Postpartum Monitoring App

BME 200/300

Wednesday, December 13, 2017 Client: Dr. Kara Hoppe (DO) affiliated with UnityPoint Health-Meriter Department of Obstetrics and Gynecology Advisor: Professor Willis J. Tompkins Department of Biomedical Engineering

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Abstract

Hypertension is the leading cause of maternal death postpartum. Primarily, hypertension is categorized as high blood pressure, but after prolonged periods of elevated pressure, several more severe symptoms can arise. If a diagnosis is delayed for an extended period of time, there is an increased risk of stroke and heart attack. Dr. Kara Hoppe (DO-OB GYN), who specializes in high risk pregnancies at UnityPoint Health-Meriter Hospital Madison, Wisconsin, is working on a program to reduce hospital readmission for new mothers with hypertensive disorders. Currently, Dr. Hoppe uses a package put together by Honeywell to monitor patients' blood pressure, heart rate, weight and oxygen levels remotely. Her initial work has reduced hypertensive specific hospital readmission to almost zero. However, the Honeywell system received subpar reviews from the nurses, doctors and patients in terms of user-friendliness. Dr. Hoppe approached our team to create a mobile application that would include bluetooth data upload, cloud data transfer to Meriter hospital, and increase user friendliness so she could continue her work with a new package better suited for her staff and patients' needs. Our team has successfully created a proof-of-concept app that works on Android devices. While this does not have bluetooth functionality or cloud data transfer, the proof-of-concept app proves that Dr. Hoppe's ideal app is feasible and can help direct future work on the final app's design. Once the initial features are implemented in a iOS app, more features can be added to increase ease of use and communication between practitioners and patients.

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I. Introduction

Preeclampsia contributes 9% - 26% of global maternal mortality, and 32% - 44% of preeclampsia occurs postpartum. The onset of preeclampsia can occur anywhere from 48 hours to six weeks after giving birth [1]. Thus, a postpartum hypertension monitoring app is indispensable when it comes to reducing the amount of hospital readmissions for new mothers. Consistent monitoring for the first six weeks postpartum allows for patients and physicians to see regular measurements of key vital signs commonly used to diagnose hypertension. Current monitoring apps on the market focus primarily on tracking blood pressure over a long period of time for personal use, and appeal more to those suffering with chronic hypertension. These apps also lack the physician-to-patient interaction and HIPAA-compliant data transfer that would decrease the need for traditional postpartum hospital visits. New mothers, who are monitored over a limited period of time, would benefit more from utilizing an app specifically designed for them [2].

This semester, our team of five BME students designed a working proof-of-concept app that will guide future work, specifically an iOS based app that will meet the design specifications set by our client. Ideally, the end product will decrease or eliminate patient readmission postpartum due to hypertensive disorders. The app will provide a medium for physician-patient interaction, patient monitoring and video conference with healthcare specialists.

II. Background

For a patient to be considered hypertensive (postpartum or otherwise), their blood pressure must be over 140 mmHg systolic and/or over 80 mmHg diastolic on two or more occasions more than four hours apart [3]. Preeclampsia is characterized by hypertension and signs of organ damage, such as protein in the urine indicating impaired kidneys [4]. While the causes of postpartum preeclampsia are not widely understood, healthcare providers believe that its onset starts at delivery, even though symptoms aren't evident immediately [5]. Symptoms can develop as early as 48 hours or as late as six weeks after giving birth, thus increasing the importance of postpartum check-ups and home monitoring. It is also important to recognize that while anyone can become hypertensive, there are warning signs that postpartum hypertension may occur in a given patient. These include, but are not limited to: high blood pressure after 20 weeks of pregnancy, obesity, a family history of high blood pressure, age under 20 or over 40, or multiple pregnancies (twins/triplets). Women who have any of these warning signs are at an increased risk of developing postpartum hypertension and can especially benefit from home monitoring [6]. If left untreated, hypertension and preeclampsia could increase one's risk for aneurysm, stroke, coronary artery disease, heart failure, and dementia [7].



