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A Mobile ECG System for the Evaluation of Cardiovascular Risk

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Abstract. Problem: Cardiovascular diseases (CVD) are the number one cause of death globally. The World Health Organization estimated that 80% of the deaths caused by CVD take place in low and middle-income countries (LMIC). Objective: This paper describes the development of a mobile Electrocardiogram (ECG) system designed to support the evaluation of cardiovascular risk. Methods: The system was developed using low-cost technology, implemented under the open-source platform SANA and adding an ECG signal to the process of cardiovascular risk evaluation. Results: Main functionalities of the system include a visualization and analysis of the ECG signal in the Android mobile device, calculation of four cardiovascular risk scales, standard ECG transmission using the European Data Format (EDF), and integration into an Electronic Health Record system. Ten experts recommended 28 different application scenarios for the system, and evaluated its performance (100%) and relevance of the functionalities (89%). Conclusions: The paper demonstrates the feasibility to develop a low-cost, open source, mobile ECG System able to support the evaluation of cardiovascular risk and potentially useful for other health promotion and prevention programs and scenarios, especially in LMIC.

Keywords. Cardiovascular risk, cardiovascular diseases, ECG, Mobile Health.

1. Introduction

Cardiovascular diseases (CVDs) are considered the main cause of death in the world. In 2012, 17.5 million people died because of CVDs, representing 31% of the total global deaths during that year [1]. The World Health Organization (WHO) indicates that 80% of the deaths caused by CVDs take place in low- and middle-income countries (LMIC). Research on mHealth technologies supporting the prevention and control of CVD are relevant, especially in LMIC because of the low number of specialists, e.g. cardiologists, and the unequal distribution of them; the lack of campaigns focusing on CVDs prevention, and the high economic burden of the disease calculated as nearly USD 1000 billion per year [2].

Cardiovascular risk (CVR) is commonly defined as the increased risk of developing a heart attack, stroke, heart failure and other diseases or complications. The Framingham Risk Score (FRS) is one of the most popular instruments to calculate CVR.

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FRS estimates the 10-year risk for coronary heart disease based on parameters such as: age, sex, LDL cholesterol, HDL cholesterol, total cholesterol, blood pressure, smoking, hypertension and dyslipidemia. A systematic review performed by the authors found evidence on the improvement of common CVD assessment models using Electrocardiogram (ECG) [3], for example, Badheka, et al. concluded that the addition of the ECG to the FRS improved the model and the evaluation of CVR [4]. However, ECG is not yet routinely used in CVR evaluation because its cost-effectiveness has not been demonstrated, especially in population-based studies.

The objective of this paper is to describe the development of a low-cost, open source mHealth solution designed to support CVR evaluation by including ECG as one of the input parameters to estimate the risk.

2. Methods

The software development process deployed in the project is a specialization of the Rational Unified Process. Three stages were considered for the system's development. The first stage was a pre-feasibility study to determine whether the project is viable and it was performed by a systematic review of literature reported in [3] and a mobile apps review reported in section 2.1. The second stage was the system's implementation, defining the systems architecture and functionalities. Finally, the third stage was the evaluation of the developed mobile system.

The system development was supported through the SANA platform. SANA was created by the Massachusetts Institute of Technology (MIT), and provides an open-source mobile platform that allows health workers to collect different types of information about patients. Once the data is collected, it is sent to a central server by using different Web technologies (REST and SMS technologies). Then, specialized clinicians (e.g. cardiologist) analyzed the data stored in an Electronic Health Record (EHR) platform called OpenMRS [5]. For the system's evaluation, the DESMET methodology was deployed [6]. DESMET is a popular evaluation methodology in software engineering, which proposes different evaluation methods. The most suitable one in the context of the project is the so-called "Feature Analysis Survey".

3. Results

3.1. Mobile Apps Review

In order to characterize the mobile apps available, a search over three repositories for Android, iOS, and Windows Phone Apps was performed. The search terms used were ECG, electrocardiogram, cardiovascular risk, cardiology, cardiovascular disease. The eligibility criteria used for this review were: only apps in English and Spanish were considered; apps not directly related to CVD (games, cholesterol management apps, etc.) were discarded. A total of 61 apps were reviewed (35 on Android, 16 on iOS, and 10 on Windows Phone). The main conclusion was that it was not possible to find any mobile app that combines ECG capture, CVR evaluation and integration with an EHR system.

