AIR PATCH

An innovative continuous wheezing-detection patch designed to mitigate reliever inhaler overuse and achieve better asthma control

Angela WANG: Overuse Research, Artwork
Clarice TAN: Device Design, Artwork, Algorithm Research
Daria AZHYSHCHEVA: Cost and Acceptability Research
Matthew YEUNG: Background research, Graphic Design
Xiang Ying KHAW Background research, clinical trials, feasibility and social acceptability, proposal
Zachary TAN: Detection algorithm research and proposal

Our References

CONCORD COLLEGE

What is Asthma?

Chronic inflammatory condition of the airways which can result in coughing, wheezing, chest tightness and shortness of breath. Asthma may develop as a child or present symptoms for the first time during adulthood. Currently, there is no cure for asthma but symptoms can be kept under control with the correct treatment.

The effect of badly controlled asthma to quality of life

- **Sleep Disturbances**: Poorly controlled asthma can lead to sleep disturbances, causing fatigue and decreased concentration.
- **Educational Challenges**: Children with asthma may experience frequent absences from school, reduced participation in activities, and potential bullying from peers.
- **Work-related Issues**: Adults with poorly controlled asthma may face difficulties attending work regularly, leading to missed workdays and decreased productivity.
- **Mental Health Impact**: Research indicates a strong association between asthma and higher levels of anxiety and depression, negatively affecting overall quality of life.
- **Social Limitations**: Ongoing asthma symptoms may require individuals to avoid certain environments or activities, potentially limiting social interactions and experiences.

Asthma attacks kill three people in the UK each day and every 10 seconds someone has a potentially life-threatening asthma attack

Wheezing

Wheezing occurs due to localised obstruction of the airways, spanning from the larynx to the small bronchi due to the oscillations within partially constricted airways. Firstly, air flows through the constricted airway at a high velocity, decreasing the gas pressure according to Bernoulli's principle. Further, the internal airway pressure gradually increases allowing for a partial reopening of the airway lumen.

Overuse of Reliever Inhalers

Reliever inhalers contain short-acting beta-2 agonists which aid in the dilation of airways. Many asthmatic patients have overreliance on their reliever inhalers leading to breathing difficulty, fever, death and anxiety.

Asthma + Lung UK conveys that 1 in 5 asthmatic patients are overusing their reliever inhalers (triple the recommended amount annually). This overuse leads to increased risk of asthma attacks, hospitalizations and deaths. Thus, the problem lies within asthmatic patients not knowing when to use their reliever inhalers and mistaking them as short cures.

With notifications signalling asthmatic patients to use our smart inhalers, we hope to prevent the overuse of reliever inhalers. We believe that controlling the use of inhalers is crucial in treating asthma.

Our Proposal -Think continous glucose monitoring but continuous wheeze monitoring for asthma

Objectives:

- **Detect** early warning signs of asthma attack
- **Prevent** overuse of beta-2 agonists inhaler

How it works:

1. The sensor turns out through the app on their phone
2. Identifies oncoming asthma attacks through a calibrated sound detection algorithm
3. Sends a warning to the patient through an app on their phone, reminding them to use their smart inhaler
4. Smart reliever inhaler delivers the exact amount of beta-2 agonists to the user based on the severity of the wheezing
5. Silicone adhesive to reduce risks of allergic reactions
6. 24/7 monitoring for nocturnal asthma
7. Powered by battery packs

Once wheezing or silent chest is detected by the device's algorithm, the device emits a Bluetooth signal to the user's device which emits a visual and auditory warning, reminding them to use the smart inhaler provided. The Bluetooth signal is also received by the smart inhaler, which releases the exact volume required to stop the symptoms of the asthma attack. Finally, the algorithm continues monitoring the patient's breathing frequency and rate to ensure it returns to its regular range - if further use of inhaler is required, another signal will be sent to the inhaler.

Pros and Cons

Pros:

- Promise that we will treat asthma attacks early before symptoms worsen
- Reduces carbon footprint due to the reduced overuse of reliever inhalers as inhalers account for 13% of NHS carbon footprint within primary care

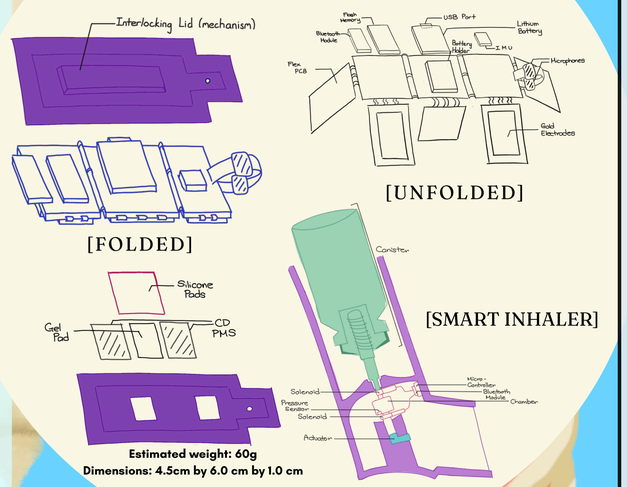
Cons:

- A large database is needed but we will conquer this by using a large database of respiratory sounds provided by collaboration with NHS
- Long term hardware replacement
- Labour cost of training asthma nurse and patient education

Acceptability

The Air Patch promises to prevent the progression of asthma attack by treating symptoms early and prevent overreliance on reliever inhalers. Asthma is a disease which can be lived with so we allow patients to improve their quality of life by keeping their symptoms under control. Further, the asthma nurse will be taught to teach asthmatic patients on the correct method of using our Air Patch and inhaler.

Hardware of Air Patch



Physical Components and Software

Air Patch

Double microphones: One exterior facing, the other interior facing

- Allows for more efficient removal of exterior noises via algorithms for clearer wheezing sound detection
- protected with a layer of thin gortex for water resistance yet for sound penetration

Flex PCB: Flexible

- Allows for compact folding and less space taken up within the device creating a more seamless medical intervention
- Can bend to the contours of the wearer's body, making moving around with it more comfortable and discrete
- Contains the wheeze detection algorithm, but does not analyse the severity.

Bluetooth Module: Transmits recorded wheezes via Bluetooth signals to the smart inhaler to dispense the correct dosage of beta-2 agonists specific to each frequency of wheezing.

Gel Pad: Thermoresponsive

- Sensitive to changes in temperature; the gel within it will expand to increase the distance between the skin and the device's circuitry if the board short circuits or overheats.

Carbon sensors (CD PMS): Measures ECG signals

- Converts these signals into derived respiratory information by processing the correlation of heart rate to tidal volume, allowing for another data point to see the change in tidal volume in the patient during their attack and ensure an accurate volume of beta-2 agonist to be dispensed.
- It acts in tandem with the wheezing frequencies detected to distinguish between wheezing from asthma attacks and other respiratory infections which may result in wheezing as to prevent false positives and unecessary inhaler usage.

Silicone Pads: Flexible conductive surface for bendable connections between layers

IMU: accelerometer to detect breathing rates which will be used to detect silent chest

Li-po batteries (45mAh): The device has a working life of 30 hours

- The battery holder contains the battery pack which is sealed with an interlocking mechanism to allow the device to be water resistant
- Each Air Patch comes with 2 battery pack with a USB port for charging so patients can replace the battery packs while one charge.

Adhesive : 3M Medical Tape 1526 (breathable, hypoallergenic adhesive)

Inhaler

As it monitors the wheezing sounds from the lungs, an algorithm compares the severity of the wheezing to the **ICBHI Respiratory Sound Data Base,** analyses them and deduces the severity of the asthma attack. Consequently, it calculates the amount of medication required and sends this information in the form of pressure detection within the second chamber - as pressure is directly correlated to the volume; and mass of the liquid within the chamber.

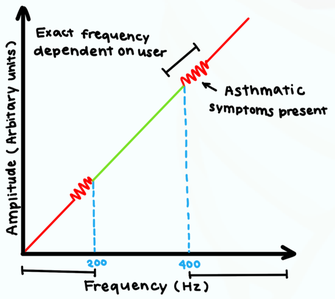
Pressing down on the canister opens the first valve, releasing the metered dosage into a second chamber with a pressure sensor in it. The pressure sensor automatically dedicates the dosage required in the chamber via the Bluetooth Module on the Air Patch.

Once the pressure threshold has been reached, the first valve closes and the second opens, dispensing the medication into the actuator, and releasing it in a fine mist.

It works in a similar fashion to a normal inhaler and uses a commercial medical canister

Wheeze Detection Algorithim

- Wheezes are usually louder than the underlying breath sounds, so the microphone in our device can detect drastic increases in the amplitude of sound waves, which indicate a sudden increase in noise as compared to the surroundings.
- The American Thoracic Society defines wheezes as high-pitched continuous sounds with a dominant frequency of 400 Hz or more
- The higher the frequency, the more severe the wheeze – however, if the frequency drops below a certain margin (for instance 200Hz, the wearer may be experiencing Ronchi, which are coarse, rough sounds experienced by constricted larger airways. This will also trigger inhaler use
- Silent chest' is a serious asthma attack symptom, with no auditory indicators such as coughing and wheezing. Our device can detect silent chests by noting a rapid increase in the user's breathing rate - severely asthmatic patients tend to have a breathing rate of > 30 breaths/minute. This breathing rate increase is detected by a miniature accelerometer (the IMU) sensor on our device which measures the expansion and contraction of the chest cavity through 3-axis acceleration.
- The algorithm also includes noise exclusion – removing ambient sounds, voices, heartbeat sounds and more which would create uncertainty in the detection of a wheeze.



