Android-Based Tocodynamometer and Fetal Heart Rate Monitor

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tocotronics

Contents

Clinical Problem

A tocodynamometer is a medical device used to measure the frequency and duration of uterine contractions. It is used quite often in hospitals to monitor the condition of a woman's pregnancy. Typically, a tocodynamometer is used at around 39 weeks into a woman's pregnancy. It uses a pressure sensing button that must be strapped tightly to the patient by the nurse or other assistant. This button sends a signal to a box that processes the stimulus. It can output plots and analyses of the contractions [1].

The problems with this device are simple and well-defined. The patient is dependent on a nurse to strap on the button sensor in exactly the correct position. The patients must remain still to ensure that the reading is based on contractions and not on any shifting of position that may occur while the patient is in pain. Considering that the device is bulky (~1' x 1' x 0.5'), expensive (~$10,000), and difficult to use, the current applications of the toco are confined to specialized hospitals. Many low resource hospitals do not have tocos and, in general, the toco device is not portable or convenient [2].

Another component of pregnancy care is a fetal heart rate monitor. This is another device that is generally confined to hospitals. Specialized equipment must be used due to the inherent challenges of filtering the relatively small fetal heart rate signal from the more prominent electrical signals present in a pregnant woman. Consideration of this device is important because the fetal heart rate monitor is often used in conjunction with a toco to help doctors understand the state of the pregnancy and make important decisions [2].

The combination of the tocodynamometer and the fetal heart rate monitor simply compounds the problem discussed above. Current methods of fetal monitoring are expensive (~$10,000), bulky (~1' x 1' x 0.5'), difficult to use, and often only found in specific hospitals.

We made several observations in discussions with our clinical contacts that served to guide and refine our intuition and understanding of the problem. These will become critical in helping us craft an elegant and useful solution. First, it was made very clear that the use of the strap as a component of the tocodynamometer is very frustrating and inconvenient. Second, we realized that the readings of a toco and fetal heart rate monitor cannot simply be computationally analyzed or viewed by the patient. Interpretation of the the data is complex enough that we should simply filter and package the results to be sent to a doctor.

Finally, we were informed of some important considerations for an in home or low resource device. Physicians will not choose to adopt and recommend a device that creates concerns over malpractice. Using remote monitoring technologies, doctors will not be able to check the patient's vitals or obtain clues that may only be available in person. Moreover, another medical liability is that in such remote monitoring, the doctor may not be able to provide necessary care if a problem is found. Doctors do not want to perform tests and collect data on patients that are inaccessible. There is a liability in knowing a patient is in distress, and if the patient is at home, the doctor may not be able to help. In the following discussion, we will strive to carefully define the use case of our device so that it provides the maximum benefit without creating liability for physicians [3].

Scope of the Problem

Epidemiology

There were 3,953,590 registered births in the United States in 2011. This statistic is a measure of the incidence of childbirth. On average, gestation lasts 280 days. A simple calculation yields that the prevalence of pregnancy in the US is about 3,032,891. This statistic indicates the number of pregnant women in the US at any given moment [4]

From 2010 to 2011, the number of births occurring in the US decreased by 1%. This change is small enough that we do not have cause to be concerned about a change in the size of our market [5].

Pregnant women are generally aged 15-44 years with 25.6 years as the mean age at first birth. This is very positive because women of this age are generally smart phone owners and open to the use of technology [5].

Economic Impact

From 2004-2010, the average total price charged by hospitals for pregnancy and newborn care was about $30,000 for natural delivery and $50,000 for a C-section. Commercial insurers paid an average of $18,329 and $27,866. Given that the rate of C-sections is about 33%, pregnancies cost the healthcare system about $145 billion per year [6].

This very large total encompasses many costs throughout the pregnancy, including prenatal visits, diagnostic tests, prenatal supplements, and any care during the actual birth. The primary factor in this total is the cost of hospitalization, treatment, and medication during delivery. By providing a device that helps patients monitor the state of their pregnancies remotely, we hope that we may be able to mitigate some of this cost [6].

Considering cost from the device perspective, most tocos are priced in the $5,000-$20,000 range. We aim to provide a product that we sell at close to $200. This will include the app and all of the additional materials. We hope to further refine this price to make it attractive to low resource hospitals that want a simple solution to tocodynamometry [1].

Current Treatment Options

A variety of treatment options should be considered when attempting to solve this problem. These options can be subdivided into two categories, direct and indirect sensing. An analysis of these categories follows (Table 1).

