Preliminary Report - Continuous Monitoring of Asthma Control

BME 200/300 - Fall 2016

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This project entails creating an efficient and accurate method of continuously monitoring asthma symptoms in severe asthmatic patients. Currently, the symptoms of an asthma exacerbation are not sensed by the patient until days after the exacerbation has begun. These asthma exacerbations are typically only diagnosed in clinic, which results in a delayed start to the patient's asthma action plan (AAP). The implementation of a continuous asthma monitoring shirt will alert patients to begin their AAP before needing to make unnecessary trips to the hospital, thus saving a large portion of hospital resources that are being used on asthma related visits. This asthma shirt will be composed of two microphones, built into a shirt, that sit on each side of the patient's lower back. They will record three common asthma exacerbation symptoms: respiratory rate, coughing, and wheezing. As the project continues, this report will expand to include testing results and implications from data analysis.

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Introduction

In the United States alone, approximately 26 million people suffer from asthma with related costs estimated to be $60 billion annually [1]. There is no cure for the disease, so patients are forced to treat their symptoms rather than cure them. In recent years, there has been an increase in the number of asthma diagnoses, and with that, an increase in severe asthma patients [2]. These severe asthma patients, while only 5-10% of total asthmatics, have symptoms that are more intense and more frequent. Consequently, this small population accounts for a disproportionate amount of health-care cost, hospital admissions, doctor visits (both scheduled and unscheduled) and emergency services [2]. These patients have asthma action plans (AAP) in place to treat asthma exacerbations before they become too severe, but many times the symptoms are not felt for a couple of days. If the symptoms of these asthma attacks could be detected earlier, the patient's AAP could be started sooner, saving both time and resources. This could potentially be solved with a device that continuously monitors asthma symptoms.

Currently, there are no devices that can continuously monitor asthma symptoms and alert patients when an asthma exacerbation has started. Often, a spirometer test is used to assess an individual’s asthma. One measurement commonly used from spirometry is FEV1, or forced expiratory volume in 1 second [3]. It uses the maximum amount of air an individual can forcefully exhale in 1 second to gauge lung function [4]. This is often done in a clinic after the patient begins to notice symptoms. Home based spirometer tests do exist, but these are less common, do not measure continuously, and are typically used after symptoms are felt as well.

The main asthma symptoms, wheezing, coughing, and change in respiratory rate, are often not experienced by the asthma patients for a couple days after the they begin to appear. A device that could detect these symptoms sooner would lead to faster implementations of AAPs. While the target patient for a device such as this would be a small percentage of asthmatics (those with severe asthma), they use a large portion of the medical resources. If a device could alert the severe asthma patients to the signs of an asthma exacerbation earlier than current methods, it poses the potential to save significant amounts of time, money, and resources while also potentially decreasing the severity of the asthma attack.

Background

Asthma is a chronic condition characterized by inflammation and narrowing of the bronchial tubes [2]. These two tubes, which are branches of the trachea, are crucial to the function of the respiratory system since all air entering and leaving the lungs flow through them [5]. As the airways constrict, breathing becomes increasingly difficult and the performance of the respiratory system suffers. The respiratory system is responsible for supplying oxygen to the red blood cells while simultaneously removing carbon dioxide. When the respiratory system does not work correctly, the lack of oxygen can cause major issues [5]. A complete lack of oxygen, known as anoxia, or even a decrease in oxygen, known as hypoxia, can be fatal. Asthma is responsible for 3,300 deaths annually in the United States alone [1]. Even just four minutes without sufficient oxygen to the brain can cause brain cell death, and the results can be permanent.

There are four main symptoms of asthma: coughing, wheezing, chest tightness, and shortness of breath [1]. Nevertheless, the specific symptoms felt and their severity can vary from one individual to the next. Unfortunately, this can cause the disease to go unrecognized, under diagnosed, and undertreated [6]. Asthma severity can greatly increase from poor or inconsistent treatment, which makes the asthma more difficult to control and treat [2]. An asthma exacerbation is an acute worsening of the disease. Often, asthma triggers are responsible for the attack. These triggers can be airborne such as pollen, pet dander, mold, smoke, and chemical fumes [1]. Other triggers include sickness (often the cold or flu), exercise and stress. When asthma exacerbations occur, their symptoms may not be felt by the patient for a few days. This causes the symptoms to worsen and makes treatment more difficult.