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For the discussion of Apple iOS vs Android, research we conducted showed that a slight majority of smartphone users have devices that run an Android operating system. This majority is rather small; however, as of June 2017, 53.3% of smartphone users' have an Android device while 44.9% have an iPhone [8]. Figure 1 represents the usage statistics of Android vs Apple. While they're close, Apple appears to be rising much more quickly, indicating that it may surpass Android in coming years. Another survey conducted by Comscore recorded the number of users who have an Apple, Android, or another brand of smartphone in the US (not just those who bought one in the past few months). This study showed Android with 52.3% and Apple with 37.8% as of January 2013, a larger margin reported compared to other surveys conducted [9].

Due to the relatively limited knowledge that the team had about Bluetooth functionality, we conducted more research in order to figure out how to connect to the Welch Allyn bloodpressure cuff. We found that there are two main types of Bluetooth— Basic Rate/Enhanced Data Rate (BR/EDR) and Low Energy (LE). BR/EDR allows for continuous connection of two devices, and thus, is not the type we focused on for our project as we only needed temporary connections to transfer data. LE Bluetooth connectivity allows for short bursts of connectivity and can connect one device to another (point-to-point or 1:1 connectivity), one device to many (broadcast or 1:m connectivity), or many devices to many other devices (mesh or m:m connectivity) [10]. For security reasons, we ensured that our connection was 1:1 so that our patient's data was transmitted only to the device with our app, not to any devices in the area. Information was also gathered pertaining to the physical mechanisms by which the data is transferred via Bluetooth. It was in this research that we learned that Bluetooth devices are always transmitting data, they just constantly switch the frequency of transmission randomly within a set range (2.402 GHz - 2.480 GHz). When the devices "pair," they both go to the same set frequency and then randomly change their frequency in tandem so that they are always transmitting on the same frequencies to allow sharing of their data [11].

Our client, who proposed the project to the BME design course, is Dr. Kara Hoppe, an American Board certified obstetrician and gynecologist. She attended medical school at Midwestern University in Downers Grove, IL and now currently works at UnityPoint Health-Meriter Hospital (Meriter) in Madison, WI, specializing in high risk pregnancies, hypertensive disorders, and complex maternal medical conditions [12].

Meriter currently has a home-tracking postpartum monitoring program through Honeywell and despite its mostly positive rating (54% for extreme satisfaction [13]), some improvements are still needed. For instance, the program currently has patients manually type blood pressure and heart rate into the app. This is inconvenient and allows for potential user error. The interface was also rated moderate in difficulty and low for autonomy by the 54 patients who completed the survey. Furthermore, the nurses found manually entering vitals data (heart rate and blood pressure) to be tedious and time consuming and would prefer the data to automatically upload into the hospital's Epic database.

III. Preliminary Designs





Preliminary designs were developed early in the semester for a welcome page, vital measurement page, and login page as seen in Figure 2. The app also includes buttons to access hospital information, required vital measurements (blood pressure, heart rate, weight, etc), progress reports, data export, video conference setup, and postpartum hypertension information.

The vital measurement page includes a "connect" button to connect user's phone to his or her monitoring device via bluetooth and a "start" button to begin the measurements. Besides the two buttons, the screen includes a timer to record how long the measurement has taken and the numerical values of the measurement, such as the sample blood pressure (120/80) shown in our sketch above. If the user's blood pressure, for instance, is much higher than the standard or recommended threshold, the numbers

shown on the screen turn red; if the user's blood pressure is around the threshold, the numbers turn yellow as a sign of warning; unsurprisingly, the numbers show green if the user has a normal and healthy blood pressure.

As for the login page, it follows the traditional format of a login page, which includes places to enter ID and password and a link to contact the hospital in case of forgotten credentials.



Figure 3: Software flow diagram showing screen interactions and navigation flow

The software flow diagram (Figure 3) shows interactions between screens and how the user can navigate within the app. The main menu is central to the app and allows access to all other screens. This is to address a common patient complaint by making the app more user-friendly and allowing for complete freedom of navigation within the app. All of the measurement screens are accessed independently and in any order, which was also desired by patients.



Figure 4: Hardware block diagram showing ideal interactions between the iOS app, Bluetooth monitoring equipment, and databases.