Background

Treatment Category	Treatment Option	Benefits	Risks
Direct Sensing	Use a device (straps with velcro, elastic bands) that mechanically attaches to patient and can be used to simultaneously determine both fetal heart rate and the length and time between uterine contractions.	Allows for direct sensing of contractions and physical conditions of patient	Could cause stress on the patient since device might be somewhat constrictive. Difficult for the nurse to use. Is inaccurate when the patient moves and shifts.
Indirect Sensing	Detect contractions and fetal heart rate based on electrodes or wireless sensors placed on patients body with gentle adhesives.	Less cumbersome than a large physical device. Could be less expensive. Patient movement is not restricted as it does not interfere with the reading.	Creates a complicated filtering and analysis problem. Not proven or widely used.

Table 1. Treatment options and their associated benefits and risks for measuring contractions and fetal heart rate.

Cycle of Care

There are two alternative cycles of care. These cycles involve monitoring contractions at the hospital and monitoring contractions at home.

Fetal monitoring refers to the process of monitoring pregnancy following gestation through labor and delivery. Depending on their risk level, pregnant women are monitored at different intervals. One important parameter that is monitored is maternal contractions, which typically involves the use of an external toco [7].

In a hospital labor room, a woman is connected to two noninvasive fetal monitors: the tocodynamometer and fetal heart monitor. The two monitors simultaneously produce a graph of the two waveforms on a labor strip. During the active phase of labor, the team of obstetrics conducts a pelvic exam to note the course of labor every two hours. During these exams, the team notes the cervical dilation and effacement. Effacement refers to the process where the cervix shortens and becomes thinner as the baby drops closer to the cervix.The graph that simultaneously shows mother's contractions and the fetal heart tones can be used to see how the baby is responding to the mother's contractions and to make sure that the baby is obtaining sufficient oxygen. The graph can be used to differentiate between late decelerations, early decelerations, and variable decelerations [8].

The toco typically used in a hospital is equipped with a large pressure sensor held down by a band strapped to a woman's stomach. The nature of the device prevents a woman from being able to move around.

At home, the Home Uterine Activity Monitoring (HUAM) is used to detect the onset of preterm labor. HUAM involves the use of a monitoring device that the patient is instructed to use every day for two one hour periods. The recordings are sent to a base station where nurses analyze the transmitted data in an attempt to detect the onset of preterm labor and provide advice to the patients [9]. Similarly, the BellyBeats Fetal Doppler Monitor can be used to monitor the fetal heart rate from home. Home fetal heart rate monitors can be risky because it is often difficult for inexperienced patients to distinguish between the whooshing sound of the mother's pulse or blood flow and the baby's heartbeat [10].

If a baby is born premature, a stay at the Neonatal Intensive Care Unit (NCU) may be required. NCUs typically employ respiratory therapists, occupational therapists, dietitians, lactation consultants, and neonatologists. The baby will likely require respiratory assistance through means such as ventilator and feeding through means such as intravenous lines and umbilical catheter [11]. From 2010 to 2011, the number of births occurring in the US decreased by 1%. This change is small enough that we do not have cause to be concerned about a change in the size of our market [12].

