Postpartum Monitoring App

BME 200/300

Wednesday, October 11, 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

Team Members:
Alex Zoellick - Team Leader
Aleysha Becker - BSAC
Rachel Minehan - BWIG
Jacky Tian - BPAG
Lucas Ratajczyk - Communicator

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 conditions that arise. Vital protein are expelled in urine and the elevated pressure decreases blood flow to heart, brains and kidneys. Stroke and heart attack are increasingly likely as a result of the decreased blood flow. Thus, Dr. Kara Hoppe (DO), who specializes in high risk pregnancies at UnityPoint Health-Meriter Hospital Madison, Wisconsin, is working on a program to reduce death and hospital readmission for patients with hypertensive disorders. Currently, she employs a package put together by Honeywell to track and monitor patients blood pressure, heart rate, weight and oxygen levels remotely. Due to her initial work thus far with the Honeywell system, hospital readmission due to hypertensive related issues has dropped close to zero. However, the Honeywell system received less-than-ideal reviews from the nurses, doctors and patients. Dr. Hoppe approached our team of BME students to create an iOS app that would provide the same information as the Honeywell package. This semester, bluetooth data upload, cloud data transfer and user friendliness are the major features the team hopes to employ in this system so Dr. Hoppe can continue her work with the new system. Once the new system is up and running, more features such as video conferencing, personalization, push notifications, etc. can be added in order to make the application more well-rounded and easier to use.

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I. Introduction

Preeclampsia causes 9% - 26% of global maternal mortality, and 32% - 44% of preeclampsia occurs postpartum. The onset of preeclampsia can present anywhere from 48 hours to six weeks after giving birth [1]. Thus, a postpartum hypertension monitoring app is necessary to reduce the number of hospital readmissions and fatalities associated with this disorder by encouraging patient compliance and greatly increasing the convenience associated with postpartum care. Current monitoring apps focus primarily on tracking blood pressure over a long period of time for personal use. This system is more appealing to people with chronic hypertension as opposed to patients, like new mothers, with a relatively limited time period over which they must be monitored for preeclampsia [2]. These apps also lack the physician-to-patient interaction and HIPAA-compliant data transfer that would decrease the need for traditional postpartum hospital visits.

This semester, our team of five BME students will design, test, and implement a device that 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 due to hypertensive disorders. The app will provide a medium for physician-patient interaction, patient monitoring and video conference with healthcare specialists (nurses, doctors, etc.).

II. Background

For a patient to be considered hypertensive (postpartum or otherwise), their blood pressure must be over 140mm Hg (systolic) and/or over 80 mm Hg (diastolic) on two or more occasions that are more than four hours apart [3]. Preeclampsia is characterized by hypertension and signs of organ damage, such as protein in the urine indicating damage to the kidneys [4]. While the causes of postpartum preeclampsia are not widely understood, healthcare providers believe that its onset starts at delivery, even though symptoms don't become evident immediately after [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 specific flags that postpartum hypertension may occur in a given patient. This could include, but is by no means 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 show these symptoms are at an even greater risk and can especially benefit from at 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].

Our client, who suggested 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 [8].

Meriter currently has a home-tracking postpartum monitoring program through Honeywell and despite that mostly positive rating (54% for extreme satisfaction [9]), some improvement is 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 a potential higher percent error on the user's end. 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.

Once logged in, the app will allow patients to record their vitals (blood pressure - BP, heart rate - HR, and weight) through a bluetooth connection to BP/HR monitor and manual input of weight, securely transfer this data to their physician of choice, set alerts for themselves to remember to take measurements, communicate with their physicians and nurses through video chat appointments, and view their progress since the beginning of the monitoring period.