For severe asthma patients, approximately the top 10% of the total asthma population, asthma exacerbations can be more common and their symptoms more extreme [2]. Even after the asthma is under control, it can take up to a month for the patient's lung function to return to normal. This heightened airway inflammation and extended recovery time can take a toll on the bronchi. The tissue destruction and airway remodeling in severe asthma patients creates a “chronic wound” with ongoing epithelial injury and repair [2]. Over time, these conditions can lead to thickened and stiffer airways, which are more resistant to anti-inflammatory drugs. This demonstrates that the damage from asthma exacerbations can last long after the asthma is under control.

The best solution to this problem is prevention. Dr. Sameer Mathur is an allergist working at the UW-Madison School of Medicine and Public Health. His knowledge and experience with asthma has prompted him to look for new alternatives to asthma treatment and prevention. He believes that if the symptoms of an asthma exacerbation can be detected even before the patient feels them, the asthma can be treated more quickly and easily which could ultimately reduce the number emergency room visits, hospital admissions, and even deaths. The goal is to create a wearable “asthma shirt” that will be able to detect various lung sounds that are characteristic of asthma-- specifically coughing, wheezing, and respiratory rate. With the guidance of Dr. Mathur, the team was able to come up with specific produce design specifications. The full PDS can be found in Appendix 2, but a few important features are noted below.

The device created must be able to accurately and reliably detect the different asthma sounds of the lungs. This is crucial to ensuring the results are precise and consistent. The device will be integrated into a shirt. At this stage, the size, weight and aesthetic are not important parameters of interest. The shirt will be in direct contact with the patient, so the material of the shirt and the device should be safe and reasonably comfortable on the skin. In addition, the device should be able to run for at least four hours at a time for testing. The group has a pre-approved IRB protocol that allows the shirt to be tested on asthma patients undergoing methacholine tests. These tests last approximately four hours and hence, the device should run for that amount of time. More protocol specifics will be discussed in the Testing section of this report.

Preliminary Designs

The first design that we considered was a thermistor mask. This mask would include a thermistor within voltage divider that feeds into a non-inverting amplifier, and the final output would be fed into a microcontroller. This circuit would be contained within a housing attached to the mask, and the thermistor would be placed inside of the mask. Due to the variability of a thermistor's resistance as the external temperature changes, the output voltage would change in a predictable way depending on the temperature within the mask. This would allow us to accurately predict the breathing rate of the patient. As the patient's breathing rate increases, the temperature inside of the mask would increase, and the opposite as the breathing rate decreased. Since the mask is only able to take measurements based on temperature, coughing and wheezing data would not be obtainable. Figure [1] in Appendix 1 gives an example of the type of mask that would contain the thermistor and circuit.

The next design that we considered was an asthma shirt with built in microphones to detect the asthma symptoms. The two wired microphones would be placed over the patient's lower back. Although two microphones could complicate the analysis of the data, it is necessary to take readings from both of the patient's lungs as each lung could have different lung sounds. These microphones are then fed into LabVIEW for post analysis. The group will then create predetermined thresholds of frequency for coughing, wheezing, and respiratory rate. The recorded data from the patient would then be compared to these thresholds to determine whether the patient is showing signs of an asthma exacerbation.

The third, and final design, would replace the microphone from the previous design with an electronic stethoscope. The same thresholds would then be determined for the asthma symptoms and compared to the data that is recorded by the electronic stethoscopes to determine if the patient is having an exacerbation. Figure [2] in Appendix 1 gives an example of how the microphones and electronic stethoscope would be incorporated into the asthma shirt.

Preliminary Design Evaluation

Criteria (weight) \ Design	Thermistor Mask		Microphone		Electronic Stethoscope	
Patient comfort (25)	2/5	10	4/5	20	4/5	20
Effectiveness (20)	2/5	8	4/5	16	4/5	16
Ease of Use (20)	2/5	8	4/5	16	4/5	16
Cost (15)	5/5	15	5/5	15	1/5	3
Adjustability (10)	3/5	6	4/5	8	3/5	6
Safety (10)	4/5	10	5/5	10	5/5	10
Total	**55**		**85**		**71**	

Proposed Final Design: Microphone

Patient Comfort is defined as the level of comfort in the overall experience of using the device. We chose this as a criteria because the device is being created for use in the patient's everyday life. In order to obtain useful data, the device must be worn for at least four hours per day. Due to its frequency of use, the patient's overall comfort level is extremely important, thus justifying our highest overall weight. We gave both the electronic stethoscope and the microphone a score of 4/5. For both of these devices, the patient will have readings taken from either their back or chest areas. They both received such a high score due to the minimal discomfort that would be necessary to take breathing readings. The thermistor mask would collect data by being placed over the mouth of the patient while they are breathing, creating a higher level of discomfort. For this reason, the thermistor mask received a score of 2/5.

