Original Paper

A Platform to Record Patient Events During Wearable Physiological Monitoring

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Abstract

**Background:** Patient journals in clinical studies have been used as valuable resources in clinical studies. However, these journals are often underutilized, due to inefficiencies and ambiguities associated with handwritten patient reports. The increasing number of mobile phones and mobile-based healthcare approaches presents an opportunity to improve communications from patients to clinicians and clinical researchers through the use of digital patient journals.

**Objective:** The objective of this project was to develop an iPhone based platform that would enable patients to record events and symptoms while sensors simultaneously collect clinical data.

**Methods:** This platform consists of two major interfaces. an iPhone for patients to record their journals and wireless sensors for clinical data collection. The clinical data and patient records are exported to a clinical researcher interface, based on a Mac Pro desktop. The data and journal are then processed and combined into a single time-series graph for analysis.

**Results:** Body temperature data were obtained in a four hour span on a 22 year-old male, during which the subject simultaneously recorded relevant activities and events using the iPhone platform. After export to the clinical researcher’s desktop, the digital records and temperature data were processed and fused into a single time-series graph. The events were filtered based on specific keywords, allowing easy and prompt data analysis.
Conclusion: We have developed an inexpensive and user-friendly patient journal platform for use in clinical studies that gives clinicians and researchers a simple method to track and analyze patient activities and events in conjunction with clinical data.

Keywords: telemedicine; mHealth; mobile health; data collection; smart phone

Introduction
There have been an increasing number of telehealth and mobile device healthcare management approaches based on the emerging field of patient-centered outcomes, which focuses on medical outcomes related to physiological metrics, as well as metrics important to patients, such as quality-of-life. For example, these modern care management approaches have used an electronic health record system as a child physical abuse alert system.[1] Additionally, care management has been implemented with information technology to improve asthma outcomes in adult populations, and mobile applications have been used to encourage compliance with oral chemotherapy and symptom management.[2,3] It has been reported by the Institute of Medicine that improvements in communication between patients and clinicians are needed to reduce health inequalities, and these improvements have started to become focused on telehealth and mobile devices, such as their use in sleep medicine.[4,5] One possibility to bridge the gap in communication between patients and clinicians is through the use of mobile-based digital records that function as journals for patients to record their events and activities securely and remotely. These have potential uses in clinical research, as well as in clinical practice.
Currently, patient-recorded events are typically incomplete or used inefficiently, due to ambiguity about what should be reported, absence of standard vocabulary to describe the events, the inconvenience of reporting events at the times they occur, inaccurate timing, difficulties with reading patients' handwriting, and fusing the records with clinical physiological data.

Such journals are often handwritten. In a previous study, researchers monitored skin temperature to identify circadian rhythms, and patients were instructed to keep a diary of their daily activities, such as showering, eating, and medication intake; but, even though the patient journals included major events such times of awakening, meal times, and medication doses and times of intake, the journals lacked smaller events that may have been important to the study, such as heating/cooling of the room, body position changes, and entering and exiting the room. There were also minimal options to quantify the patient events.[6,7] Additionally, although there are current options for health and symptom-logging applications on the iPhone, these applications lack the ability to use voice dictation for hands-free recording, pre-set graphical images for ESL or nonliterate patients, data export and integration with physiology, or data analysis features.[8–10]

We propose to simplify patient reporting by using iMessage on a dedicated iPhone and to fuse clinical data with patient-reported data for analysis. We hypothesize that the iPhone's ability to collect physiological data wirelessly and to have multiple options to record patient events would allow for more accurate characterization of clinically valuable events during long-term monitoring in research.
Our objective was to design an iPhone-based platform capable of semi-automatically recording reportable events while simultaneously and wirelessly collecting clinical data and then fusing the data into one graph for data analysis, such as identifying statistically important clinical events. Continuous temperature monitoring with skin temperature patches has been performed by several research groups\[6,11\], focusing on using wearable electronics or cell phones. Our specific goal was to customize iMessage software in order to combine skin temperature data with patient reports.

Methods

Concept and Block Diagram
The concept of using a secure iPhone, along with its various capabilities in iMessage, was implemented for clinical research purposes, as seen in Figure 1.
Figure 1. Block diagram depicting fusion of physiological data and patient reportable events data into one time-series graph. The Patient Interface consists of body sensors (for example EKG, temperature, etc.) and a dedicated iPhone wirelessly connected via Bluetooth with the sensors and their respective applications. The iPhone capability includes the built-in iMessage application, which allows:

- Simple Texting
- Texting with Replacements of Abbreviations, which can be used to implement a pre-set vocabulary for specific clinical research
- Dictation (voice recognition)
- Graphical Stickers, which are pre-set graphical images/icons designed for specific clinical research, for example, monitoring of heart fibrillation with EKG, circadian temperature changes, pain scores in time and location, etc.
- Photo Images collected by the patient

The Clinical Researcher Interface consists of a Mac Pro desktop (2013, Apple Inc.), a lightning cable to export reportable events, and a portable flash drive (c20i JumpDrive, Lexar) to export physiological data from applications. The desktop software includes iMazing (2.5.3, DigiDNA) to export reportable events to an Excel (15.34, Microsoft) format and MATLAB (R2017a, Mathworks).