The blood pressure cuff takes measurements of blood pressure and heart rate and will send this data to our app on the patient's mobile device via Bluetooth, as shown in the hardware block diagram above (Figure 4). The app then sends the patient data to the patient vitals database associated with Meriter and exchanges information with the healthcare provider (Meriter) for the video conferences between patients and physicians/nurses.

The preliminary design ideas above were used to create a skeleton iOS app in XCode. The software flow diagram was referenced in implementing app navigation. The team was successful in finishing the storyboard so that the screens interact correctly and the user can navigate between them (Figure 5). Additionally, the team completed preliminary code on the Viewcontroller for connecting to Bluetooth devices (Appendix IX), but was unsuccessful in connecting to the Welch Allyn cuff we received from Dr. Hoppe. The code included a method to randomly generate a UUID (universally unique identifier). UUIDs are used to allow devices to distinguish themselves from one another.



Figure 5: The XCode Storyboard implements navigation between screens within the app.

IV. Preliminary Design Evaluation

Due to the lack of traditional design and fabrication required in software development, the team created an extensive matrix of possible features and a rigorous evaluation criteria to narrow down the features to a manageable number. After initial decisions, the remaining features were evaluated in a design matrix to determine which features the team will try to complete this semester. Spaces marked with "N/A" did not factor into the design's overall score, rather, the score was given as the overall percentage of possible points accumulated.

Criteria	Bluetooth Data Entry	Cloud Export to Hospital	Video Conferencing	Hospital Information	Export to Epic Database	Manual Override
HIPAA Compliance (20)	(5/5) 20	(3/5) 12	(4/5) 16	N/A	(3/5) 12	(5/5) 20
Accuracy/Precision (20)	(5/5) 20	(5/5) 20	N/A	N/A	(5/5) 20	N/A
User Friendliness (20)	(5/5) 20	(5/5) 20	(5/5) 20	(5/5) 20	(5/5) 20	(5/5) 20
Data Entry to App (10)	(5/5) 10	(3/5) 6	N/A	N/A	N/A	N/A
Data Entry to Hospital (10)	(3/5) 6	(5/5) 10	N/A	N/A	N/A	N/A
Feasibility (15)	(5/5) 15	(3/5) 9	(3/5) 9	(5/5) 15	(1/5) 3	(5/5) 15
Safety (3)	(5/5) 3	(5/5) 3	(5/5) 3	(5/5) 3	(5/5) 3	(2/5) 1.2
Cost(2)	(5/5) 2	(5/5) 2	(5/5) 2	(5/5) 2	(4/5) 1.6	(5/5) 2
Total	96	82	83	100	75	97

Table 1: Design Matrix of features proposed by Dr. Hoppe and thought of by team members. The three designed with the total score highlighted in green and the one in yellow are the team's focus this semester.

Design Criteria:

HIPAA Compliance - Designs are evaluated on their ability to protect private patient information such as name, address, illness, etc. Those that scored highly in this category show little to no risk of revealing private patient information.

Accuracy and precision - Designs are evaluated based on their ability to correctly transfer information from one medium to the next. This could be from the monitor to the app, the app to the hospital, etc. Those that scored highly in this category will transfer the exact number from the beginning medium to the next.

User Friendliness - Designs are evaluated based on how easily the user will be able to navigate the feature while using the app. Those that scored highly in this category will require little to no explanation after the first use.

Data Entry (Monitor to App) - Designs are evaluated based on how well they read in information from the measuring monitor to the app. Those that score highly in this category will pair with and transfer to the app easily while inputting the correct information.

Data Entry (App to hospital) - Designs are evaluated based on how well they transfer readings that are already in the app to the hospital database. Those that score well in this category will quickly, accurately and precisely upload the data to the hospital database.

Feasibility - Designs are evaluated based on how easily they can be completed this semester. Both time and skill are considered here. If the team doesn't possess the ability to complete a certain feature it was not considered as highly as those that can be implemented. Those that scored highly in this category are completable in the time frame given and do not require software development skills beyond the ability of the team. Data export to Epic databases will not be the team's focus this semester as it would require time and collaboration with Epic that the team does not have this semester.

