Mindful Health Technologies: providing real-time chronic illness management tools for critical care teams

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***Abstract*—We present the development of a novel chronic illness patient management system for physicians, nurses and other critical care team members. This system combines automated transmissions from a cellular network based pulse oximeter and a web based dashboard application that can be viewed by authorized care team members. This management tool will help improve the communication between physicians and remote patients with chronic illnesses such as congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) while they are outside of the hospital. A first iteration prototype and web application were developed and tested showing 100% transmission success between the device and web application. A second iteration of both the oximeter device and web based dashboard application are currently underway in order to improve the form factor of the device and the robustness of the web application. Ultimately this monitoring system could reduce patient mortality, hospital readmissions and emergency room visits and therefore significantly decrease the costs associated with those events while improving patient quality of life.**

I. INTRODUCTION

Patients with chronic diseases such as high risk of congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) do not require continuous monitoring in a hospital, however, could greatly benefit from periodic oxygen saturation monitoring to determine their state of health. Effective monitoring is challenging in a home setting with current technologies due to range limitations of current devices and issues with patient compliance. There are currently many Bluetooth pulse oximeters on the market[1] that patients can use to take their own oxygen saturation reading and sync it to a base station within 33 feet[2] of the device such as their smart phone or personal computer. These readings are not automatically sent anywhere; they are simply stored on the user's base station. Similarly there are many Bluetooth personal wearable fitness devices on the market such as the Fitbit that can additionally sync the user's information from their smart phone to a cloud database where it can be accessed through the web. However, a clinical grade wearable biosensor system has yet to be developed. With healthcare costs on the rise and shifts in healthcare regulation, remote monitoring development and studies have been rapidly progressing[3]. In particular, the United Kingdom Department of Health began a study titled The Whole System Demonstrator Programme in 2008. They completed a 12 month randomized control trial of telehealth remote monitoring with CHF, COPD and diabetes patients. The study compared a group of patients using technology for remote monitoring to a control group whom only used standard health care practices. The overall goal of the study was to see if technology as a remote intervention made a difference in hospital readmissions among other things. The findings indicate that if this type of remote monitoring technology is used correctly, telehealth can deliver a 20% reduction in emergency admissions, a 14% reduction in elective admissions and a 14% reduction in bed days. Additionally they showed a 45% reduction in mortality rates with the use of telehealth monitoring. These results prove that constant communication between a physician and patient can drastically improve patient quality of life and in addition reduce costs associated with readmissions. The type of telehealth monitoring that this study employed was in fact extremely basic. The patients were asked to take a clinical reading at the same time each day and communicate that reading to the researchers. Symptom questions and educational messages were also sent to the patient. The readings and symptom data were then uploaded to a monitoring center where the information could be monitored and analyzed by health care professionals whom could contact the patients if needed[4]. This type of monitoring is not realistic in an uncontrolled environment since patients may choose not to comply with the requests and it would be very time consuming for care team members. We propose to use this same remote monitoring idea and incorporate the latest advances in technology to provide a pulse oximeter device that automatically takes and transmits oxygen saturation readings over the cellular network to one or more health care physicians simultaneously.

II. HARDWARE DESIGN

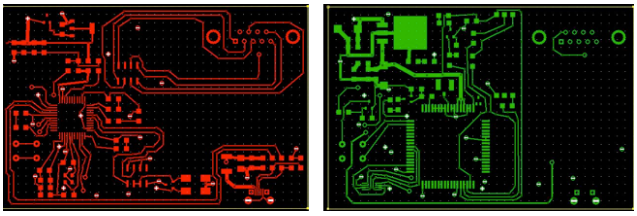

Fig. 1. Circuit board layout of POGO 2.0 designed using Eagle PCB design software.

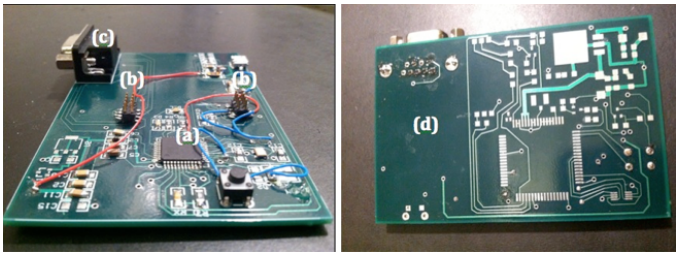

Fig. 2. POGO 2.0 populated with ATMega32U4 microcontroller (a), BCI board connectors (b), and BCI sensor DB9 connector (c). Seeedstudio GSM shield will be populated on the opposing side (d). This partially populated board runs like the currently used Arduino and BCI board but with a new USB interface.