Effectiveness is defined as the accuracy with which the design will be able to capture information related to asthma symptoms. We gave effectiveness a weight of 20, which is tied for our second highest weight. This category was included because accurate and effective data collection is extremely important in the diagnosis of these asthma symptoms. The thermistor mask received a score of 2/5 due to the possibility of complications related to the ambient temperature that could come from other external sources. Also, the thermistor mask could only be used to measure breathing rate. The microphone received a score of 4/5 and was tied for our highest score because it can effectively measure the sound of someone breathing and has the potential to block out ambient noise with the use of thresholds in the post-analysis. The electronic stethoscope received a score of 4/5 as well because electronic stethoscopes effectively detect breathing sounds while canceling out ambient noise.

Ease of Use is defined as the ability of the design to be implemented effectively. It is crucial that a wide number of patients and doctors are able to use the device easily and efficiently. Due to it's importance in the success of the product, this category also received a weight of 20. The thermistor mask was given the lowest out of all with a score of 2/5. While the mask does produce results, its use is cumbersome and invasive, not allowing the patient to perform everyday tasks while data is being taken. The microphone and the electronic stethoscope were both tied for the highest with a score of 4/5. In both cases, the design would be built into a shirt. The patient only needs to put on the shirt in order to start using it, making it very easy to use. At this point, the system would still need to be hooked up to a computer instead of being wireless, which is why they did not receive a full 5/5.

Cost is defined as total expenses needed to create the device. This category received a weight of 15, which is one of the lower scores. Due to the limited funds available for this project, cost is a constraint on our design, but nevertheless we felt other categories were more important to the design. The thermistor mask and microphone received perfect scores of 5/5. These designs would be the cheapest to make since they consist of various inexpensive pieces. Lastly, the electronic stethoscopes received a score of 1/5, since it is by far the most expensive. The cost of these instruments are much greater than the other designs, and therefore they were assigned the lowest score.

Adjustability is defined as the amount of change we can make in our design to fit our patients needs. This includes where we can put the device on the patient and our ability to move it or adjust is for better comfort or usefulness. We gave it a weight of 10 because it once you have it on, it shouldn't need to move. We chose this category because it is important for the device to be adjustable because the better the fit, the better data we can record. We gave the Thermistor mask a 3/5 due to the lack of customizability of a standard face mask to add to the patient's comfort. The microphone received a score of 4/5 because we will be designing the housing and shirt for the patient to wear. This gives us a tremendous amount of ability to move things around and play with where everything goes. The electronic stethoscope received 3/5 because we have to buy an already made stethoscope. This doesn't allow us as much design freedom because we have to follow whatever specifications come along with the stethoscope.

Safety is defined as how likely the patient would be able to perform the diagnosis without being harmed. We gave safety a weight of 10 because we believe that none of these designs would cause the patient any serious pain or would be dangerous. We still want to consider the patient's safety because this is a medical device that the patient will use extensively and we want to minimize the potential for the patient to be injured. We gave the thermistor mask a 4/5 because it covers the patient's face and if the patient has a hard time breathing this might make it even harder for the patient to breath. We ranked both the microphone and the electronic stethoscope a 5/5 because it does not pose a great safety threat. The patient will not be in direct contact with the circuit, so even if it were to fail, the patient would not be harmed.

Fabrication/Development Process

Materials

The materials will consist of two microphones, a microphone casing, an arduino, numerous wires, along with other equipment that is offered to us through the Bioinstrumentation lab. The two microphones will be used to pick up the audio signals from the lungs. The microphone casing will be needed to hold the microphones and decrease ambient noise levels that could cause interference with the audio signal. The wires will send the audio signal from the microphone to the arduino, which will then relay the signal to the LabVIEW program for post analysis. The total price for this project is not known at this time but arduinos cost roughly $30 and the two microphones roughly $20 depending on the quality of the microphone. Most of the other items are inexpensive, so our goal is to keep the overall price of the asthma shirt under $100.

Methods

In order to make the prototype we will need to first order microphones that are able to detect the low frequency noises within the lungs such as change in respiratory rate, coughing, and wheezing. We will then have members of our team, with green pass credentials, machine the housings for our microphones. This housing will be large enough to contain the microphones and help to cancel ambient noise, but small enough to maintain the patient’s comfort once it is placed within the shirt. The microphone will then be connected to the to the arduino microcontroller which will be housed within a small pocket on the side of the shirt. A complementary circuit might be implemented if the audio signal needs filtering or amplification, but this is not known at the time. Finally, the microcontroller will be connected to the LabVIEW program for post analysis.