Cycle of Care

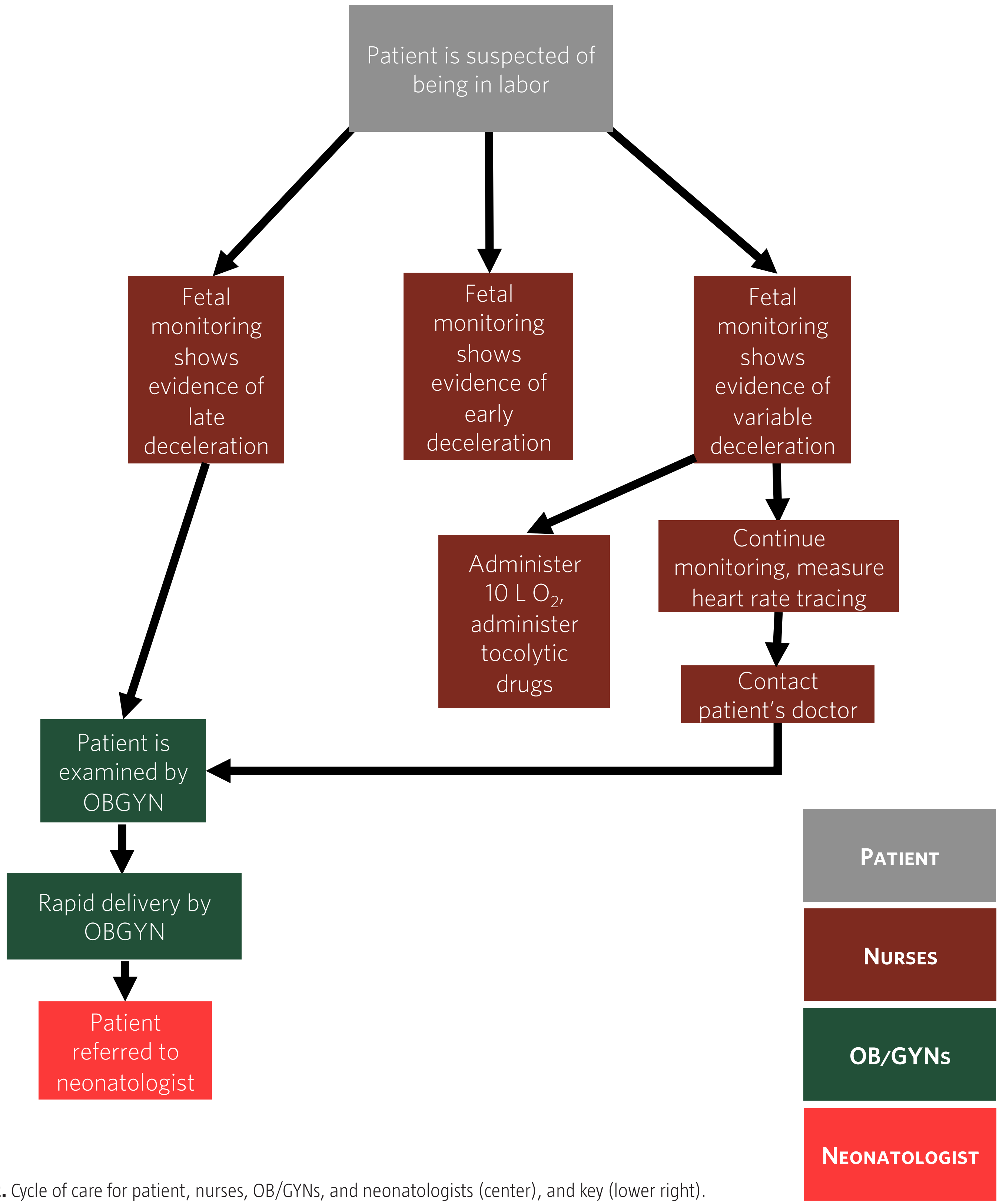

Table 2. Cycle of care for patient, nurses, OB/GYNs, and neonatologists (center), and key (lower right).

Stakeholder Analysis

Stakeholders	*Primary Benefits*	*Primary Costs*	*Assessment of Net Impact*
Patients	1) Allows patients to have easier acces to a toco through their local doctor. 2)Allows patient to go to their local doctor instead of needing to drive miles to go to a large hospital for each visit.	1) Doctors may not be trained to read these devices. 2) The doctor would need to have some sort of communication with the nearest large hospital around or at the time the patient has a visit with her local doctor.	Positive: More patients will have local access to device. Positive: Patients will have to make less trips to a further away hospital.
OB/GYNs	1) Have more information about a woman's pregnancy. 2) Spend less time with each patient so they can ultimately see more patients.	1) May need to learn how to use new device. 2) Potential to receive lower pay due to less interaction with the patient and less hospital visits.	Positive: Doctors will know more about the patient's pregnancy to better treat her. Neutral: Costs and benefits outweigh each other - no net benefit or cost.
Nurses	1) Nurses have a toco that is easier to use and does not require a strap. 2) Nurses can save time by seeing patients only as they are about to give birth.	The readings utilize a different technology which aims to be easier to use.	Neutral: Costs and benefits outweigh each other - no net benefit or cost.
Facilities	1) Provides a resource where there is none. 2) External tocodynamometers may not be necessary in every exam room anymore saving money. 3) Patient does not need to spend as much time in the hospital.	1) Requires facilities to have electrodes and smart device. 2) Scheduling of facilities would have to adapt to accommodate the use of the application.	Positive: Mobile tocodynamometry increases resources in the facilities.
Payers (Health Insurance)	1) Patients may be able to go to a local and convenient hospital with less equiptment. 2) Patients spending less time in the hospital results in fewer fees that need to be paid by insurance companies.	1) May result in an additional charge health insurance companies need to pay as a result of an additional service. 2) Patients bypass the service that their health insurance provides to use an independent service.	Negative: Total cost may go up because companies must pay for an additional service. Postive: Total cost of delivering babies may go down because patiens will spend less time in the hospital.