Our pulse oximetry device, effectively termed POGO, is a wearable, hands-free, base station-free, fully automated device that measures SpO2 and heart rate data and sends it periodically via the GSM network to an encrypted online database. Our device allows the user to go about their everyday lives without having to remember to report their own measurements or stay within 30 feet of their Bluetooth enabled base station. While the patient is wearing our device, the critical care team receives real-time data that can be used to administer preventative care before potentially fatal exacerbations.

The first iteration of the circuit board has a mounting area for the Smith's Medical BCI Pulse Oximetry module, a wireless GSM transmission module, and an ATMega32U4 microcontroller. The base was developed using the open hardware EAGLE files from Seeedstudio (GSM module) and Arduino. A simple USB interface is included to debug and program the ATMega32U4. The POGO 2.0, our second iteration, represents the first step in the miniaturization stage for patient comfort/portability and power usage efficiency for battery life. The ATMega32U4 has now replaced the Arduino from the POGO 1.0 and hosts the pulse oximetery and GSM module. At 15-minute intervals, a TCP/IP connection is made with Xively (internet database) to upload the relevant physiological data retrieved from the pulse oximetry module.

Smith's Medical BCI quality engineers recently confirmed that the board we sent them to troubleshoot was damaged during our development, and suggested that the problem was our use of 5.0V logic with their 3.3V board. We are ordering a new board and implementing it with a digital logic level converter to avoid the same mistake.

III. Software Design

In order to effectively visualize data in a remote environment, a web based dashboard application will be incorporated into our overall system design. The application will be easily accessible by care team members and physicians from any authenticated client-side web browser. This application includes a real time alert system to provide notifications to care teams and physicians when monitored patient's data falls below pre-defined thresholds.

The Ruby on Rails framework has been selected as the back-end platform for development for our application to provide a stable server side implementation and handle HTTP requests from client interactions. This framework is used to create an authentication and authorization system to allow care team members to register for our application and access the patient's data.

In the browser, users interact with the application through a front-end framework called Bootstrap and associated HTML5, CSS, and JavaScript technologies. Once authenticated, care team members have access to the dashboard application as seen in figure 3. In this region, site wide statistics are displayed such as current active patients along with the number of patients above set thresholds and those who are below them.

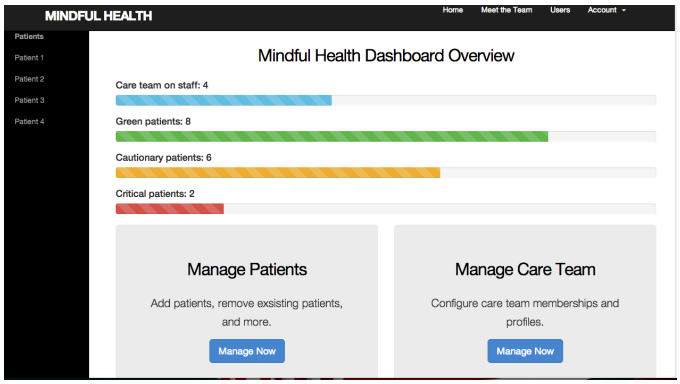

Figure 3. The main dashboard application used by care team members and physicians

Users can select individual patients, which will bring them to their profile. This area will display relevant graphs of data being stored in a remote database retrieved from the hardware.

IV. Hardware Prototype Testing

The prototype POGO 2.0 will be tested for SpO2 and heart rate concurrently with a Nonin Onyx II finger pulse oximeter while resting and also after running for 10 minutes. The POGO 2.0 measurements must be within 2.5% of the Nonin measurements across the entire test to accept them as equivalent. POGO 2.0 measurements will be taken at the Xively online database level to ensure that data fidelity is maintained while sending it from the device through the GSM network.

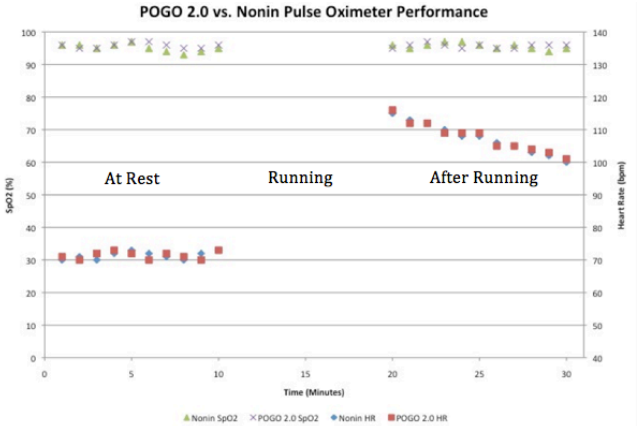

Figure 4. Sample chart of what data should look like during testing between Nonin and POGO 2.0 pulse oximeters. The first 10 minutes will be sampled

with the subject at rest and the last ten minutes will be after running for 10 minutes.