Safety - Due to the low injury risk associated with using a mobile app, all designs, except for one, achieved the same score. Manual Override scored a lower for safety because of the risk associated with the ability of a patient to use this app in a manner that is not recommended by physicians.

Cost - Due to the low cost associated with software development, all categories, except of data export to Epic, scored the same. The main cost for this entire project is the licensing fee to distribute the application.

Proposed Final Design:

The proposed final design is a proof-of-concept app developed for Android devices. This app does not implement some of the desired features, such as HIPAA-compliance and Bluetooth data transfer, but it does demonstrate that a user-friendly, hypertension-monitoring app with complete freedom of navigation is feasible. Moreover, an experienced Swift programmer can quickly and easily take our XCode skeleton and use it in conjunction with the proof-of-concept as an implementation guide to develop the final iOS product.

The proof-of-concept app implements many of Dr. Hoppe's initial desired features, including storage of vital measurements and tracking progress of these measurements over time. While an ideal app would use Bluetooth capabilities to receive blood pressure, heart rate, and weight measurements directly from a Bluetooth-enabled scale and blood pressure cuff, the group didn't have time to implement that functionality. Rather, our final product uses manual entry to store measurements in a database on the phone. In the case of blood pressure, after the measurement is submitted, it is printed in either red, yellow, or green, which correspond to very unhealthy, borderline unhealthy, and healthy measurements respectively. These color thresholds can be adjusted for each patient if necessary, allowing for customization based on individual patient needs. To store data, each measurement has a unique tag with the username, date, and type of measurement (blood pressure, heart rate, or weight) that allows it to be accessed from the database. The username as part of the tag allows multiple users to use the app on the same device, and still track their individual progress.

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4	5	6	Done	4	5	6	Done	4	5	6	Done
7	8	9		7	8	9		7	8	9	
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Figures (6, 7, 8): Screenshots of screens used to take measurements. These screens implement manual entry into a database to store health data within the app.

The Track Progress screen used statistical analysis to allow users to assess how their health has progressed throughout the monitoring period. The user can use a toggle to select a measurement to track - either blood pressure, weight, or heart rate - and the current date. The app will then calculate and display the most recent measurement taken, and averages over the last week and last month.



Figures (9, 10, 11): Screenshots of the Track Progress screen being used to assess (left to right) blood pressure, weight.

On the export data screen, users can send the data from their devices to an online database. This transfers all of the health data from the database within the app into an online database that can be accessed independently of the device used to take the measurements. This online database, however, is not HIPAA-compliant and therefore couldn't be used with actual patients' protected health information. Therefore all data submitted and exported in the proof-of-concept app was generated for functionality testing purposes only. After pressing the start import button, "Upload successful" will print on the screen if export completes without any errors.



Figure 12: Screenshot of the export data screen used to upload data from the database on the device to an online database

The proof-of-concept app follows the same software flow that an ideal final iOS app would (Fgure 3). The home screen is central to navigation within the app, and is reachable from every screen. This diagram also depicts how measurements are taken independently of each other rather than all at once in a specified order. This addresses one of the common patient complaints with the currently system - a lack of freedom within the app.

G Home	🔊 🛠 🔋 🕬 📶 12% 🗎 9:31 PM
	Welcome to PPM!
	Take BP Take HR
	Take Weight Track Progress
00:12	Export Data Video Conference
	Logout
	Decorded by Decore
	Recorded by Webser

Figure 13: The home screen in the Android app implements the software flow diagram and allows for complete freedom of navigation within the app

V. App Development Process

Materials:

In order to develop an iOS blood pressure monitoring app, XCode - a software development environment to create applications for iOS devices - was installed each team member's Mac computers (Appendix II). XCode allows for all stages of app development from the beginning the screen layout through the intricacies of the coding process. iOS software licenses are necessary to distribute the finished product. A bluetooth-enabled blood pressure cuff by Welch Allyn was used to wirelessly take patient vitals (Appendix III). The code is listed in Appendix XI and the storyboard is in Appendix XII.

After realizing a functional iOS app couldn't feasibly be accomplished within the semester, an Android proof-of-concept app was developed using AppInventor - an online Android app development interface developed by the Massachusetts Institute for Technology. While App Inventor couldn't be used to build a HIPAA-compliant app, the group had much more experience with it and was able to produce a working app to present. This working app could also be used as an implementation guide for future work.