Table 3. Stakeholder analysis for patients, doctors, nurses, facilities, and payers as it relates to an android based tocodynamometer and fetal heart rate monitor.

Needs Filtering

Needs Statement

The Need

A convenient, sophisticated, and inexpensive device that allows one to monitor the frequency and duration of uterine contractions.

The Problem

The shortcomings that the existing solutions have:

- Hospital tocodynamometers are bulky (~1' x 1' x 0.5') and expensive (~$10,000) [11]
- There are no portable, safe, and comfortable tocos available to patients
- Testing new toco devices is difficult
  - There are limited ways to simulate uterine contractions
  - Many other muscles are near the area of interest
    - The signals of these muscles need to be ignored
- Home tocodynamometers are expensive and often require nurse supervision
- Women lack a convenient and inexpensive way to monitor uterine contractions

Needs Criteria

From a preliminary set of needs, several points can be filtered out to create a more focused objective. The filtering process is affected by several variables. One of the main factors to consider is what the team wants to accomplish with this device. Independent of solution it is safe to say that the team is leaning towards a relatively low-cost, off the shelf device that can be operated without extensive experience to allow a patient to share contraction and heart rate information with her doctor. Any needs that are conflicting with the team's goal generally should be filtered. Our team's goal in this case covers a few areas including but not limited to budget, pricing, location, ease of use, etc. Once the preliminary filter has been applied the needs will be rated on importance on a scale of 1-5 where 5 is an absolute requirement and 1 is maybe a nice feature. Then the top needs will be taken as the central focus of the design.

Needs Filtering

Smartphone based tocodynamometer.	Although the solution for the project has already been somewhat defined, it is important not to incorporate a solution into the need.	**-**
Perform accurate enough readings to detect frequency of uterine contractions.	Our research indicates that the two main measurements taken by tocodynamometer devices are the frequency and duration of uterine contractions. To design a similar system it is reasonable to make a requirement that our device will be able to make the same measurements [12].	**5**
Perform accurate enough readings to detect duration of uterine contractions.	Our research indicates that the two main measurements taken by tocodynamometer devices are the frequency and duration of uterine contractions. To design a similar system it is reasonable to make a requirement that our device will be able to make the same measurements [12].	**5**
A way to find out if a woman is pregnant.	The target is women who are already in the later trimesters of pregnancy.	**-**
A way to find out which month / state of pregnancy a woman is in.	This does not apply.	**-**
A way to determine if and when to give certain medications.	This need is relevant and could be useful, but it does not fit the immediate scope of this device. It can maybe be considered for a future revision/ feature.	**-**
Be able to tell the patient when she needs to go to the hospital.	This need would be applicable to in-home use. However, because of the liabilities we have discussed with in-home use, we are targeting the device to low resource hospitals.	**1**

Needs Filtering

Be able to tell the doctor that he needs to tell the patient to push.	The device will not be used for this purpose.	**-**
Be able to use at home.	This reflects the teams goal to make a device that should be easy to use and not rely upon the experience of a doctor. However, we have previously discussed significant liabilities with in-home use. For that reason, we are planning to target our device to low resource hospitals.	**1**
Be able to use in a low resource hospital.	This reflects the teams goal to make a device that should be easy to use and not rely upon the experience of a doctor. However, we have previously discussed significant liabilities with in home use. For that reason, we are planning to target our device to low resource hospitals.	**5**
Be able to use in non-medical environments.	This reflects the teams goal to make a device that should be easy to use and not rely upon the experience of a doctor. However, we have previously discussed significant liabilities with in home use. For that reason, we are planning to target our device to low resource hospitals.	**1**
Be able to differentiate between real contractions and ‘fake’ contractions.	Not within the scope of this project. It would be useful, but it isn’t entirely necessary.	**-**
Be used to monitor development of contractions during the last trimester.	This need is largely an extension of the primary need. Should the device be useful during labor, it is likely that it can be useful during the last trimester as well, but this shouldn’t be a focus of the project.	**1**
Need to give tailored recommendations based on weight and other symptoms.	Based on discussions with clinical contacts, the data should be presented to a doctor, who will be responsible for making these recommendations.	**-**

Be able to reduce the time the patient has to be at the hospital by helping them to avoid coming in too early.	The device should be used in a hospital setting.	-
Need to create a relatively low cost solution.	This need is important and should be maintained to remind us that the goal is to make an affordable product.	**5**
Need to create a portable device that can be carried with the patient.	This need is important because it emphasizes one of the advantages this device would have over what is currently available.	**5**
Be able to send data to trained doctors and nurses to interpret the information.	This is absolutely vital. Nurses and doctors will be responsible for interpreting the readings of the device.	**5**
Incorporate fetal heart rate to make data more informative.	This is a goal of ours but not the first priority. This information superimposed with information about uterine contractions will help determine whether it is safe to proceed with labor.	**5**

Table 4. First level filter of needs where green = pass, yellow = modified, and red = fail. 1-5 ratings represent a scale of importance where 5 is an absolute requirement and 1 is maybe a nice feature.