V. Software Testing

To ensure the accuracy of our software system, the test-driven development paradigm will be utilized in our implementation. This style of testing requires writing an automatic testing suite designed to initially fail. This forces the developer to design the system around failed tests originally and then write the code to make the tests pass, ensuring the testing suite dynamically updates and passes with each iteration. For these purposes, the testing frameworks RSpec and Cucumber will be used. These tools allow testing based on scenarios such as user authentication and authorization, existence of content, and accuracy of results in calculations. This will be used for unit testing purposes. Testing data integrity will also be important as patient information passes from the database to our front-end visualization. Finally, integration testing will be performed to ensure the entire workflow from the device to the browser is accurate and intact.

VI. Network Integration Testing

The networking processes that provide connectivity between the POGO2.0 and web based dashboard are critical for platform efficacy, and must be tested to ensure the consistent and reliable transfer of patient data. First, a control dataset, consisting of 60 measurements, will be simulated and provided to the POGO2.0 system. The device will then be set with a transmission cycle of one measurement per minute. Each transmission will be sent through the GSM network, into Xively networking middleware. An event driven, asynchronous background networking process within the web application stack will collect each measurement from the Xively API, and store it into the Web application database. The initial transmission timestamp and a timestamp identifying when each measurement was inserted into the database successfully will be recorded. Using these data, the mean device-to-database transmission speed will be calculated. Additionally, the measurements in the database will be analyzed versus the simulated measurements to indicate if any data was altered though the various parsing and data-interchange formatting. Finally a ‘data fidelity ratio’ will be calculated by dividing the number of correct measurements in the database by the number of points in the simulated dataset, giving an indication of how many measurements were lost or corrupted versus stored with total accuracy.

VII. Acceptance Testing

In order to determine whether our software performs the way real users, namely health care professionals, expect it to, acceptance testing will be assessed and analyzed. We will take a ‘black box’ approach by not providing the user with any functionality information for the software. We will interview a variety of professionals with varying titles and ages and ask them to perform a set of tasks that we believe are pertinent to the application. Tasks such as ‘perform a patient search’ or ‘find the most recent reading for patient 1’ may be asked. After the user performs the task they can then rate on a scale from 1-10 on how easy/ intuitive the solution was. These rankings can be collected, sorted and analyzed based on age, position in the hospital and the task performed. From there we can gain insight into what improvement need to be made on the user interface and the opinions of different populations of users.

VIII. Results & Discussion

While no results have been collected presently, the following discussion suggests the implications of specific test results on future work. The core Hardware, Software, and Network Integration test results are paramount, as the platform could not be deployed clinically given failure of any of these tests. High ratings are desired from User Validation testing are desired, however, the interface can be changed iteratively and utmost simplicity is not critical for effective application usage and performance. Passing or exceeding results for each respective test represent a platform containing an accurate, clinical-grade GSM pulse oximeter that consistently and reliably provides healthcare professionals with near real-time physiological data through easy-to-use web software. Future work would involve deploying this platform at one or more CHF clinics for a 6 to 12 month pilot study. This pilot study would require a participation of 5 to 15 randomly selected patients per clinic, with a control patient group of equal or larger size. The goal of said research would be to assess the impact of this platform on patient mortality rates, number of bed days, hospitalizations, and interventions, as well as patient and care team satisfaction. The outcome of this study would provide initial insight to the efficacy of the *pogo* platform versus the current methods of CHF patient management. The desired result would consist of a decrease in mortality rate, hospitalizations, and bed days, with an accompanying increase in early interventions, and patient and care team satisfaction.

IX. Conclusion

In effect, the *pogo* platform allows care teams and patients to be connected at all times, from nearly any US location, providing a sense of safety and security to patients and care teams alike. By enabling earlier detection of disease related exacerbations, quality of care can be improved as care teams deliver preventative treatments earlier in the symptomatic lifecycle, avoiding hospitalizations that would potentially occur if conditions grow in severity without treatment. Furthermore, it is anticipated that the combination of preventative treatments in non-hospital or emergency room settings and the potential reduction in hospital bouncebacks and bed days provide a significant reduction in the cost-of-care for these patient groups. If successful, the *pogo* platform could be brought to market to enable these benefits for patients across the US and globally. An important feature of the *pogo* platform is the potential for very large volumes of longitudinal patient data to be analyzed, allowing for a better understanding of the evolution CHF and COPD diseases over time. Using modern machine learning and neural network techniques, these insights could be applied and refined in the *pogo* platform for alert generation and prognosis prediction as

well. It is also important to note that the core wearable GSM and software technologies can be applied to better understand and manage a variety of other diseases, including wearable EEG for Epilepsy related disorders, connected Blood Glucometers for Diabetes, and many others.

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