Testing:

After a working prototype of the app is developed, testing will be conducted to check data transfer speed. This can be done by opening the app on a cell phone and opening the vitals database on a computer, and manually timing how long it takes for new vital information to be transferred. Data transfer speed is important to keep physician databases up to date, as well as to allow timely communication and action with healthcare providers in the case of unhealthy vital measurements.

A survey will be conducted of postpartum women who used the app. This survey will allow patients to rate the app on various features and user-friendliness. The feedback from the survey will provide practical, meaningful data on the usability of the app. From there, to determine how well this rendition of the app compares to the current system, the survey data will be examined for future improvements.

If time permits, the app will undergo field testing with new mothers after hospital discharge and the readmission. The team will analyze readmission rate and compare it to typical postpartum hospital readmission, which is about 2%. Ultimately, this is the best barometer to determine the effectiveness of the final product and how well it solves the overall goal of reducing postpartum hospital readmission.

VI. Results

The bluetooth and cloud data transport features were not established, thus we were unable to test the data transfer speed, both from the device to the app and from the app to the hospital database. The current method employs manual data entry, causing the data transfer speed to be completely user dependent. Additionally, due to the time it took to create a working prototype, the team was unable to survey patients on the effectiveness and user friendliness of the application. The outcomes of the project are furthered discussed in both sections VII (Discussion) and VIII (Conclusions).

VII. Discussion

Ethically, the biggest concern in developing and testing a postpartum hypertension monitoring app is ensuring HIPAA compliance to protect patient vital information. Because our current iteration does not possess HIPAA compliant data transfer, it cannot realistically be implemented at Meriter hospital. Securing patients' personal information is the most important task of this application. Outside of the concern for secure data transfer, as the app is digital, it doesn't present unique safety concerns to users.

Though the initial application design in Xcode never came to fruition, our final product is a working proof of concept of many of the original ideas. Despite the group's relatively extensive collective coding background, designing the app in Xcode and learning swift simultaneously proved to be too difficult of a challenge to accomplish in one semester. Complex ideas on Xcode such as bluetooth connectivity and database creation were difficult to code, while creating screen interaction was quickly figured out. After several attempts to connect via bluetooth to the Welch Allyn blood pressure cuff were unsuccessful, our focus was turned to creating a product that worked by the end of the semester. Thus, we created an Android application with manual data entry in order to provide Dr. Hoppe with a working product that would achieve many of her goals.

Moreover, the sudden turn from iOS development to an android system may seem curious, but as our background research show, there is about a 50/50 split of the market between android phones and iPhones. So, switching to android doesn't limit our target audience; if anything, it increases our audience.

VIII. Conclusions

The team designed a proof-of-concept app that runs successfully on android devices. Users are able to record blood pressure, heart rate and body weight through manual entry. Unlike the current program by Honeywell, users are able to navigate the home screen and choose which vitals they want take and when. This allows for a higher level of user autonomy and was one of the original modifications Dr. Hoppe requested. Currently, our proof-of-concept app does not have bluetooth functionality but this feature could be implemented at a future date. See section IX (Future work) for more details. While this map is not intended to act as the finished product, it will help guide the development of the final design. Along with the proof-of-concept map, the team has developed an X-Code skeleton which can be used in developing the final iOS based app. The skeleton includes a screen layout (storyboard), screen connections, and the preliminary Viewcontroller to start Bluetooth connection. Though the team has not conducted formal tests or spoken with Dr. Hoppe's patients, several tests were conducted using the information of fellow team members. Most of these tests consisted of team members manually entering data to test various functionality (ex: entering BP at various levels to test the output text color change) and to ensure that users could freely move between the various screens.