III. Preliminary Designs

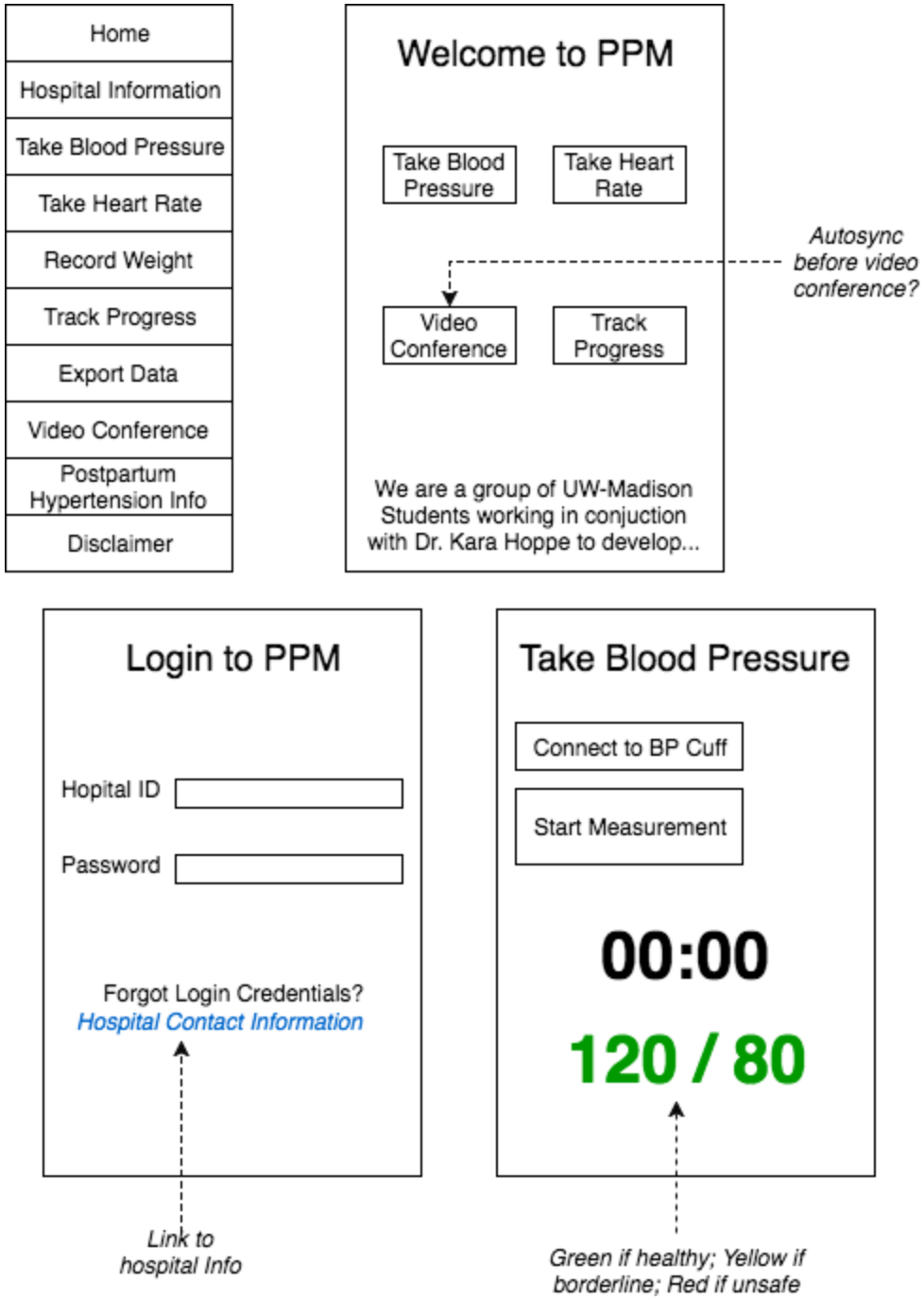

Figure 1: preliminary screen layout designs

Preliminary designs (Figure 1) were developed for a welcome page, vital measurement page, and login page. The app will also include 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 will include 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 will include 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 will turn red; if the user’s blood pressure is around the threshold, the numbers will turn yellow as a sign of warning; unsurprisingly, the numbers will 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.

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	(1/5) 0.4	(5/5) 2
Total	96	82	83	100	73	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.

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. Data export to Epic is marked lower due to the high cost of storing information within Epic's expansive network.

Proposed Final Design:

After the extensive evaluation process, the three highest scoring features and one one additional feature were chosen as the focus of this semester's design project. A screen displaying the hospital information scored a perfect 100 due to the relatively low-risk and high ease of implementation. This screen will include address, phone number and hours of the chosen hospital. Bluetooth data entry scored 96 and will be included as it is the driving force behind the project. The blood pressure cuffs distributed by the hospital are

bluetooth enabled thus the app must connect via bluetooth to read in the data. Manual override is implemented throughout the entire app, rather than being one specific feature. Patients will be able to enter the data in their preferred order and physicians/nurses will be able to make changes as they see fit. The final feature implemented this semester is the ability to export the data to the hospital over the internet. Though it didn't achieve the highest score, there is no purpose to creating the app and logging the data if it isn't sent to the hospital. Thus, it must be included to meet the overall design requirements.

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 will be used to wirelessly take patient vitals (Appendix III).

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

As the app is still in initial development stages, no testing data has been acquired or analyzed thus far. Testing data will be uploaded to this report later.

VII. Discussion

Ethically, the biggest concern in developing and testing a postpartum hypertension monitoring app is ensuring HIPAA compliance to protect patient vital information. As the app is digital, it doesn't present unique safety concerns to users.

VIII. Conclusions

The team will design, test, and implement an app that will allow patients to record blood pressure, heart rate and body weight, securely transfer this data to their physician of choice and communicate via video chat with their physicians and nurses to receive professional treatment recommendations. The app must be able to interface with a bluetooth blood pressure monitoring cuff (which will also monitor heart rate) and send this data to the hospital's database. Ideally, this app will reduce or eliminate patient readmission due to postpartum hypertension disorders by allowing patients at risk for this life-threatening disorder to have remote access to physician monitoring and recommendations. The team has not conducted tests or completed the app as of right now (10/8/17) and as such, has no data to analyze the efficacy of the app or experiences they would like to alter for the next iteration.