Final prototype

Our final prototype will consist of two microphones connected to an arduino. When in use, the two microphones will be fixed to the back of asthma shirt in a predetermined position to maximize data collection of the asthma sounds.

Testing

As of now we have not done any testing, as we have not yet fabricated the asthma shirt. After we have fabricated the asthma shirt, our initial testing will be done on the team itself to verify the accuracy and consistency of the device for normal lung functions. We will try to detect a normal breathing signal to determine this. The next step will be determining the thresholds for respiratory rate, coughing, and wheezing in asthma patients. Dr. Mathur has a pre-approved IRB protocol that allows the team to test the shirt on asthma patients undergoing methacholine tests. This test will stimulate an asthma exacerbation in the patient and our device will be able to record the change in respiratory rate, coughing, and wheezing sounds as the lung function decreases. This data will be used to determine different frequency thresholds for coughing, wheezing, and respiratory rate of patients undergoing asthma exacerbations.

Results

At this time we have not conducted any tests because we do not have a finished prototype. Results will be reported as soon as data is obtained.

Discussion

After we have determined the thresholds for diagnosis and performed testing on asthma patients through Dr. Mathur's IRB protocol, we will have the proof of concept that Dr. Mathur needs to continue developing the shirt. If our results indicate that the asthma shirt is able to successfully and accurately alert the patient of an asthma exacerbation it will deem the shirt as a useful method in preventing dangerous asthma attacks. This would mean that the shirt can further be developed to reach its potential as a continuous monitor for asthma controlling. In the future, the team hopes to be able to add other functions to the shirt for monitoring asthma, such as thermistor bands that measure lung volume changes. As mentioned earlier, this application of continuous asthma control will help reduce the high usage of hospital resources on asthma related incidents, and will help severe asthmatics live with a higher sense of security.

Conclusions

The creation of an asthma shirt holds the potential to decrease the number of emergency services, hospital admissions, and doctor visits for those with severe asthma. Since the asthma symptoms felt by patients can be delayed for up to two days after the exacerbation has started, the patients are already experiencing decreased lung functions. By reducing the time between the start of the asthma attack and the start of the AAP, the level of inflammation and amount of lung function lost can also be reduced. This is especially important for severe asthma patients whose asthma exacerbations are more intense and harder to fight. In addition, it takes these patients longer to return to full lung function as well. Any time saved can greatly improve the quality of life for severe asthma patients. There is no cure for asthma, and so the only solution is treatment. The asthma shirt poses great potential not only to change the way asthma is treated but also to prevent asthma exacerbation before they become severe.

References

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Appendix 1

Figure [1] : Thermistor Mask
http://justnebulizers.com/media/catalog/product/cache/15/image/a6711d7f987d93e940f67d503f6808af/R/-/R-MASK-003PCN-BI-01.jpg

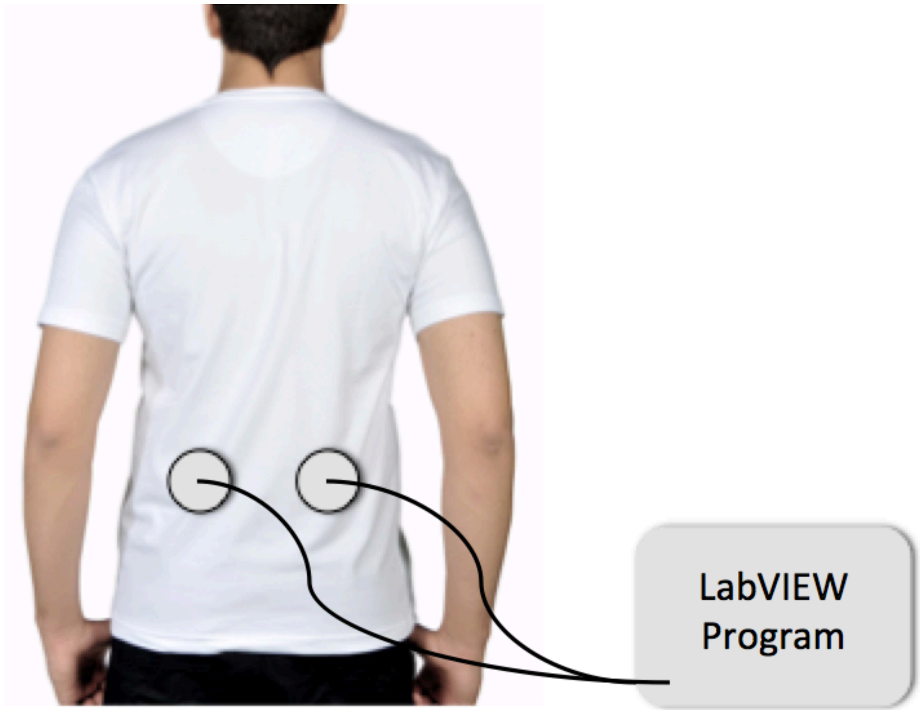

Figure [2] : Microphone and Electronic Stethoscope placement

Appendix 2

Continuous Monitoring of Asthma Control
Preliminary Product Design Specifications