IX. Future Work

The most central goal is ensuring HIPAA compliance. Ideally, this could be accomplished using this semester's XCode skeleton in conjunction with the Android proof-of-concept to develop a fully functional iOS app. Right now, the app has the basic essential features down - manual data entry for blood pressure, weight, and heart rate. From there, the data is stored on the device until it is exported. The next steps include establishing bluetooth data transfer, video conferencing and cloud export to the hospital database. These features are essential as they are the basic features Dr. Hoppe requested and the current Honeywell system employs all these features. Once the iOS app is fully operational, the team will conduct a short survey of Dr. Hoppe's patients to see if they prefer the new application and improvements that should be made. Additionally, the implementation of push notifications is an easy way to remind patients when to take their vitals, and will help the patients better communicate with the hospital staff. For the long-term success of the application and overall wellness of the patients, there are several other features to implement outside of those that are necessary for the app to function. Primarily, this includes a short questionnaire that patients complete everyday to assess overall health. This provides the physicians a way to monitor the ever-discrete symptoms that go along with hypertension (nausea, headache, fatigue). Aside from compiling more patient information, interface customization is another long-term goal of this project. The ability to do small things such as change backgrounds make the app more familiar and appealing to use over the six-week monitoring period.

Ideally, Meriter hospital will be able to aid in the process of incorporating Fuze and Epic into the application. Fuze is a video chat method that the hospital currently employs for protected connection between patients and healthcare providers. The incorporation of Fuze in the app allows for secure communication without needing a separate app. Meriter hospital uses Epic databases to store information. If the app sends the data straight to Epic, it eliminates the need for the nurses to manually enter the information. The time saved can be used to take care of other patients, or simply to have a break during the day.

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Appendices

Appendix I: Preliminary Design Specifications

BME 200/300 Design Remote Patient Postpartum Monitoring App Fall 2017 Alex Zoellick, Aleysha Becker, Jacky Tian, Rachel Minehan, Lucas Ratajczyk Preliminary Design Specifications

Function:

The device will consist of a mobile app in conjunction with a bluetooth-enabled blood pressure cuff and heart rate monitor to measure outpatient vitals and transfer those readings to a nurse database. Ideally, this will decrease or eliminate patient readmission postpartum, especially relating to hypertension. The app will provide a medium for physician-patient interaction, patient monitoring and video conference with healthcare specialists (nurses, doctors, etc.).

Client requirements:

- The application will be bluetooth enabled.
- The application will automatically read in monitor values without internet connection.
 Data could possibly be uploaded to Epic databases.
- The application will connect to the internet to allow for other features with the primary concern being data sharing.
- The application will sync with the A&D Multi-User blood pressure monitor.
- The application will work with the patient's existing smart phones and tablets.
- The app will allow the freedom to record measurements in the order of their choosing.
- The app may utilize Fuze, a mobile communication platform for communication between physicians, nurses and patients. It is currently used by Meriter Hospital.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

The app will be used daily for six weeks post-discharge. Patients will monitor their blood pressure and heart rate twice daily. The app can be used offline for data collection, but will be synced to the internet to share the collected data with healthcare staff.

b. Safety:

The device will require a warning that app and video conference on the app do not replace mandatory scheduled visits with a medical professional and prescribed medications may not provide full treatment for postpartum disorders. In order to protect private patient information, the app will adhere to HIPAA standards and requirements [1].

c. Accuracy and Reliability:

The app will read in measurements from several bluetooth devices to the smallest degree allowed by the device. Measurements read on the program will always reflect those taken by the connected devices.

d. Life in Service:

The app will work for the entirety of a patient's six-week monitoring period. Furthermore, the app will ideally be updated to run effectively with new operating systems soon after they are available. Features such as video nurse conferences and physician consultations will be limited to hospitals hours, but measurements can be taken and uploaded at any time of the day.

e. Operating Environment:

The app will run on major smartphones including iOS mobile devices and Android Devices. Ideally, the app will be able to output data directly into spreadsheets the nurses are using, as the current product requires all data to be manually input into the system from a report that is formatted poorly and not useful.

f. Ergonomics:

The app will be user friendly and simple to navigate for smartphone users of various ability levels.

g. Aesthetics, Appearance, and Finish:

The app will have professional yet uplifting look that makes users trust in the ability of the app and comfortable using it. Colors will follow a UW theme (red and white) and users, physicians, and nurses will all have avatars.

