, to the nearby health care provider or even to the emergency dispatch center. Furthermore, software could be extended to provide assistance for physical training or for workers that often face life-threatening situations, such as firemen, policemen, etc.

2.3 Secure data transmission and storage

Bluetooth Smart technology enables encryption of transferred data between the ECG sensor and the personal terminal. The measured data are only temporarily stored on the personal terminal storage and are accessible to be processed by other software. Transfer of data to the cloud is again encrypted and largely depersonalized – personal data is never transmitted with the measurement. It is also only not required (although it can be) to be stored on the cloud. In the end, aside from the users themselves, only authorized medical personnel possess the personal information of the subjects of measurements.

2.4 Cloud software

Medical and informal caregivers can access the measured data and their visualization on the cloud according to their permissions, which are managed with a safe and reliable accounting system. Since the PCARD system is on the cloud, customized interfaces can be provided for various medical personnel profiles to aid them in using, viewing, and analyzing the data. Private users also get custom interface to access their own data, although they may instead use only their personal terminal without ever connecting to the cloud.

The data on the cloud also offer a unique opportunity for scientific exploration to advance the medical knowledge. Never before have ECG measurements of multi-day length and enriched with subject's activity data been available in large quantity. PCARD offers an interesting new Bigdata problem – immense quantities of novel data type to be explored with statistics and data-mining algorithms. Although processing this data will be difficult, the state-of-the-art Bigdata techniques should be able to tackle it. If not, the Bigdata is being heavily researched and should provide adequate tools soon enough.

Opening the PCARD interfaces for custom made applications and add-ons that communicate either with the cloud or the personal terminal software provide the opportunity to extend the pre-designed use cases of PCARD. A more suitable representation of the measured data for the laymen may be discovered, or the possibility for the patient to better monitor his or her vital functions added. We have already developed an Android application that provides a comfortable option for tele-monitoring the heart activity, and display the real-time data from the electrode. The options for using the measured data are endless, however, they will have to be approached with caution, since sensitive personal data are at stake and should be protected with great care.

2.5 Personal computer software

During the pilot studies, future cloud software functionality is emulated by modified NeuroEKG software for personal computers [13]. NeuroEKG (see Figure 3) is a software package for semi-automatic analysis of ECG and correlated bio-signals, e.g., blood pressure. It will be used within the pilot studies for the prototyping, testing, and evaluation of algorithms and procedures.

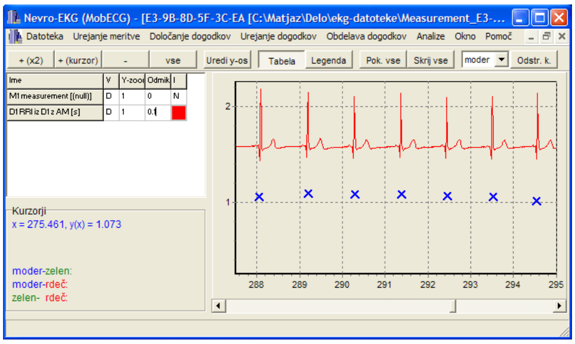

Figure 2: A sample screen from NeuroEKG application with an ECG channel (red curve), measured with PCARD system and the detected individual heart beats (blue x-es).

To pave the way for greater integration of mHealth services into health care and the daily lives, the medical personnel should first get a better understanding of what mHealth offers. Pilot studies will partially also focus on familiarizing the participating medical staff with the PCARD capabilities and limitations. Their understanding of ECG processing should evolve in this time, and their requirements towards the software should mature. NeuroEKG will serve well to showcase the software capabilities, to manually try out various algorithms, and to discuss ways of automating software processing. Thus the pilot studies will help mature the requirements for cloud-based software and for possible future evolution of PCARD system.

2.6 Pilot studies of PCARD platform applications

In order to show that the proposed system for the monitoring of mobile health is applicable at the various stages of the integrated health care, four pilot studies were designed for validation and evaluation of the medical, scientific, social and industrial impacts.

2.6.1 POAF - UKC Ljubljana

Postoperative atrial fibrillation (POAF) is a common complication of cardiac surgery. It results in many complications and increased healthcare resources [14]. Despite substantial findings in prediction and prevention of POAF, there is still some uncertainty about the risk stratification and the management of POAF.

Department of Cardiovascular Surgery of the University Medical Center Ljubljana (UKC Ljubljana) extends previous studies [15][16] and introduces a clinical study about the mechanisms of atrial fibrillation through recognizing dynamics of heart rhythm and electrophysiological properties of the heart after cardiac operation. This clinical study will use the PCARD system for constant monitoring of patients after a surgery and evaluation of malignancy of the rhythm and estimation of electrophysiological properties. Within the pilot study, a tablet showing current heart rhythm will be posted near the patient's bed and the analysis of the ECG will be done off-line. If the study is able to demonstrate constant on-line monitoring with automatic recognition of certain events is beneficial, the required functionality will be implemented in PCARD to provide on-line analysis.

The constant all-day ECG monitoring with PCARD will start immediately after the surgery, and end on the fifth day after the surgery. Atrial fibrillation is expected to occur in some of the monitored patients in this time frame. It is theorized that such monitoring should enable preventive activity, based on detected anomalies prior to the fibrillation itself.