Needs Filtering

Taking the highest rated needs we have the following:

Absolute Requirements

Perform accurate enough readings to detect frequency and duration of uterine contractions
Be able to be used in a low resource hospital
Be a portable and low cost solution
Be able to send data to trained doctors and nurses to interpret the information

Desirable Requirements

Be able to be used in home
Incorporate fetal heart rate monitors to make the data more informative

Description of Operation

Signal Gathering

There will be a series of 1" x 1", cloth, adhesive electrodes attached to the patient that will measure both uterine contractions and fetal heart rate. The device will be provided with instructions on the exact position to place the electrodes in order to obtain accurate readings. The patient will carry an arduino board that will collect the readings from the electrodes and relay the data to a smartphone using short range Bluetooth radio.

This radio technology would be standard on most phones and should be capable of transferring the data needed from the nodes within the radio data transfer speed limitations. The nodes in conjunction with the 'on-patient' hardware should perform an initial level of basic filtering in order to eliminate problematic noise (mostly from external radio devices) that could interfere with later software level filtering but not to the extent in which it would raise the price of the device drastically.

Signal Filtering and Processing

While the phone is receiving packets of information from the nodes we will design software that will take some N number of packets that will then run through a series of software level filtration systems. The amount will depend on the phone and be based on the how many packets the phone can filter in the amount of time it takes to get a certain amount of packets. In other words we would want to have it that it will store up packets and then filter them together while the phone is collecting another N packets. This would be our alternative to live filtering, which has severe limitations due to maintaining real time data. After the signals have been filtered they will be written into some sort of storage for more analysis. We plan to look further into this next semester.

Data Sharing

In order for the doctor to be able to get the data remotely, the application will send out packets of data on a timed interval that will include raw, filtered, and any interpreted signals to be analyzed. This preferably will go to a server located at the hospital or at a central location. In order to protect the user's data, the information will be encrypted such that only the hospital's devices would be able to properly interpret the data.

Use in Low Resource Hospitals

A patient should be able to go to the local hospital and use our device rather than needing to travel to a specialized women's hospital. Our device will expand the capabilities of the local hospital and create convenience for the patients.

The measurements can be viewed by a doctor in real time or transmitted to a doctor at a remote location. The advantage of this scenario is that if there are any problems, the patient is in a position to immediately receive care.

The problem with in home use is that the patient needs to be able to quickly receive assistance. The device should not be used at home unless the patient has in home care or a plan in place to rush to the hospital. If the patient does not have these capabilities, the doctor should not agree to use of the device in home. The device must not create a situation where the doctor knows that the patient is in distress, but is unable to help because there are no medical professionals with access to patient.

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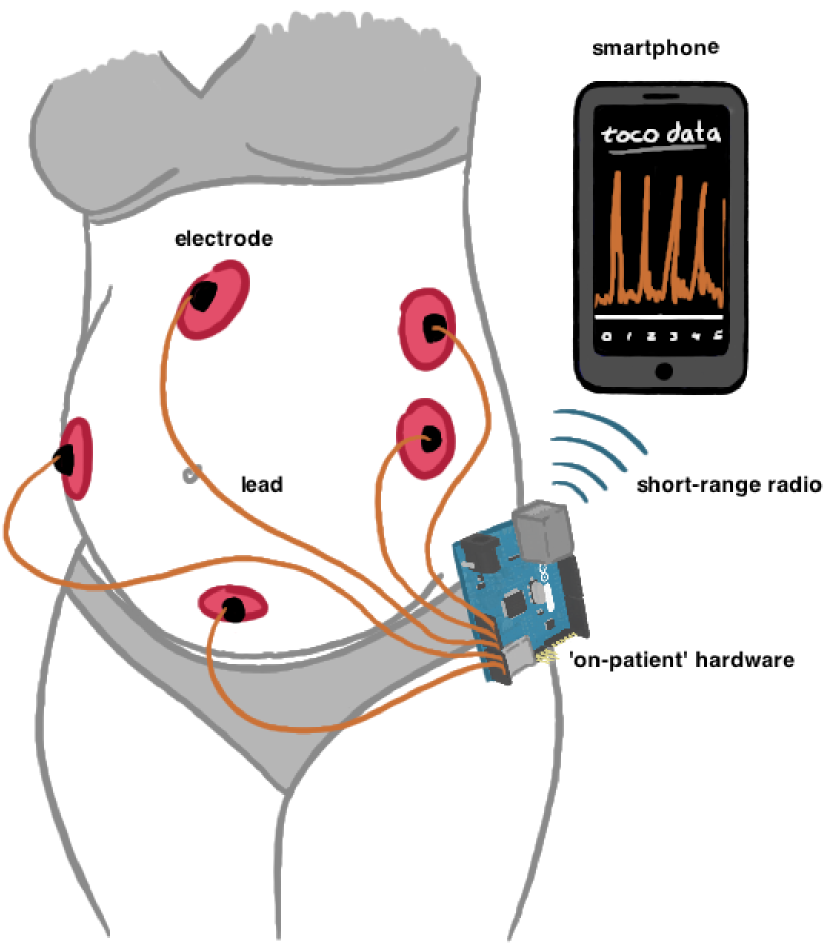

