Development of an mHealth Open Source Platform for Diabetic Foot Ulcers Tele-consultations

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Abstract. Diabetes is one of the foremost causes of death in many countries and a leading cause of blindness, renal failure, and non-traumatic amputation. Therefore, diabetic foot ulceration and amputation cause extensive burden on individuals and health care systems in developed and developing countries. Due to the multi-disciplinary requirements for the treatment of diabetic foot ulceration, telemedicine has been introduced to facilitate the the access of the patients to specialized health professionals. In this paper the development of an open source mobile health platform is presented, able to support diagnostic algorithms, with the use of a smartphone.

Keywords: Telemedicine, m-health, diabetic foot ulcers

Introduction

The prevalence of diabetes mellitus is growing at epidemic proportions worldwide and it is predicted to rise due to longer life-expectancy and changing dietary habits. Type 2 diabetes, formerly non-insulin dependent diabetes mellitus, accounts for the majority of the diagnosed cases. The greatest rise of type 2 diabetes is likely to be in developing countries such as Africa, Asia, and South America [1].

Diabetes is associated with many complications related to microvascular, macro-vascular, and metabolic etiologies. These include cardiovascular, cerebrovascular and peripheral arterial disease; neuropathy; retinopathy and nephropathy [2]. One of the most common complications of diabetes in the lower extremity is the diabetic foot ulcer. The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25% [3], though the prevalence of foot ulcers varies per continent, country and specific ethnics minorities within one country [4].

The burden of the diabetic foot ulcers in particular is high since it includes reduced functioning, increased sick leaves, increased financial costs for both the health care system and the societal perspectives. In addition to the direct costs of treatment of the diabetic foot complications, there are also indirect costs relating to loss of productivity, individual patient and family's cost and deterioration of the quality of life [5]. Diabetic foot continues to be the most common underlying cause of non-traumatic lower extremity amputations in the US and Europe [6].

It is possible to dramatically reduce the incidence of amputation through appropriate management and prevention programs. Considering the vast personal, social, medical, and economic costs, many countries have adopted policies to this direction [7].The treatment of the diabetic foot patients is however challenging and requires a systematic approach to the complete assessment of these patients. The multidisciplinary team-approach to diabetic foot disorders has been demonstrated as the optimal method to achieve better results [8].The provision of such integrated care varies from country to country due to many reasons and it is difficult to be achieved [5].

Due to the multi-factorial pathology of diabetic foot ulceration, telemedicine has been suggested as a way of enabling the experts to monitor an increasing number of patients more regularly [9-13]. The aim of this research was to adapt an existing pilot mobile telemedicine platform, called Sana [14], that supports audio, images, location-based data, text, video and allows for clinical decision pathways through tele-consultation based on the diabetic foot tele-monitoring.

Methods

The open-source Sana platform (released under a permissive free software license, the Berkeley Software Distribution - BSD license) [15], is being used in the first diabetic foot tele-monitoring prototype. Sana is a mHealth project based at the Massachusetts Institute of Technology (MIT) that offers an end-to-end system that connects healthcare workers to medical professionals [16]. The tool allows healthcare workers to transmit medical files such as notes, audio and video through a cell phone to a central server for archiving, incorporation into an electronic medical record and reviewing by a remote specialist for real-time decision support [17].

The complete Sana system consists of at least one phone and a web-connected server. The server runs the medical records system of choice and the Sana Dispatch Server program (MDS). The Sana Dispatch Server is responsible for communication to and from phones registered in the system. The data is received via lower-level synchronization, packetization and multimodal transfer that the Sana-enabled phones perform, three strategies to ensure reliable, low-cost data transfer. In addition to this, the Sana Dispatch Server has plug-ins that allows it to interface with different medical records systems. Sana is currently fully-compatible with OpenMRS [18], using an OpenMRS plug-in for the Sana Dispatch Server and a custom-patched version of OpenMRS, which extends it to have a queue of pending diagnoses in addition to allowing data such as images to be tagged to a patient record.

Moreover, the medical records system also runs on the server or a separate machine if desired. To sum up, the system infrastructure and design allows for modularity and interoperation.

Sana is highly customizable and, with the branching capability (that show different questions and results based on previous selections), allows physicians to make their own decision-tree diagnostic utilities for common procedures. Sana's front-end for data and media capture is accessible through a fully programmable workflow interface, that runs on the phone and doesn't need remote doctor's review. These workflows can be dynamically loaded onto phones running Sana. The back-end provides an intuitive user interface for management of medical data.

Procedures are step-by-step workflows, and are at the core of Sana. In most scenarios, a procedure is a set of pages that have questions or prompts. For the needs of the specific procedure, the available diagnostic algorithms project [12,19] can be used. The prototype procedure developed is being called "Diabetes Mellitus Follow-up" and appears in the Sana encounters stored on client devices. Procedures are defined in a simple XML format. All the information regarding installation and deployment of new procedures can be found at the Sana Wiki [17].