IX. Future work

In the short term, the app will eventually be able to send patients push notifications reminding them to take vital measurements, and prompt the users to take those vitals in a physician-desired order. After taking vitals, patients will take a short survey to assess their status and test for other symptoms of preeclampsia, such as dizziness, nausea, or shortness of breath. The patient will be able to connect via HIPAA-compliant video conferencing or text chat with physicians they choose and are comfortable with.

In the long term, the app will eventually be able to upload patient vital data directly to Epic databases, and will utilize Fuze for video conferencing with healthcare providers. The app will also have customization options, such as page color and background picture, to make the app more enjoyable to use.

References

[1] ACOG. Hypertension in Pregnancy: Report of the American College of Obstetricians and Gynecologists' Task Force on Hypertension in Pregnancy. Obstet Gynecol. 2013;122(5):1122-1131.

[2] K. Nouse. (2016, August 19). *Top Four Blood Pressure Monitoring Apps* [Online]. Available: https://www.engadget.com/2016/08/19/top-4-blood-pressure-monitoring-apps/

[3] K. Sharma and S. Kilpatrick . [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmed/28426127

[4] Mayo Foundation for Medical Education and Research (2017). *Preeclampsia* [Online]. Available: http://www.mayoclinic.org/diseases-conditions/preeclampsia/symptoms-causes/syc-20355745

[5] Mayo Clinic Staff. (2015). *Postpartum Preeclampsia.* [Online]. Available: http://www.mayoclinic.org/diseases-conditions/postpartum-preeclampsia/basics/causes/con-20035395

[6] Family Doctor. (2017). *Postpartum Preeclampsia*. [Online]. Available: https://familydoctor.org/condition/postpartum-preeclampsia/

[7] Mayo Clinic. (2016, November). *High Blood Pressure*. [Online]. Available: http://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/high-blood-pressure/art-20045868

[8] UW Health. *Kara K. Hoppe, DO.* [Online]. Available: https://www.uwhealth.org/findadoctor/profile/kara-k-hoppe-do/10016

[9] K. Hoppe, “Home telehealth monitoring for Postpartum Hypertension: A pilot Intervention”. University of Wisconsin-Madison.

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: https://www.engadget.com/2016/08/19/top-4-blood-pressure-monitoring-apps/

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[5] Maxwell Software. (2016). *BPCompanion* [Online]. Available: http://www.maxwellapps.com/apps_16_bp_companion.html

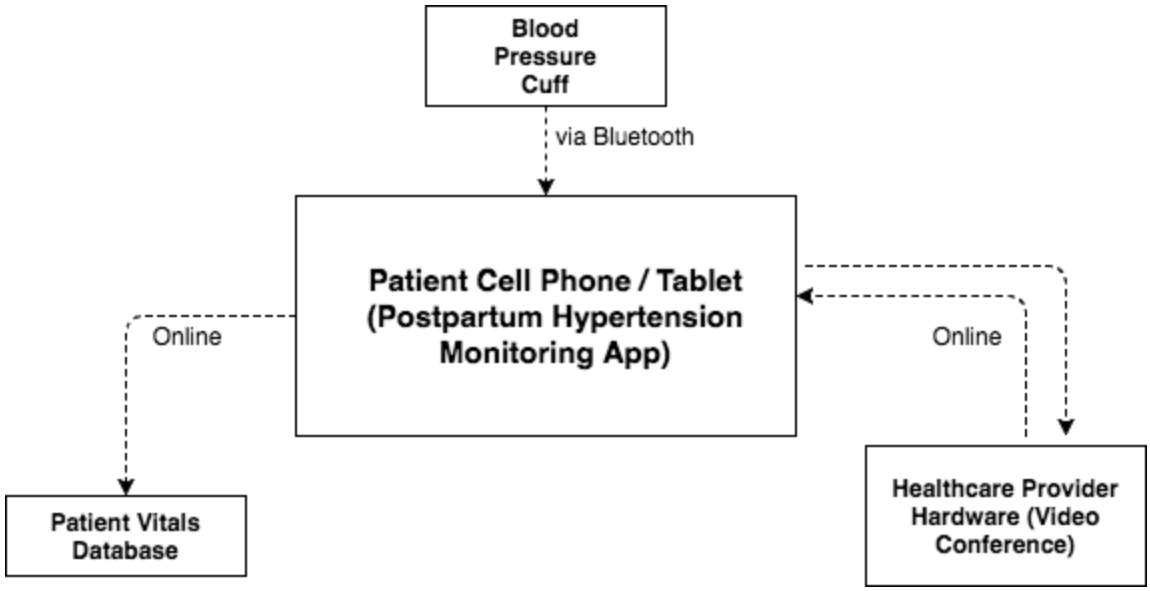
[6] Evolve Medical Systems, LLC. (2012). *Smart Blood Pressure (SmartBP)* [Online]. Available: http://www.evolvemedsys.com/faq

[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

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
XCode	iOS App Development Interface	Apple Inc.	N/A	9/27/2017	2	$0.00	$0.00	https://developer.apple.com/xcode/downloads/
						TOTAL:	**$0.00**	

Appendix III: Hardware Block Diagram



Appendix IV: Software Block Diagram