Firstly, a dedicated iPhone will be given to each patient. Patients will then text, dictate, use graphical stickers, or collect photo images in iMessage to report events pre-approved by clinicians. Physiological sensors will be placed on the patients’ bodies. Applications will be activated, and patients may then go to their room or possibly home. Duration of monitoring is dependent on acquisition frequency and the battery capacity of the iPhone and sensors. Secondly, at the end of the monitoring period, patients will send the iPhone back to the clinical facility where the clinical researcher will download the reportable events by connecting the iPhone and Apple desktop via the lightning cable, and after that the researcher will export physiological data via a portable flash drive. Thirdly, data will be reformatted on the desktop through Excel, which allows them to be readable by a MATLAB script. Finally, the MATLAB script will generate a graph that fuses the physiological data and reportable events, allowing visualization of physiological changes and subsequent reportable events on the same time-scale. These data can be filtered based on specific reportable events, duration of the events, and any other clinical research criteria.
Hardware
For the Patient Interface, we used an iPhone (version 6, Apple Inc.), though more recent versions would work as well, and a HomePod (2017 version, Apple Inc.), which acts as a microphone for patients to use Siri dictation. For temperature monitoring demonstration purposes, we used the Temp Pal skin temperature sensor (model STP-MB01-1, iWEECARE Co.).[12] On the Clinical Researcher Interface, we used a Mac Pro (2013, Apple Inc.), a lightning-to-USB cable (Apple Inc.), and a portable flash drive (model c20i JumpDrive, Lexar Inc.).

We implemented the temperature acquisition process using wearable skin temperature patches connected via Bluetooth to an iPhone, which allowed us to also create patient reports and fuse them with physiological data on a dedicated iPhone device.

Software
There are several iPhone capabilities that we used to create the reports. Firstly, with Apple’s intelligent personal assistant, Siri, it is possible to use voice recognition so that patients will be able to dictate their records verbally. Furthermore, Siri can be used in a hands-free manner by speaking the keywords “Hey Siri.” Next, with Apple’s instant messaging service, iMessage, patients can securely create time-stamped logs of their events and activities. iMessage has the capability of using both texting and voice dictation. With both methods, patients send themselves a text message containing what they wish to record, and the text message serves as a digital log of their activities and events. Thirdly, iPhones come with a text replacement feature for typing, whereby users can set keywords or letters that will then autocomplete to form predefined words,
phrases, or sentences. This will allow patients to easily and accurately type their records with fewer keystrokes and fewer typing mistakes or misspellings, while also avoiding slightly different written versions of the same event. This will also give patients a standardized dictionary for specific keywords and events. Finally, iMessage has the ability to use “stickers” in addition to text, so patients can generate messages visually and quickly from a standardized dictionary pre-set by the clinical researchers. Using the iPhone application Assembly (version 1.5.7, Pixite LLC), we have a set of twenty stickers that patients can choose from to use in their journals (Figure 2).[13] Assembly also allows for creation and customization of stickers.
Along with iMessage, we used the *TempPal* application (version 1.5.1, iWEECARE Co.) to record skin temperature simultaneously with the reportable events. Finally, we used the *MobileManager* app (1.2.0, Lexar Inc.) on the iPhone to transfer temperature data from the iPhone to the Mac.

On the Mac, we used the third-party application *iMazing* (version 2.5.3, DigiDNA Sàrl Inc.) to export iMessage texts into a .csv format.[14] *iMazing* is a simple and user-friendly back-up and transfer/export application for the iPhone. We used *Excel* (version 15.34, Microsoft Corp.) to reformat the temperature data and reportable events data.

Finally, using MATLAB (version R2017a, MathWorks Inc.), we created a simple script to extract data from both files and fuse the temperature data with patient-recorded events into one single graph. If patients used stickers in their journals, the stickers are converted to text in the script as well. See Multimedia Appendix 1 for a more in-depth operating procedure.

**Results**

A healthy 22 year-old male used the pipeline to record his body temperature and activities and events over a four hour session. The data were processed on a Mac Pro desktop and combined into a single time-series graph, an example of which is shown in Figure 3.
Figure 3. Temperature data taken for four hours using a TempPal temperature sensor. The sensor was placed on the right-chest of a healthy 22 year-old male. The patient logged activities and events using iMessage text-typing and Siri. Below the time axis is the dictation axis, which shows the patient-recorded notes at each corresponding time point. The words “END” denote that the prior event/activity has been completed.