2. Production Characteristics

a. Target Product Cost:

Ideally, there will be minimal cost associated with the development of this app. Prospective costs could include licensing fees and hardware procurement. Total system costs will include the mobile device and associated bluetooth hardware. The user is responsible for the cost of the mobile device while the hospital will provide the necessary monitoring equipment.

3. Miscellaneous

a. Standards and Specifications: international and /or national standards, etc.

Our app and bluetooth device would fall under the jurisdiction of the sub committee of the FDA, center for devices and radiological health (CDRH). It is necessary that all medical devices are registered with the FDA[2]. However, our device will most likely fall under the class I category and will likely be exempt from premarket notification as our product falls under the medical device data systems.

HIPAA compliance [1] will be necessary in transferring patient information to the nurse database. This private information can range from vital sign readings to patient names and addresses. The app must be password protected and encrypted with accordance to HIPAA standards. Recommended and hospital-issued monitoring equipment used in conjunction with the app will be FDA approved.

b. Customer:

Customer requests and needs will be analyzed with data from the client once the information is readily available.

c. Patient-related concerns:

Patient privacy is the utmost priority of this project. HIPAA standards [1] and regulations will be followed to ensure no patient information is made public or used commercially. Furthermore, information will not be shared with anyone to whom the patient has not given consent.

d. *Competition:* Are there similar items which exist (perform comprehensive literature search and patents search)?

Currently, the client and a team developed an existing program that was successful in reducing patient readmission. There also are existing blood pressure monitoring apps that do not fulfill all client-specified requirements, especially relating specifically to pregnancy. These home blood pressure monitoring apps are also targeted for patient blood pressure monitoring needs [3], rather than developed with a health provider-to-patient relationship in mind as desired by the client. These top apps also use email to export data [4], which doesn't fulfill the client's goal of eliminating manual data entry by the nurses. Many of the top blood pressure monitoring apps [3] - Family Lite [4],

Blood Pressure Companion [5], Smart Blood Pressure Tracker [6], and Blood Pressure Watch [7] - are available for iOS devices, supporting the idea that an iOS app will reach a majority of the intended users.

- [1] State of California. (2017, July 24). *What is HIPAA* [Online]. Available: http://www.dhcs.ca.gov/formsandpubs/laws/hipaa/Pages/1.00WhatisHIPAA.aspx
- [2] U.S Food and Drug Administration Code of Federal Regulations, Title 21, Part 801, 2017.
- [3] K. Nouse. (2016, August 19). *Top Four Blood Pressure Monitoring Apps* [Online]. Available: <u>https://www.engadget.com/2016/08/19/top-4-blood-pressure-monitoring-apps/</u>
- [4] Taconic System, LLC. (2012). *BPMonitor Lite* [Online]. Available: http://www.taconicsys.com/app/bpmonitor-lite.html
- [5] Maxwell Software. (2016). *BPCompanion* [Online]. Available: http://www.maxwellapps.com/apps_16_bp_companion.html
- [6] Evolve Medical Systems, LLC. (2012). *Smart Blood Pressure (SmartBP)* [Online]. Available: <u>http://www.evolvemedsys.com/faq</u>
- [7] (2017). *Blood Pressure (BP) Watch* [Online]. Available: https://play.google.com/store/apps/details?id=com.boxeelab.healthlete.bpwatch&hl=en

Appendix II: Materials

ltem	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
	iOS App Development							https://developer.apple.com/
XCode	Interface	Apple Inc.	N/A	9/27/2017	2	\$0.00	\$0.00	xcode/downloads/
	Online Android							
MIT App	Development							http://appinventor.mit.edu/e
Inventor	Interface	MIT	N/A	11/29/2017	1	\$0.00	\$0.00	xplore/
						TOTAL:	\$0.00	

Appendix III: Code for Login Screen



Appendix IV: Code for Blood Pressure Measurement Screen

Appendix V: Code for Conference Screen

Appendix VI: Code for Upload Screen

Appendix VII: Code for Heart Rate Measurement Screen

initialize global username to [get start value	
initialize global date to 1 " "	
initialize global (HR) to 🔰 🖱 🖉	
when Home .Click	
do open another screen with start value screenName	" Home "
startValue	get global username 🚽
when Submit .Click	