3.2. System´s Architecture

The system's architecture took into account the main concepts and operations of the SANA platform. This platform simplifies the integration process for sending the collected data to the EHR OpenMRS through a server called Mobile Dispatch Server (MDS), as shown in Figure 1. The system's architecture complies with some architectural principles defined in IEEE 11073-10406. This standard establishes a normative definition of the communication between personal basic electrocardiograph (1- to 3-lead ECG) devices (called agents) and managers (e.g., smart phones, personal computers, etc.) to ease interoperability [7]. So, the developed system is composed of an agent, a manager (i.e. smart phone) running on Android, the MDS server, and the OpenMRS EHR server. The agent serves capturing the ECG signal from the patient. This is done by a microcontroller that controls an AD8232 ECG device (low-cost non-professional device, used for prototyping purposes), a microSD-card memory reader for temporarily storing the signals, and a small LCD screen for displaying messages to the health worker, who operates the system. The signal is sent via Bluetooth from the agent to the manager, where the signal is graphed, processed and analyzed. The signal, together with other collected information related to CVR, is sent to the EHR OpenMRS via HTTP and the MDS API. The authorized physician accesses the collected data in the OpenMRS for providing a diagnosis using the platform.

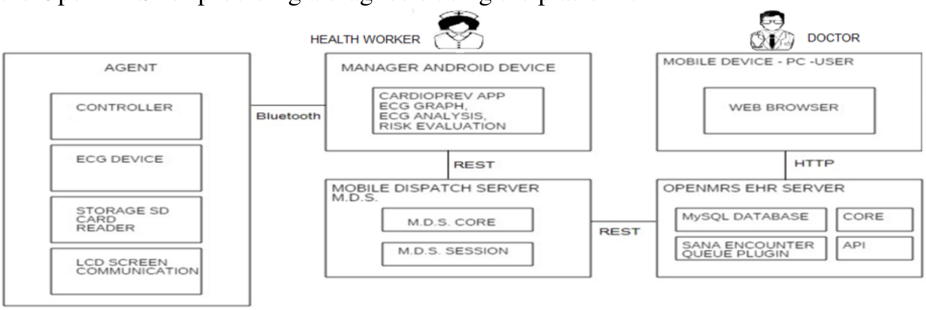

Figure 1. System's architecture.

3.3. System Functionalities

Figure 2 presents the main User Interfaces (UI) of the mobile application. For guaranteeing safety and privacy of health information, only the properly authorized users (defined by OpenMRS roles) can access patient's data. Therefore, an authentication process is required in order to obtain the ECG signal and to use the mobile system's functionalities (Fig. 2a). The system allows the health worker to: a) select Bluetooth devices for starting a connection process (to enable in further developments connections with devices different from the built ECG Recorder), b) create, or search for, a patient, c) select the ECG's duration in minutes, d) get the signal sent by the agent through Bluetooth, e) watch the signal (Fig. 2b), and f) watch the analyzed parameters on the signal. Those parameters are: a) the beats per minute, b) the average duration of RR interval, c) the standard deviation of these two parameters, d) the pRR50 (percentage of RR consecutive intervals with a difference >50 milliseconds), e) the QT segment duration, and f) the RMSSD (Root Mean Square of Successive Differences), as shown in the Fig. 2c. Furthermore, the system allows the health worker to collect data related to CVR in a group of questions, and, based on this data, to get a

CVR evaluation (Fig. 2e). For that purpose, the four scales: FRS, Grundy Scale for serious events, WHO Scale, and Kaplan-Meier Score are used (Fig. 2f). Finally, the health worker can send all collected data, including the ECG signal (stored in European Data Format, EDF), to the EHR system in order to be managed by the healthcare professional using the OpenMRS client.