Results

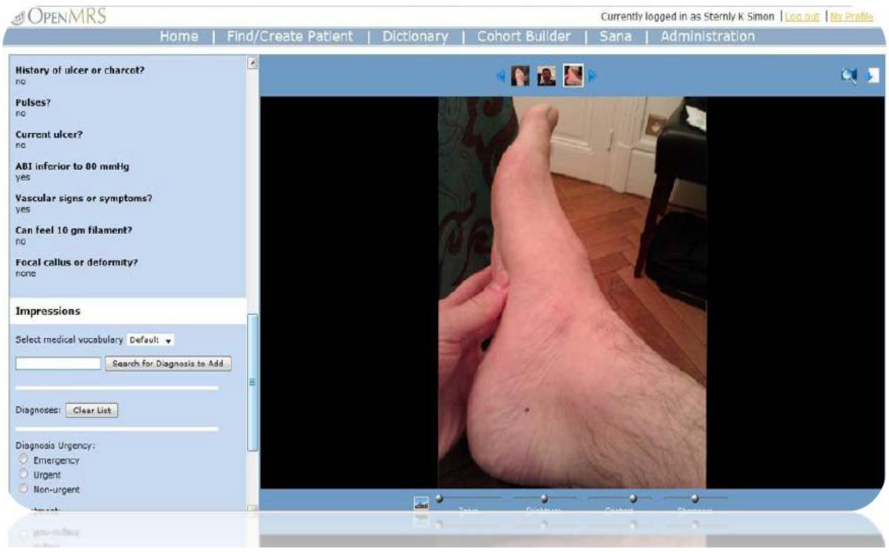
The developed m-health platform, creates and records a personal ID for each patient with his medical history on the server. During the visit of the health workers at the patient house, the online medical record of the patient will be updated with the upload of high-resolution images and/or video of the ulcer as well as obtaining measurements such as peripheral blood pressure, blood sugar level and foot-skin temperature. The interactive telemedicine consultations with a home health-nurse can be supported by a decision pathway running on the Android phone, assisting the management of diabetic foot ulcers.

More specific, the developed application includes a three-step system that a health worker can use during a tele-consultation of a diabetic foot patient. In the first step of the procedure the health worker enters patient ID in order to connect with the personal records of the patient (or to create one if the patient is not registered), runs the diagnostic algorithms, take pictures, review the photographs, validates the procedure and sends the data to the server (Fig. 1).

Fig. 1 Screenshots of the smart phone running the application

The server allows the specialized doctor to log-on and see the data, review the patient's information and images. Clicking on the procedure or on the patient's name, a new window opens, which displays all the information to be sent to the server. In particular, the doctor can display the pictures zoom in/out, vary the contrast and download the picture if further image analysis needs to be performed (Fig. 2).

Fig. 2 Image viewer of the back-end Electronic Medical Record system



After reviewing the information the doctor fills a form in order to give his/her feedback on the data that have been sent. As soon the review is completed, the doctor can send back his feedback to the phone so that the health worker can read through it. The platform can support both synchronous and non-synchronous operation.

Discussion

Telemedicine platforms can allow the treatment to be carried out by non-experts such as visiting nurses and general practitioners under the tele-guidance of specialized experts. These alternatives can reduce the high costs of out-patient treatment and the lack of specialized personnel in both developing and developed countries. Both synchronous and non-synchronous telemedicine platforms are available.

The past few years, innovative mobile information services that improve patient access to medical specialists for faster, high quality, and more cost effective diagnosis and intervention have been developed thanks to open-source and free to use platforms.

In order to develop Sana system, technological choices have been made. In particular choices such as using Smart phone and not simple cell phones, and the choice of Android for the Operating System (OS) and of the OpenMRS for patient's health record.

Smart phones run complete operating system (OS) that provide a platform for application developers. There is a number of different OS available. In particular the Android OS was released in 2008 and observed a growth of 615.1% between 2009 and 2010 [20]. This highlights the penetration of Android OS into the market and justifies its choice by Sana which aims to choose the future open source most widespread operating system in order to render its application available for the most people in the world currently. There are however alternative OS in the market able to support a similar m-health platforms. Interoperability of the telemedicine platforms is a major challenge for the market, and to this end the Continua Health Alliance has been established aiming towards interoperability of ehealth platforms. [21]

OpenMRS is an Open Medical Record System that was created in 2004 for developing countries and in order to provide them with an efficient information management system [18].

The tele-monitoring of diabetic foot, as many other telemedicine applications, is a challenging procedure but it has its limitations. In particular, it does not always guarantee accurate diagnosis or successful outcomes. For this reason the platform should be used and follow proposed clinical guidelines [22].

There is limited experience in the international literature on mobile systems used in diabetic foot tele-monitoring. A Danish qualitative study (13) indicated that that it is possible for specialized doctors in a hospital to conduct clinical examinations and decision making at a distance, in close cooperation with the visiting nurse and the patient, using a mobile phone. The study reported that that visiting nurse experienced increased confidence with the treatment of the foot ulcer while the patients expressed satisfaction and felt confidence with this new way of working.

At the moment , a large RCT study -Tele Ulcer project within the Renewing Health large scale RCT EU funded project [23], takes place in the Region of Southern Denmark, aiming to test the clinical, economic, organisational and patient-related consequences of home treatment of diabetic foot ulcers via tele-consultations. However the platform used does not involve a m-health platform supporting the study nurse with an diagnostic algorithm .

Conclusion

The proposed diabetic foot tele-monitoring platform has the potential to support a tele-consultation between specialized doctor and the health worker visiting the patient, enabling the clinicians to provide an alternative tele-care service. However, intense validation of the developed platform is required via a clinical trial to evaluate its clinical validity and cost-effectiveness.

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