DatePicker1 - Day -

DatePicker1 - Year -

• 7 •

Appendix VIII: Code for Home Screen

Appendix IX: Code for Track Progress Screen

Appendix X: Code for Weight Measurement Screen

initia	alize global username to (get start value
initia	alize global date to 🖓 " 🔲 "
initia	alize global weight to 🕻 " 🔲 "
whe	n Home Click
do	open another screen with start value screenName "Home "
	startValue / get (global username -)
whe	
do	set Error
	🖸 if 🔰 TextBox1 🖜 . Text 🗸 🖃
	then set Error . Text to text Enter weight.
	else if get global date a EEO
	then out Error Toxt to a Enter today's data
	set Error . Text to P Enter today's date.
	else set global weight v to [TextBox1 v . Text v
	call TinyDB1 . StoreValue
	tag (😒 join (get global username 🗸
	get global date -
	valueToStore det global weight
	set Error Text - to i i join get global weight -
	saved. "
whe	n DatePicker1 JAfterDateSet
do	set global date to is join DatePicker1 . Month
	· 7 *

DatePicker1 🔹 . Year 👻

Appendix XI: XCode Viewcontroller

```
//
// ViewController.swift
// PPM
//
// Created by Alex Zoellick on 9/24/17.
// Copyright © 2017 Team 63 BME Design. All rights reserved.
//
import UIKit
import CoreBluetooth
class ViewController: UIViewController, CBCentralManagerDelegate, CBPeripheralDelegate {
  var manager:CBCentralManager!
  var peripheral:CBPeripheral!
  override func viewDidLoad() {
    super.viewDidLoad()
    // Do any additional setup after loading the view, typically from a nib.
    manager = CBCentralManager(delegate: self, queue: nil)
  }
  override func didReceiveMemoryWarning() {
    super.didReceiveMemoryWarning()
    // Dispose of any resources that can be recreated.
  }
  let btWEIGHT_NAME = "Fat_Measure"
  let btWEIGHT_SCRATCH_UUID = CBUUID(string: "f9b1fb66-c421-11e7-abc4-cec278b6b50a") //FIXME
  let btWEIGHT_SERVICE_UUID = CBUUID(string: "f9b2017e-c421-11e7-abc4-cec278b6b50a") //FIXME
  //Scan for devices
  func centralManagerDidUpdateState(_ central: CBCentralManager) {
    if central.state == CBManagerState.poweredOn {
       central.scanForPeripherals(withServices: nil, options: nil)
    }
    else {
       print("Bluetooth not available.")
    }
  }
  //Connect to Devices
```

private func centralManager(central: CBCentralManager, didDiscoverPeripheral peripheral: CBPeripheral, advertisementData: [String: AnyObject], RSSI: NSNumber) {

let device = (advertisementData as NSDictionary).object(forKey: CBAdvertisementDataLocalNameKey) as? NSString

```
if device?.contains(btWEIGHT_NAME) == true {
    self.manager.stopScan()
```

self.peripheral = peripheral
self.peripheral.delegate = self

```
manager.connect(peripheral, options: nil)
}
//Get services
func centralManager(_ central: CBCentralManager, didConnect peripheral: CBPeripheral) {
    peripheral.discoverServices(nil)
}
//Get characteristics
func peripheral(_ peripheral: CBPeripheral, didDiscoverServices error: Error?) {
    for service in peripheral.services! {
        let thisService = service as CBService
    }
}
```

```
if service.uuid == btWEIGHT_SERVICE_UUID {
    peripheral.discoverCharacteristics(nil, for: thisService)
    }
}
```

//Disconnect and try again

func centralManager(_ central: CBCentralManager, didDisconnectPeripheral peripheral: CBPeripheral, error: Error?) { central.scanForPeripherals(withServices: nil, options: nil)

}

}

}

Appendix XII: XCode Storyboard

Appendix XIII: Designer for Weight Screen

Appendix XIV: Designer for the Login Screen

Appendix XV: Designer for the Track Progress Screen

Appendix XVI: Designer for the Home Screen

Appendix XVIII: Designer for the Blood Pressure Screen

Appendix XIX: Designer for the Export Data Screen