Figure 1. System-level diagram outlining the hardware setup on the patient as well as the channels by which data will travel from from the patient to the smart-device.

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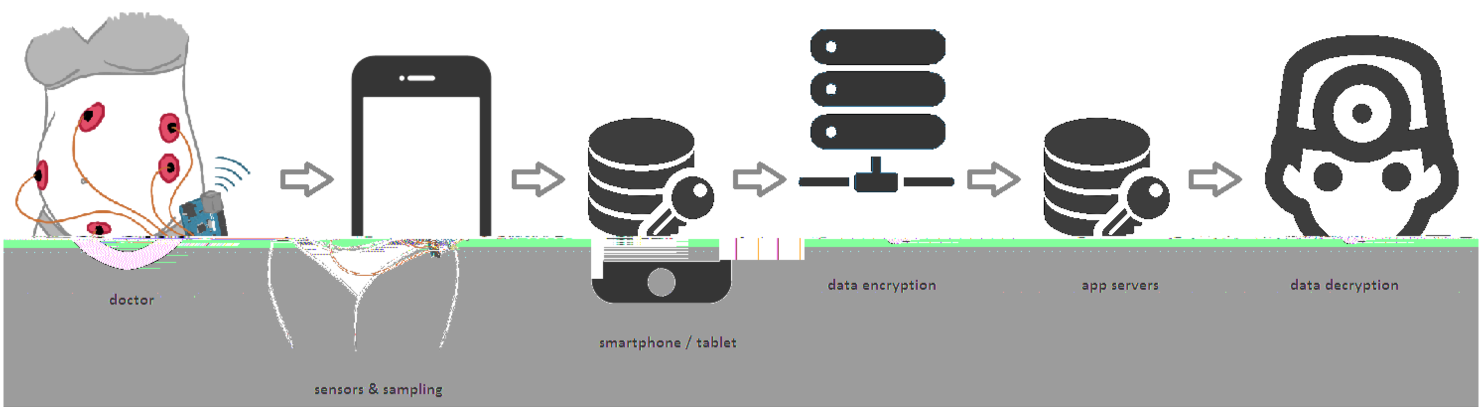

Figure 2. Tocodynamometer Service Infrastructure
The above diagram provides a high-level overview of the entire application's infrastructure. Data will originate with the patient's uterine contractions and the fetus' heart rate. Information is passed through the servers and encryption-decryption stages to the doctor who then sends a report back to the patient's smartphone via the same channels.

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User Interface

Below are a few screenshots from our prototype application (see Figure 3 and 4). Our first iteration is on the Windows Phone platform due to a lack of Android devices, but future versions will be implemented for Android. In this prototype we tried using the phone's accelerometer and gyroscope to collect data. Preliminary testing made it clear to us that this approach would not work. Using these sensors would require the patient to remain completely still for the duration of the test (ranging anywhere from 30 minutes to several hours). Also, the sensors are not sensitive to sustained signals and were only able to detect the 'edges' of our simulated contractions. To overcome these limitations we decided to switch to using electrodes. The advantages of electrodes are discussed in earlier sections.