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Function:

The function of our product will be to continuously monitor asthma patients. Oftentimes, patients who undergo asthma exacerbations do not notice the effects under two days after they have started. For example, FEV1 (forced expiratory volume in one second) oftentimes drops 20% before the patient realizes any change. Our product will be able to detect these changes and alert the patient to start their asthma action plan (AAP) and hopefully prevent emergency medical attention.

Client requirements:

- The client does not want use to try and tackle the entire "asthma shirt" but rather start on just part of it
- The first focus of the project is to design a device to monitor lung sounds (breathing, coughing, wheezing, etc.)
- The client suggested using a stethoscope inspired microphone system to capture the sounds, but the team will explore other options as well.
- The sound acquisition device will most likely need to be set up to an arduino and probably a complementary circuit system.
- There are not any "thresholds" or previously determined measurements for this type of data, so we will have to try and figure those out on our own
- The primary focus for this semester is not to necessarily have a complete, finished product by the end, but rather prove that this type of work is really plausible.

Physical and Operational Characteristics

a. Performance requirements: The microphone must accurately detect sound differences in asthma symptoms such as wheezing and coughing. Typical FEV1 will drop almost 20% before symptoms are felt by the patient. Our microphone will detect these symptoms before the patient's FEV1 drops to this level.

b. Safety: Safety is not huge concern with this device because there is very low potential for danger. The only safety concern for this will be ensuring that the microphone's circuit does not short, and cause any harm to the patient that is using it.

c. Accuracy and Reliability: The microphone must accurately detect the changes in sound of these asthma symptoms while maintaining a consistent threshold for detection. It must also not interpret outside noise as a false asthma symptom.

d. Life in Service: Due to the fact that this is continuous monitoring of asthma symptoms, there will be no limit on the microphones life in service. It will only end if there is another technology that is more effective than this microphone.

e. Shelf Life: Preferably the product wouldn't be affected by sitting around not being used since there is no organic material on it to spoil. It should mostly consist of polymers and rubber for the microphone.

f. Operating Environment: The device will have to be able to operate smoothly while being on or near the skin. This means it should be water resistant up to the point of being considered sweat proof.

g. Ergonomics: The device needs to be able to fit comfortably against the skin so as not to be uncomfortable.

h. Size: The size of the device doesn't matter as much as proof of concept at this point in the design process.

i. Weight: The main concern is that the patient will be able to wear the shirt. This means that the product will need to be light enough to wear without much discomfort. Our focus is on data collection so the weight will be addressed later.

j. Materials: Since the microphones will be placed against the skin, they must be sweat and water-resistant.

k. Aesthetics, Appearance, and Finish: The primary goal is functionality. Aesthetics will only be addressed as a concern at the end of the project if there is time.

Production Characteristics

a. *Quantity:* We will need to develop the recording system for one shirt. This design will likely incorporate 2 microphones.

b. Target Product Cost: Currently, there are no similar products like the one we are working on in which to compare the expected cost. There was a group who worked on this project last year, and were able to develop a similar shirt for just under $300. We were not given an explicit budget during our first client meeting, but we hope to keep a similar or lower cost than the previous group.

Miscellaneous

a. *Standards and Specifications: As of now this product will not need FDA approval but if it is implemented in the future for diagnosis it will.*

b. *Customer: As of now our customer wants us to just focus on the microphone. Our customer does not mind if outside noise is picked up by the microphone, as long as a good 10-15 minute period of lung sounds can be heard in a 24 hour period. The microphone must be able to distinguish between wheezing and normal lung sounds. It must also be able to send this information to an arduino to be saved and used for analysis.*

c. *Patient-related concerns: If the microphone in the shirt can not filter out outside noises the patient may worry about their privacy. There will have to be a system implemented so the patient's privacy may be protected. Another concern will be on how to properly wash the shirt. The patient most likely will not want to wear the same shirt all the time.*

d. *Competition: As of now there are no similar items that exist. The closest thing is wearable technology like fitbits and hexoskin shirts but those have nothing to do with asthma.*