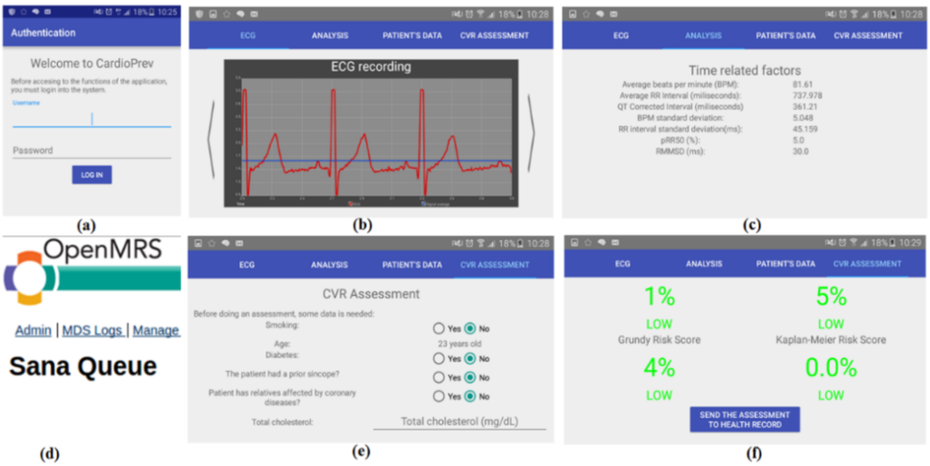

Figure 2. Application's main UI.

3.4. Evaluation of the System

The Feature Analysis Survey consisted of two parts. The first one included questions related to the presence, performance, and relevance of the system's functionalities. The second one dealt with questions about possible real use cases for the system. Ten local experts were selected according to their academic background and previous experience: 8 physicians (researchers at the Medical Faculty of University of Cauca and professionals of different hospitals) and two nurses specialized in cardiovascular surgery. The experts tested the system and completed the survey, the results are presented in Table 1.

Table 1. Main results of the system's evaluation.

ID	Functionality	Presence	Performance	Relevance
1	Authentication process	100%	100%	96.42%
2	Selection of Bluetooth devices	100%	100%	82.14%
3	Register a patient on the databases and EHR	100%	100%	96.42%
4	Search for a patient	100%	100%	92.87%
5	Selection of ECG's time of capture	100%	100%	85.71%
6	Visualization of the ECG signal on the mobile device	100%	100%	77.07%
7	ECG Signal Analysis on the mobile device	100%	100%	82.14%
8	Data entry for the cardiovascular risk evaluation	100%	100%	85.71%
9	Visualization of the CVR evaluation results	100%	100%	85.71%
10	Dispatch of data to the EHR (CVR data and ECG signal in EDF format)	100%	100%	89.28%
11	Visualization of the collected data in the EHR	100%	100%	96.42%
12	ECG download and visualization in an external open source EDF viewer	100%	100%	96.42%
	Average	**100%**	**100%**	**89.95%**

The results show that all the experts (100%) considered all developed and performed functionalities correct. Concerning the relevance, 11 out of 12 functionalities had percentages greater than 80% with an average of nearly 90%. The experts proposed 28 possible real use scenarios. Main scenarios were: a) campaigns for the CVR prevention (proposed by 8 experts), b) medical consultation (especially in rural areas, proposed by 6 experts), and c) statistical analysis on large population in order to characterize CVR profiles (proposed by 2 experts).

4. Discussion and Conclusions

In this paper, a low-cost open source mobile ECG system for CVR evaluation was presented, which is integrated in the SANA and OpenMRS open source platforms. The evaluation of the system with health experts provided promising results. Presence and performance of the systems functionalities was 100% and relevance was 90%. Experts considered that the system has the potential to be used in real scenarios. 28 different scenarios were suggested. The experts proposed scenarios mainly related to CVD prevention in rural areas. This is relevant, as 80% of CVD deaths occur in LMIC. The system allows a physician (who can be located far away from the patient and health worker) to see the data remotely (including and ECG), and provide a diagnosis on the same platform. This reduces the need of transportation and, in cases of emergencies in rural areas, allows making much faster decisions. The signal is stored in EDF format, which contributes to the interoperability of the mobile system. The experts proposed some ideas for improving the system. Future work includes a more robust ECG, including more than three leads, and an evaluation with patients. According to the systematic and Apps reviews carried out in this project, no similar systems were found.

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