The journal was filtered using the keywords “eating” and “outside”, resulting in a time-series graph (Figure 4) highlighting the times at which the subject logged any activities with the words “eating” or “outside.”
Figure 4. Filtering of the patient journal using two keywords: "eating" and "outside". The words "END" denote that the prior event/activity has been completed. Blue vertical lines denote the points when the patient is drinking water, and red lines denote the points when the patient is eating lunch. The blue line shows a temperature decrease as the patient walks outside.

Using the filtered time series graph, we can easily see that when the subject moved outside, his body temperature decreased, and when he began eating, his body temperature began to increase.

Discussion

Principal Results

Our approach is effective, inexpensive, and efficient, and it fits in well with the changing paradigm of patient-centered outcomes and telehealth. Additionally, because many patients are already familiar with iPhones, iMessage, and text messaging, our approach is user-friendly. Patients have the option to use texting with replacement and stickers or voice dictation. This makes our methods versatile for a wide variety of clinical studies and for patients from varying backgrounds, including ESL and nonliterate patients.
Furthermore, iMessage is extremely secure using end-to-end encryption, so only patients and researchers will have access the logs. We are also capable of combining the patient journals and physiological data into one graph and filtering the journals with specific keywords allowing for ease of use during data analysis.

Our methods may also be applied to the field of predictive medicine, which aims to identify patients who are at risk of disease and taking steps to treat the disease early or prevent the disease entirely. In order to predict diseases, there is a need for accurate patient-recorded events fused with physiological data. Although we chose to focus on temperature monitoring, our mobile-based platform is universal for several diseases. For example, patients who undergo cardiac monitoring will often do so remotely using wearable devices and iPhones that either send the data to a dedicated data center staffed by cardiographic technicians, or the devices will contain automated detection algorithms themselves.[15,16] Because our platform is already mobile, switching to cardiac monitoring from temperature monitoring would just involve switching the temperature sensors to EKG sensors. Unlike traditional cardiac monitoring sessions, however, our platform does not use a handwritten diary.[17]

Limitations
There are some drawbacks to our methods. Firstly, although iMessage is very secure with end-to-end encryption, and iPhones and iOS are highly secure systems as well, the use of electronically reported patient records presents a greater and potentially more expensive data security challenge than paper records.[18] In addition, our methods rely
on having a connection to either Wi-Fi or cellular-data networks, which may be difficult depending on the location and room the study is taking place in.

Comparison with Prior Work

The *Diary Health App* (version 2.4.8, The Diary Corp.) allows for voice dictation and text options for patient-recorded events, and the app has some integration with basic physiological measures, such as heart rate and body temperature; however, the application does not allow for fusion of the patient-recorded events and physiological data. Furthermore, there are no options for pre-set graphical Sticker images or photos in the patient journal, which reduces the effectiveness and user-friendliness of this application.[8]

The *Symple App* (version 2.1.9, Symple Health Inc.) allows for text options for patient-recorded events; however, there is no integration with physiological data, and there are no options for pre-set Stickers or photos.[9]

The *Penzu Health Diary* (version 3.4.2, Penzu Inc.) app allows for text and photo images for the patient-recorded events; however, there are no options for pre-set Stickers, voice dictation, or integration with physiological data.[10]

These applications also do not contain any data analysis or graph-generating features.

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<th>Journal Options</th>
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Table 1. Features of current approaches to monitor patient-recorded events. None of the approaches allows patients to use graphical Stickers, and two of the options do not allow voice dictation. Only one of the approaches allows for photo images in the
Conclusion
By taking advantage of iPhone’s capabilities and third-party programs, we have developed a simple and effective pipeline to create secure patient logs for clinical studies and to combine the logs with physiological data into one graph for data analysis. Future work under this project may focus on reading iMessages on the Mac, directly from the iMessage database. This would remove the need to physically move the iPhone back to the medical facility for data transfer, though the iPhone and Mac would need to have the same dedicated iCloud account. Another possible solution for remote data transfer is to read iMessages from iCloud backups of the iPhone every night, which would require software to read iCloud backups from the Internet. Finally, a more ambitious goal may be to build a custom app and not use iMessage at all. This would allow researchers to have more control over the data format and input, for example allowing for only certain pre-set inputs rather than free-form texting. It would also allow for improved data management by having the data sent to a secure server or stored remotely via CloudKit. Furthermore, the app could run on the Apple watch, so that the data could be shared with family members and other members of the health care and research team. This would also give patients the ability to use their own iPhone and remove the need for a special, dedicated iPhone. Additionally, the custom app would be able to include other iPhone features, such as the TrueDepth camera on the iPhone X which performs facial recognition. This can be developed with Apple’s publicly available face detection and recognition application program interface and could be used as part of a pain scale for patients.
Disclaimer: The NIH and its staff do no recommend or endorse any company, product, or service.

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Conflicts of Interest
None declared.

Abbreviations
EKG: Electrocardiogram
ESL: English as a second language
References


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