SMART BREATH

a non-invasive, wearable solution to continuous, convenient CO2 monitoring

Sources:

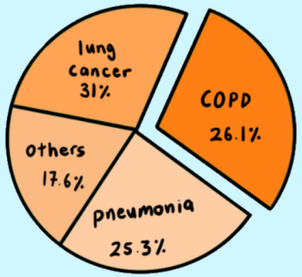
Team members and roles

Aryan Sagdeo - Leader, TCM device research
Andrew Wee - Research on COPD and pCO2 monitoring
Adrian Yee - Research on COPD and public health
Scarlet Siu - Research on COPD and symptoms
Katarina Wong - Concept art, design and device concept
Kyra Yeo - Poster design layout, art and device concept

Chronic Obstructive Pulmonary Disease (COPD): a serious public health issue

- COPD is a preventable and treatable disease with no cure
- Prevalence increases with age and many go undiagnosed until their 50s
- In UK: It is the second most common lung disease after asthma
- Respiratory diseases such as COPD accounted for 14% of all deaths in England and Wales in 2021 and COPD was the most common cause of these deaths (2)

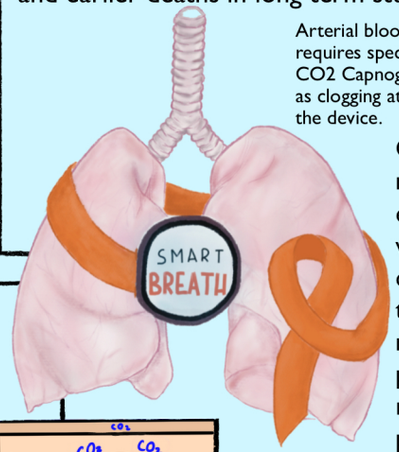
UK deaths from COPD compared with other lung diseases (2012)



Impacts of COPD:

- Decreased lung function
-Compromised ability to function in day to day activities.
- Impair one's sleep and life quality
-Higher chance of comorbid anxiety and depression
-Severe COPD leads to death due to respiratory failure, pneumonia or other comorbidities associated with COPD.

COPD is a disease that causes patients to ventilate less effectively. Thus, hypercapnia occurs when CO2 levels in blood are excessively high. The pH of the blood falls, known as respiratory acidosis (pH<7.35) This causes changes in brain activity, affecting fine muscle control and breathing (6) and is also associated with poor prognosis and earlier deaths in long term studies (7).

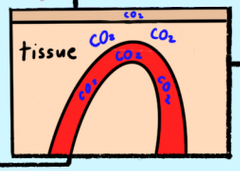


Arterial blood gas monitoring is invasive, time consuming and requires specialist equipment and trained staff. Additionally, CO2 Capnography is bulky, costly and suffers from issues such as clogging attributed to secretions or incorrect positioning of the device.

Our Smart Breath device overcomes many of these issues with simple engineering mechanisms. Coupled with bluetooth technology and currently available NHS app systems, the device enhances independent management for COPD patients and prevention of developing acute respiratory failure, allowing for personalised treatment.

Success of the device in a home setting to achieve telemonitoring could pave the way for the device to be used in a clinical setting for a near-instant, continuous, and non-invasive method of CO2 monitoring- an equivalent to the modern day pulse oximeter.

Transcutaneous CO2 (ptCO2) has great accuracy as a biomarker for respiratory failure, suggesting the potential for continuous monitoring in a non-clinical setting (9) A study found that there is a 95% correlation between PtCO2 and arterial CO2, concluding that ptCO2 is highly effective in continuously monitoring COPD patients. (10) Supervising blood CO2 levels is thus a key strategy to prevent or manage hypercapnia related conditions in patients with respiratory risk. (19)



Feasibility

Clinical trials

A model for a large-scale trial:
- Identify at-risk COPD patients through GP surgeries/referral centres such as the Royal Papworth (16).
- Calibrate device using a gold standard from a clinical setting for each individual (17)
-Collect anonymized data for pCO2 and conduct follow up appointments with GP, retest using ABG and compare results.
- Increase size of study and make improvements as needed.

Costs

Multilayer, stacked structure: roll-on-roll manufacturing allows mass production at low cost. (14)
Lightweight polymer materials (PTFE/PET) provide reasonable structural integrity and low materials cost

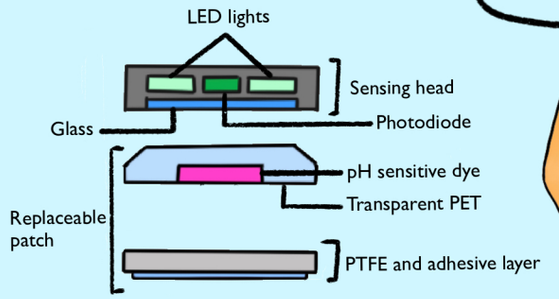
More pricey sensory components can be outsourced e.g. miniaturized lithium ion batteries
Required CPU: a processor capable of basic calculations and a Bluetooth module for mobile connectivity.

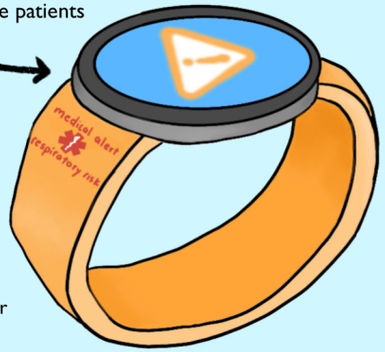
Funding will be obtained through grants for the NHS Long Term plan or patient discounts if additional funding is required (15)

PROPOSAL: a small, portable device that enables continuous monitoring of pCO2 in blood is a smart, wearable watch type monitor.
How it works: a dry-dye-based sensor
1. A pH sensitive dye is exposed to CO2 in the skin
2. CO2 causes changes in the optical properties of the dye.
3. LEDs and photodiodes detect this change and process data to output a corresponding value of CO2 level in blood.
4. Notifications are sent to a device such as a mobile phone through Bluetooth connectivity.

The sensing head could be reused indefinitely while the "patch" may require replacement for comfort , hygiene and poisoning of the dye due to "fluorescence quenching" effect of oxygen. (13)

Alert sent to NHS mobile app when CO2 levels rise above baseline: the flexible silicone band can double as a medical alert vulnerable patients





Problem:
the need to conveniently and consistently measure CO2 levels non-invasively in a non-clinical setting

Design:
designing a miniaturised sensor that forgoes the traditional Stow-Severinghaus electrode

Testing:
carrying out clinical trials and testing of device

Manufacturing:
mass producing and making the device available to general public

Application:
provision of device through General Practitioner clinics and hospitals

Advantages of our design:

-Wearable biosensors serve an irreplaceable role in the hospital such as pulse oximeters; an accurate and compact pCO2 monitoring device can enhance delivery of care and quality of life (18)
-The use of CO2 sensitive dye and close proximity to skin eliminates the need for heating the skin in some other pCO2 sensors, namely devices using the Stow-Severinghaus Electrode.