December 17, 2020

Dr. Robert "Bobby" Grisso & Dr. Edwards

Department Head & Professor of Biological Systems Engineering

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Dear Dr. Grisso and Dr. Edwards,

Enclosed please find the analysis of potential solutions report for our project, “Designing an Electronic Clinical Opiate Withdrawal Scale.” This report includes two design alternatives for the electronic clinical opiate withdrawal scale itself as well as two design alternatives to measure pulse rate, which is a symptom on the scale. The analysis of these potential solutions significantly impacts the design of the device.

Attached are also appendices containing an updated Gantt chart.

Our advisors, Andre A. Muelenaer, Jr, M.D., M.S. and Grace Wusk, have had the opportunity to review this document.

Sincerely,

Kirin Anand

Samantha Brendle

Zixuan Guo

Nicholas Nguyen

Gregory Suliga

Analysis of Potential Solutions in an Electronic Clinical Opiate Withdrawal Scale (eCOWS)

BSE 4125 Comprehensive Design Project

December 17, 2020

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Introduction

Opiate addiction has become a rising problem in the US, and today can be considered an epidemic. Since the late 1990's, there has been a steady increase in opioid misuse and subsequent death (CDC, 2015). However, the detriments from opioid dependence are more than meets the eye. Withdrawals from opioids negatively impact individuals physically, mentally, and emotionally, but there are even greater consequences. There is a variety of literature depicting the detrimental effects of opiate addiction; for instance, opioid dependence leads to a massive economic burden on society due to increasing health care costs and unemployment rates, and mortality among other things (Huecker et al., 2020). These consequences tear apart families and, in some countries, can cost up to 3% of the GDP (White House, 2017).

The eCOWS group hopes to do our part in fighting this crisis through engineering design. This group consists of Biological Systems Engineering students looking to apply what we have learned to develop a successful wearable device for those going through opiate withdrawal. We look to create a device able to monitor adults undergoing opioid withdrawal. The team has been tasked with developing such a device that can seamlessly monitor different physiological effects based on the clinical opiate withdrawal scale, to then communicate a score indicating whether the user is maintaining sobriety.

In order to develop this wearable system to measure the clinical opiate withdrawal scale (COWS) electronically, the team has established goals and objectives to ensure the project moves forward in the right direction. These goals revolve around designing a user-friendly system that can evaluate opiate withdrawal based on the already made clinical opiate withdrawal scale. This pen-and-paper assessment is frankly outdated, and in need of a more immediate electronic assessment for clinical use.

Potential Solutions

The first and most general issue our team had to solve was to create a device capable of taking objective and rapid measurements of opiate withdrawal symptoms. Objectivity and quickness of measurement could thus be construed as our two requirements.

The first proposed solution was thought of by the previous senior design team. This team came up with a MATLAB program that, when coupled with a Raspberry Pi 3b+ coding software and various sensors, outputted objective scores for withdrawal symptoms. Therefore, this MATLAB system is the first potential solution to a more effective clinical opiate withdrawal scale. The three sensors utilized were the Shimmer3 GSR+ (Galvanic Skin Response), the Polar H10, and the Reflex Eye Tracker iOS application. The Shimmer3 has a GSR+ which measures changes in sweat gland activity, and an accelerometer. Consequently, the Shimmer3 is capable of measuring electrodermal activity (EDA), electrical characteristics or conductance of the skin, and photoplethysmogram (PPG) signals. PPG signals will be discussed in further detail later in the paper. Additionally, the accelerometer in the GSR is capable of measuring acceleration forces such as movement or vibration. The three sensors gather data from a patient and send this, in the form of bluetooth streams, to the Raspberry Pi coding software. The Raspberry Pi then transfers this data to a computer, which further processes the data using MATLAB. The MATLAB code then generates scores for the withdrawal symptoms that were measured, and subjective scores that are not able to be measured by the sensors require user input. Finally, all of the scores are summed, yielding an overall clinical opiate withdrawal scale total score. Ultimately, the MATLAB system is capable of objectively measuring a number of opiate withdrawal symptoms that are listed on the clinical opiate withdrawal scale.

The second proposed design solution is what our team came up with this year: an iOS app. With an app, an electronic clinical opiate withdrawal scale could be able to be used in hospitals around the country with the same standards as the COWs. The three sensors used in the previous solution will still be used here, but the Raspberry Pi coding software will not be needed. The iOS app will use bluetooth to gather the appropriate COWs objective data from the sensors, and the patient will then answer the remaining COWs subjective questions through the app for a final withdrawal score to be emitted. In comparison with the MATLAB solution, an iOS application would be significantly more accessible. In fact, certain hospitals such as Carilion Clinic provide iPhones to their physicians, and it is a possibility that this will be a growing trend in hospitals around the country. Noting the increased prevalence of iPhones and Apple technology being adopted into hospitals, an electronic clinical opiate withdrawal scale application will be able to provide faster, more objectively accurate assessments to withdrawal patients, thereby allowing clinicians real-time data used for treatment. In comparison to the

MATLAB solution, the iOS application solution would be more user-friendly and accessible while not sacrificing objectivity or quickness of measurements.

The other issue that needed to be addressed was how to measure the opiate withdrawal symptoms with the sensors in our possession. While many of the symptom measurements were straightforward, the one symptom facing the most debate was pulse rate. The Shimmer3 GSR+ and Polar H10 were both capable of measuring pulse rate, so it was imperative to analyze both potential solutions. It is important to note that solution requirements include accuracy, reproducibility, and speed.