- Machine learning is also used in our device - to differentiate between 'wheezing' audio and 'non-wheeze' audio, the algorithm is first exposed to the ICBHI Respiratory Sound Database, which contains recordings of 6898 respiratory sound cycles of which 886 contain wheezes. Upon listening to all of the available data, the program will classify every audio file into either a 'wheeze' file or a 'non-wheeze file', thus creating its own parameters for wheeze detection. Hence, when the user has an asthma attack, the algorithm will classify it as a 'wheeze file', and send out the Bluetooth signal to the users phone and inhaler. Consequently, the algorithm creates more defined parameters as time goes on (as it obtains more data from the patient to compare against the existing database), which allows it to more accurately detect asthma attacks.

NHS Clinical Trials

1.Software AI – 6 months
Testing of AI software being able to generate the correct dosage of beta-2 agonists to each frequency of wheezing.

2. Safety of device – 2-3 months
Using the reconstructed epidermis model to check for biocompatibility of the adhesive through testing of cytotoxicity, sensitisation, irritation and infection.
According to the MDPI, guinea pigs express high-pitched frequency sounds when exposed to allergens that trigger asthmatic reactions, mimicking wheezing similar to humans. We can use this to check if the specific dosage for each frequency can resolve symptoms before an asthma attack.

3. Bench testing – 4 months
Using pre-recorded wheezing sounds, check to see if the AI algorithm will be able to recognise wheezing sounds not other lung sounds.
Testing for the battery life, response time of the Air Patch and stress test to check for durability. Further, testing for the breathableness of the adhesive through occlusion testing and wearability for 24/7.

4. Regulatory approval for clinical trials – 2 months
Submit a clinical investigation application to the MHRA for approval to start clinical trials

5. Pilot (feasibility) – 6 months
Using a random sample group of 50 asthmatic patients to test if the AI algorithm is able to recognise asthmatic wheeze relative to other lung sounds and administer the correct dosage of beta-2 agonists

6. Pivotal study Phase I – 6 months
Conduct a study consisting of 2 sample groups of 100 people to test if the Air Patch helps relieves symptoms and prevent symptoms from worsening. Patients in the sample will be given a form to complete daily for 2 months describing their symptoms each day.

7. Phase II – 1 year
Conduct a larger study with 2 sample groups of 200 asthmatic patients, gathering the number of times the Air Patch successfully resolved the wheezing

8. Phase III - 2 years
Conduct a study with a group of 50 asthmatic patients using normal reliever and preventer inhalers while another group of 50 asthmatic patients uses the Air Patch with the smart inhaler and preventer inhaler. Gather data on how successful the smart inhaler is able to prevent an asthma attack compared to the normal preventer inhaler

9. Phase IV - 2.5 years
After receiving approval from MHRA, conduct a study of 50 asthmatic patients volunteer to wear the Air Patch in their daily life. Creating a form describing the comfort, visibility and side effects experienced from the Air Patch.

PRE-CLINICAL — **CLINICAL**

Once the device passes the clinical trials, it can be distributed to G.P clinics for use by asthmatic patients.

Cost

The simple structure of the Air Patch allows for mass production at a low cost at approximately between £50-70. Thus, the projected market price is around £100. Our Air Patch long term investment and with subsidies from the NHS, the cost burden on asthmatic patients are significantly reduced. Further, the price of Air Patch can be paid in monthly instalments over the duration of 12 months.

COMPONENT	PRICE/£
Elastomeric enclosure with silicone gel liner	7-15
Microphones	4
Custom flex PCB, mounted components such as BLE Soc	18-30
Battery and charging components	5-10
Assembly	5-15
Additional development costs	5-15

The Air Patch has a thickness of approximately 1cm. Therefore, asthmatic patients can easily have their Air Patch easily hidden underneath their clothes. Furthermore, since we are utilising Bluetooth technology, no wires are visible on the body of the Air Patch, making our medical intervention even more disguisable. Approximately cost of an inhaler will vary between $50-70 including all additional parts such as Bluetooth model, solenoid valves, pressure sensor and microcontroller