2.6.2 Physicians - HCL Ljubljana

Community Health Centre Ljubljana (HCL) is a development oriented institution in primary health care with 1400 employees and with more than 400000 registered patients. The patients of HCL are treated within the medical doctrine and the ethics defined in it. HCL wishes to ensure a high-quality and time-optimal access to health care services for all of their users in all segments of acting. The patients of HCL come from the Slovene capital Ljubljana and its periphery. This is a diverse environment that includes urban and rural areas.

The proposed pilot system could trigger the penetration of the ICT and mHealth solutions in main-stream medicine in the primary care level and could improve and integrate the health care. PCARD will be used in parallel to current procedures of treating patients with unconfirmed palpitations or other heart rhythm disturbances. The patients participating in the study will already be provided with a more comprehensive care in terms of preventive and curative treatments than they would be using only the existing primary care.

2.6.3 Monitor - Terme Dobrna

Terme Dobrna (TD) is a health resort, well recognized by the two pillars: the positive impact of their natural healing factors on the health and the advanced medical treatment practices. TD is the only Slovenian thermal spa that holds international accreditation by DNV GL for quality and safety of its medical services. Medical center within the resort operates in fields of inflammatory rheumatic diseases, degenerative soft tissue rheumatism, post injury and post operation rehabilitation, and rehabilitation of neurologic (post stroke) and oncologic patients (mostly in fields of gynecology and urology). A part of TD is also *Institute for applied research in medical rehabilitation*, which aims to develop advanced, modern, evidence based, and software supported medical services that could be offered to their customers and therefore represents an ideal partner for a pilot study.

Pilot study will partly cover TD's wish to provide additional services to their customers. The goal will be to evaluate the hypothesis that visit to TD improves the persons overall health state. Within the pilot study, some of the customers could be provided with constant or intermittent health status monitoring for the time of their visits. ECG monitoring should provide enough data to evaluate or follow up on the eventual changes in person's health status. While the most important result of the study will be weather ECG monitoring can help evaluate health state changes, the customers receiving the monitoring within the study will already benefit, by receiving valuable health state information.

2.6.4 MDS - Rehabilitation Izola

Muscular Dystrophy Association (MDS) of Slovenia cares for the constant health and rehabilitation of their members. The people with special needs, such as those with muscular dystrophy, are exposed to health induced life threatening situations much more easily than the healthy population and therefore much more interested in the introduction and application of ICT-supported health care devices and services.

The study will focus on personalized health state monitoring of people staying in the MDS rehabilitation center. During the rehabilitation period, PCARD will be used for ECG monitoring, which will provide enough data to assess and analyze the heart condition. Treatment will be personalized and will include all the specificity of individual patients.

The study will shed more light on the usability of PCARD for relatively healthy population. Besides the studied assessment of short-term trend in health status, study will open up new options in: follow-up examinations for assessment of the long-term health status trends, and the impact of the physical activities on the health status. The latter could help in the preparation of personalized rehabilitation programs for more demanding customers.

2.6.5 Requirements and targets of pilot studies

The requirements and performances of the PCARD platform pilots are shown in Table 1. The success of PCARD will be validated through the opinions of all the participating actors, that is, its direct users and the medical personnel. Targets of PCARD to be implemented though the described pilot studies:

- Near zero obtrusiveness of the sensor device to the direct users.
- Intuitive operation with the sensor device and the mobile device software.
- Inclination of the direct users towards the mHealth monitoring provided by PCARD.
- Ease of use of software, both on the mobile device and on the Cloud.
- Minimal overhead for the medical personnel, even when PCARD is used in addition to the standard procedures.
- Data security and safety on the communication channels between all the actors (either users or devices) in the pilots.

Furthermore, pilot studies will help refine the future direction of development both the wireless ECG sensor and the software on all levels of PCARD.

Requirements/performances	POAF - UKC Ljubljana	Personal doctor - HCL	Monitor - TD	MDS - Rehabilitation Izola
Number of concurrently monitored users	6	3	3	2
Measurement length per user	6 days	3 days	up to 5 days	up to 5 days
Data stream capacity per user	200 Bytes/second	200 Bytes/second	200 Bytes/second	200 Bytes/second
Amount of generated data per day	0.1 GBytes/day	52 MBytes/day	52 MBytes/day	34 MBytes/day
Number of medical experts involved	6	3	3	2
Study of performance	Atrial fibrillation warning sign recognition	Palpitation detection	Short or long term health state assessment	Short or long term heart condition assessment

Table 1: PCARD platform as adapted for the follow-up of cardiac patients.

3 Conclusion

We have designed four pilot systems around the PCARD platform, designed for long-term monitoring of users at cardiac risk or those who wish to evaluate their health state, using mHealth solution for data acquisition and medical expert support for analysis. Appropriate medical expertise and the required form of the produced reports will be identified during the experimental period of the maintained pilot systems. It is expected that the responses of medical personnel to eventual changes in users' health state will be faster and more objective when using the PCARD pilot system; therefore the users will experience improved level of treatment and better correlation between their perceptive and actual health conditions.

The pilot studies alone demonstrate that the applicability of the PCARD system is not limited to hospitals and health care centers, where the added benefit of the system will enable "doctor-to-doctor" and "patient-to-doctor" communication. We expect also to obtain a large amount of user opinions about the level of obstructiveness of the protested system. Based on the pilot results, an improved and clinically evaluated system will be developed for the international market with a wide spectrum of opportunities for R&D companies.

The system can be also installed in non-specialized medical institutions, e.g. health centers, nursing and patients' homes for early postoperative care and similar. The patient-friendly approach can contribute to easier evidence-based health evaluation and to advantageous innovative services in wellness and health centers.

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