The first proposed design solution for the measurement of pulse rate was through the PPG of the Shimmer3 GSR+. PPG finds the electrical signals from light that are reflected due to variations in blood flow in an active heart. It then converts these signals to estimate a heart rate.

The second proposed design solution for the measurement of pulse rate was through the ECG of the Polar H10. The ECG utilizes the electrical signals made through heart activity and can identify a variety of waves. The P wave is the first identifiable wave, where the peak results from the depolarization of atrial muscle cells, where an SA node fires at the start. When this electrical impulse reaches the ventricles from the first atria, this produces a QRS complex. Finally, the repolarization of ventricular muscle produces a T wave. The ECG determines the distance, in number of boxes, between QRS complexes. This distance corresponds to beats per minute (BPM). For example, if the QRS complexes are a distance of one box apart, BPM = 300. If the QRS complexes are a distance of two boxes apart, BPM = 150. Three boxes apart would equate to a BPM of 100, and the BPM continues to decrease as distance between QRS complexes increases. Thus, the ECG of the Polar H10 interpolates to find the exact distance between QRS complexes and outputs a pulse rate in beats per minute that is based on this distance.

Analysis and Ranking of the Results

Both of these options (MATLAB and Raspberry Pi, iPhone application) seemed promising, along with the added benefit of continuing the work from the previous group, made it a difficult decision to make in terms of which option to pursue. Both options do what we need them to do, so in order to visualize things in a more detailed and quantitative perspective, a decision matrix was made. This matrix is displayed below in Table 1 with categories and weights we deemed appropriate for the devices.

Table 1. Decision Matrix for Alternate Design Solutions for eCOWS

Criteria	Weight	IPhone App	Sensors + Raspberry Pi
Ease of use	.25	5	2
Cost	.1	5	2
Device Safety	.1	4	4
Measurability of multiple COWS symptoms	.25	3	4
Time and accuracy	.2	4	2
Integrates well with COWS form for unmeasurable symptoms	.1	5	3
Total Score	1	23	17
Weighted Score	--	4.2	2.8

Despite the initial concern about the two systems being similar in performance, the decision matrix really helped us to identify what was important to us and to analyze the two options with high precision. Overall, the iPhone application was the clear choice, as it has the potential to perform just as well as the Pi + Sensors option, but thrives in other aspects that are very important in a clinical setting.

Many of the categories used in the decision matrix were derived from a discussion our group was able to have with Dr. Trestman, the Chair of Psychiatry and Behavioral Medicine at Carilion Clinic. In talking with him, we were able to get his opinion on our two different design options as well as what kind of things are important to a physician in a clinical setting. We learned about EHR (or Electronic Health Records) and the importance of integration with those systems. In our case, it was actually quite important to develop a system that would work well with the current COWS system in determining a COWS score from the symptoms we were not able to measure with the sensors. Expediting the process and creating less steps for the doctors, nurses, and medical assistants was more important than we thought; we consequently decided to add it to our decision matrix.

As you can see from the matrix, the application excels in every category except the measurability of COWS symptoms. While it does well, the Raspberry Pi has more potential and ability to measure more because it is only limited by the number of sensors we have. Nevertheless, the App excels in every other category. The ease of use for both the operator of the device as well as the healthcare workers transferring data is incredibly good. Everything being done wirelessly as well as potentially integrating with the EHR if the hospital uses an Apple/iPhone system (like Carilion) is very important. Cost and safety are also both important, and once again something the App option does very well. Both options are safe as the operation will always be non-invasive and comply with standards in terms of avoiding sharp/small objects, etc. Furthermore, the development of an application is relatively inexpensive. Their new XCode open source app, which makes software, has made it easy to put together the framework for our application without cost. On the other hand, some of the sensors needed for the Raspberry Pi can get expensive, so it would be costly to try and implement a system like that on a large scale. Finally, the category of time and accuracy was one we wanted to make sure to mention. It is imperative that our system provide accurate results for the patient which they both do, but the application is able to complete that in a much more timely manner than the Raspberry Pi as there is much less setup and computing time required.

Table 2. Decision Matrix for Alternate Design Solutions for Measuring Pulse Rate

Criteria	Weight	ECG	PPG
Accuracy	.6	5	3
Reproducibility	.2	4	4
Speed	.2	3	4
Total Score	1	12	11
Weighted Score	--	4.4	3.4

This matrix showcases that ECG is the superior method of measuring pulse rate when compared to PPG. It is more accurate, as there is less estimation and conversion in an ECG than a PPG. Furthermore, the pulse rate gathered from an ECG is more reproducible because an ECG is considered the standard method of measuring, and are consequently more accessible. That said, a PPG does gather and output pulse rate data faster than a ECG. Speed is undeniably an important criteria for measuring withdrawal symptoms, but the lower accuracy of the PPG does not warrant its use as opposed to an ECG.

Conclusion

In conclusion, based on the decision matrix in Table 1, the iPhone App scores better than the Sensors + Raspberry Pi. The iPhone was consequently chosen as the optimal method of a clinical opiate withdrawal scale moving forward. This is due to its safety, low cost, ease of use, and quickness. Furthermore, the ECG method of obtaining pulse rate outweighed the PPG method, and the former was thus chosen as the potential solution. This was because the ECG exhibited greater accuracy, reproducibility, and speed. Ultimately, through careful weighing of the benefits vs. detriments, the iPhone application and ECG will be utilized in electronic clinical opiate withdrawal scale.

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Appendices

Appendix 1. Gantt Chart