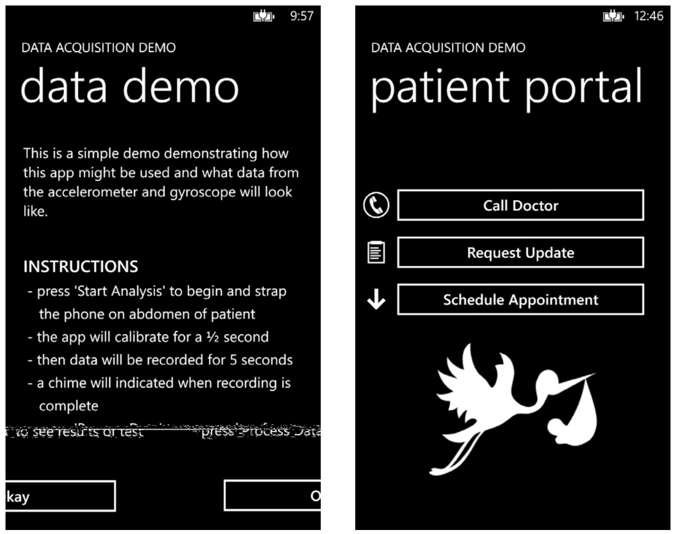

FIGURE 3. TOCODYNAMOMETER USER INTERFACE
The instructions page (left) outlining how to use the app, and patient portal (right). The instructions page reflects our old implementation where the phone's accelerometer would be used to measure uterine contractions. For future prototypes this page will be updated to describe the application of electrodes and provide further instructions on how to communicate with a doctor. The patient portal provides the patient with an interface to interact with her doctor(s). This screen gives a quick way to call a doctor, to request an update, or to automatically schedule an appointment.

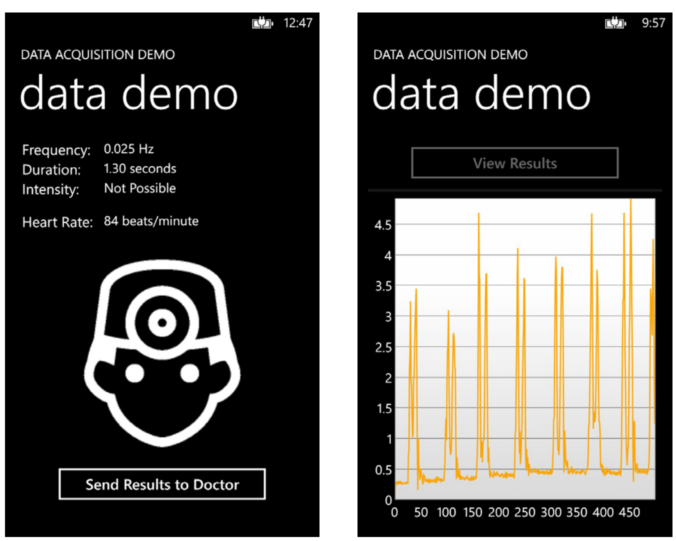

FIGURE 4. TOCODYNAMOMETER SERVICE INFRASTRUCTURE
The results page (left) and data acquisition page (right). The results page displays the results of the test. The frequency and average duration will be displayed. This may or may not be kept for the final iteration depending on how useful this information would be to the patient. Finally a button is provided to send the information to the doctor. The data acquisition page shows sample data collected from smartphone accelerometer and gyroscope. Similar data acquisition page will be presented to the patient with contraction and fetal heart rate signals.

Proposed Solution

Addressing Needs Criteria

Perform accurate enough readings to detect frequency and duration of uterine contractions

We will be using electrodes that detect and measure the electrical stimulation caused by uterine contractions. We are confident in this concept because contractions are simply striated muscle contractions, and we have demonstrated in previous courses that we can measure the electrical signal that induces these muscle contractions.

We will strive to use creative and advanced filtering techniques to ensure the accuracy of our readings. We will be able to write MATLAB code and convert it to C code to use on the android platform. This will enable us to perform the necessary processing.

Be able to be used in a low resource hospital or at home

We have minimized the required expertise and equipment in our solution. We hope to be able to use wireless electrodes that communicate with the smart phone using Bluetooth. This would mean that the only additional equipment that we require are the electrodes.

As an initial demonstration of our concept, we plan to use electrodes that attach to an arduino board. This board will then communicate with the smart phone via Bluetooth. The board will be small and our solution will still be far for convenient than existing alternatives.

Additionally, with provided instructions, it will be easy for a pregnant women to attach electrodes to herself. This is a significant improvement over the traditional strap.

Be a portable and low cost solution

The portability of the solution was discussed above. Wireless electrodes are relatively new and unproven and may drive up the cost of the solution until they become more common. The initial solution we proposed should be very inexpensive. We estimate that the cost of an arduino board and electrodes will be less than $30.

Be able to send data to trained doctors and nurses to interpret the information

The phone will process the electrode data that it receives from the arduino board via Blutetooth. It will then send this data to the doctor via wireless communication. The doctor can interpret the information and contact the patient as necessary.

Incorporate fetal heart rate monitors to make the data more informative

Measuring fetal heart rate with additional electrodes is a natural extension for this device. This problem will have its own filtering and identification challenges. We feel that after we are able to successfully measure the uterine contractions this is a logical next step.

Outline of Tasks

Schedule for Completion

January 13
Semester begins
January 20
Create IBM blog
January 27 — "Software Dry Run"
Software able to run on phone with dummy test data
February 3 — "Material Acquisition"
All hardware necessary for testing acquired; update IBM blog
February 10 — "Code Review 1"
First code review and mechanical design review as team and with TA (Kenny)
February 17
Update IBM blog
February 24 — "Code Review 2 and Mechanical Review"
Second code review and mechanical design review as team with TA (Kenny)
March 3 — "Custom Parts"
Any needed custom parts/hardware ordered; Update IBM blog
March 17 — "Mechanical Assembly"
Mechanical assembly complete; Update IBM blog; Happy St. Patrick's day :D
March 24 — "First Run Through"
First test run of device with all hardware
March 31 — "Functioning Prototype"
Have prototype working; Update IBM blog
April 7
Refine prototype
April 14 — "Testing"
First round of testing; Update IBM blog
April 21 — "Documentation"
Write necessary documentation for project
April 28
Project complete

GANTT Chart

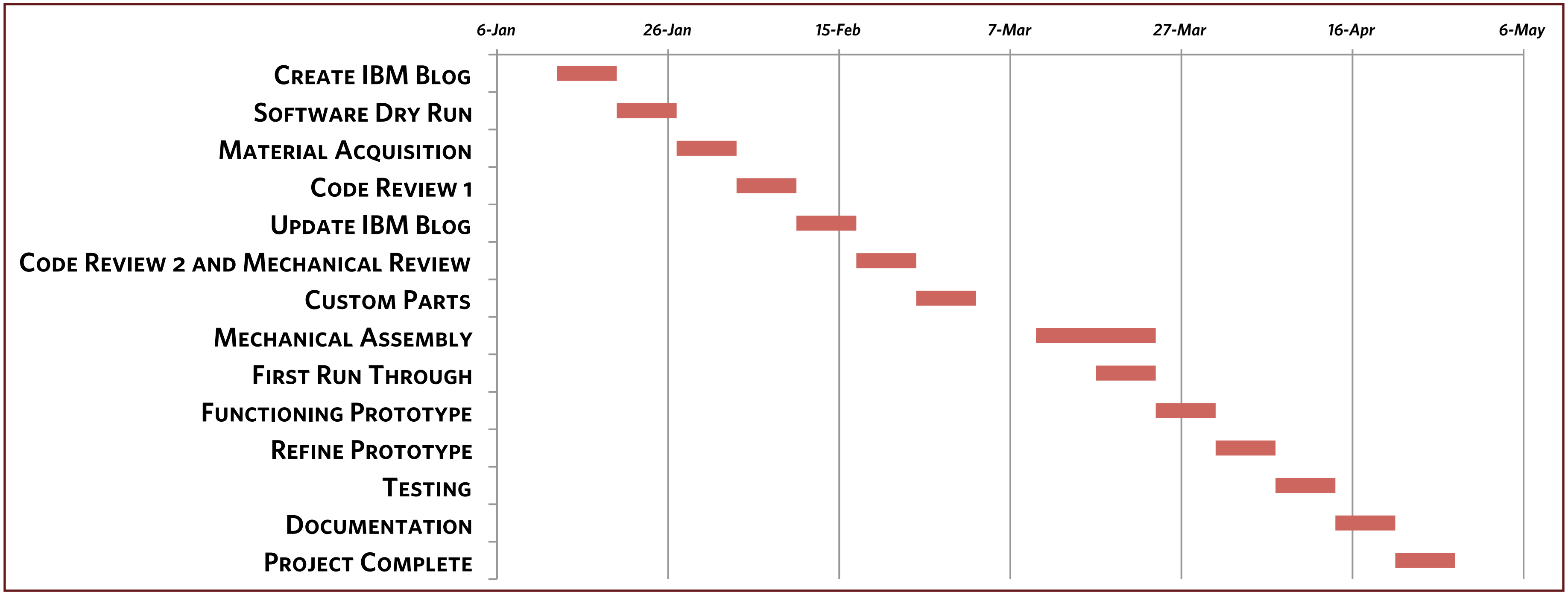

Table 5. GANTT chart for project completion in Spring 2014 semester.

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