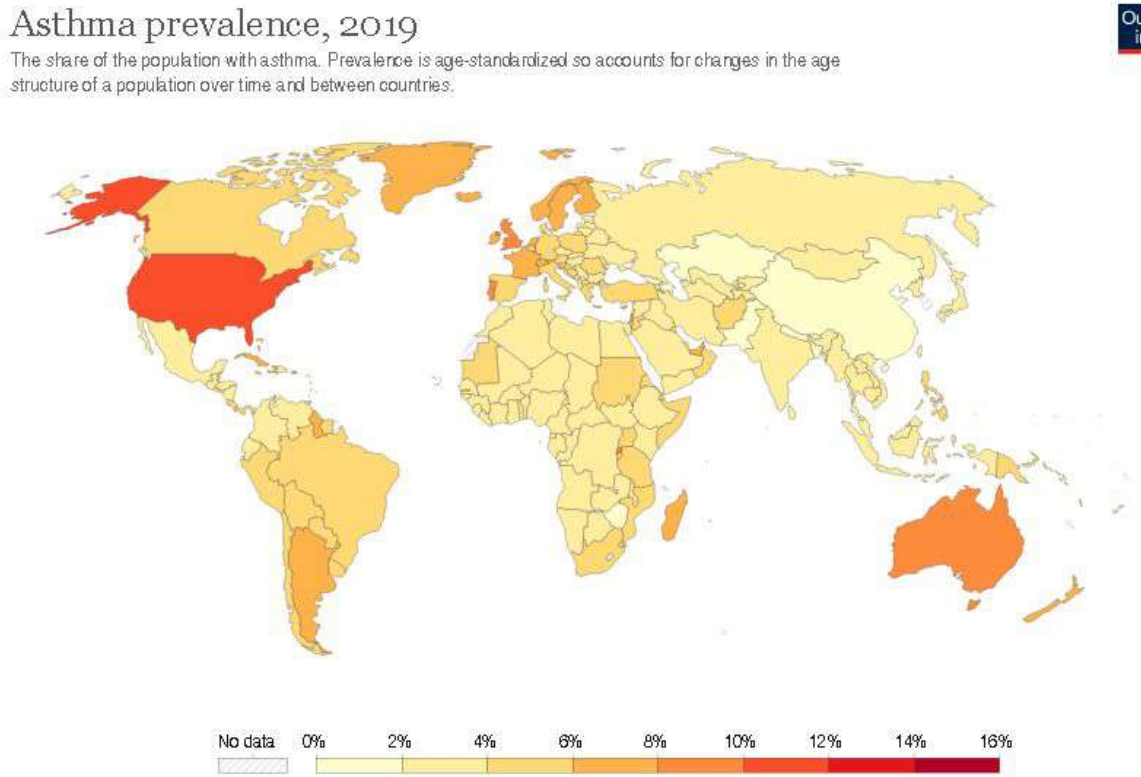
Treatment Monitoring & Early Detection of Asthma Attacks in Children

S Ananda Theertan - MI21MTECH14003

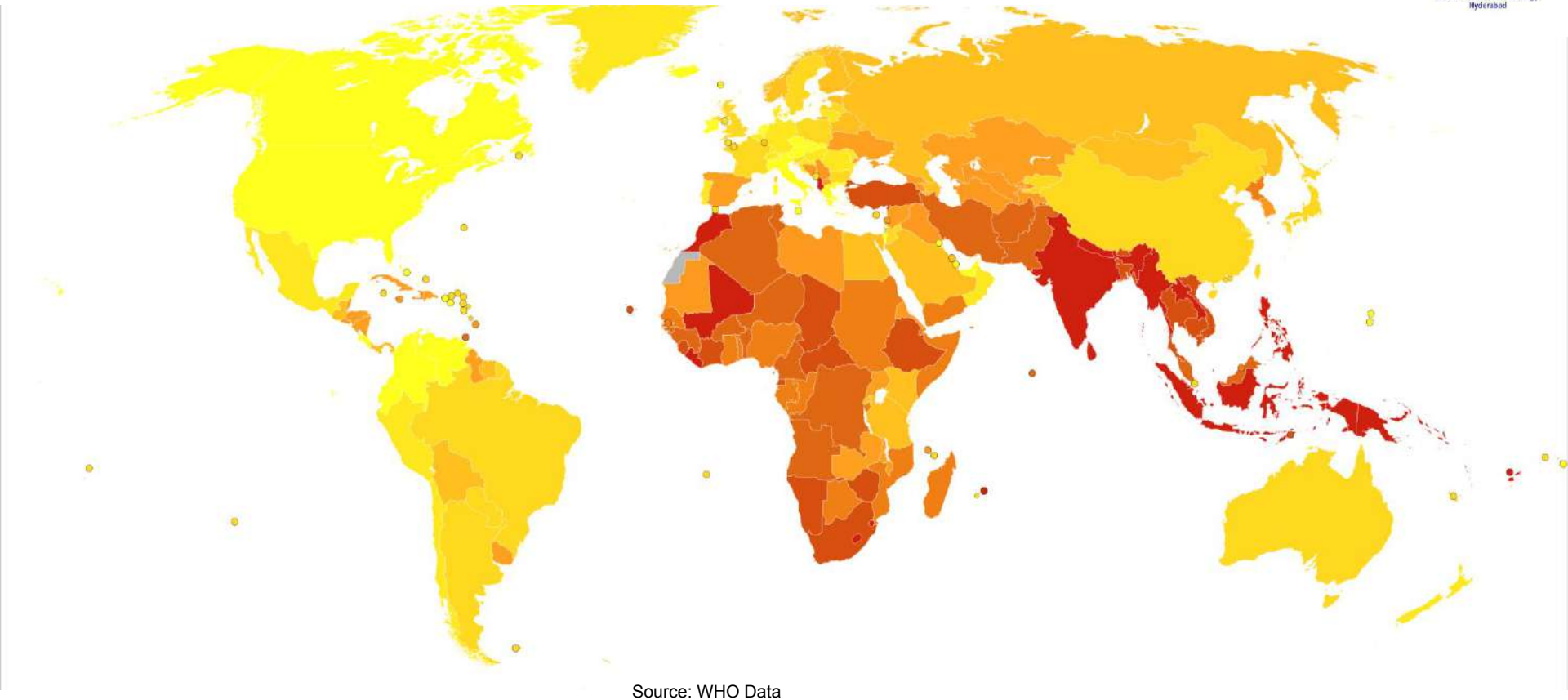
CfHE Center for Healthcare Entrepreneurship

భారతీయ సాంకేతిక విజ్ఞాన సంస్థ హైదరాబాద్
भारतीय प्रौद्योगिकी संस्थान हैदराबाद
Indian Institute of Technology Hyderabad

Why Asthma?


Asthma prevalence, 2019
The share of the population with asthma. Prevalence is age-standardized so accounts for changes in the age structure of a population over time and between countries.
Our World in Data
No data
0%
2%
4%
6%
8%
10%
12%
14%
16%
Source: IHME, Global Burden of Disease (2019)
OurWorldInData.org/burden-of-disease • CC BY

AADR - The Burden on India /DN



Source: WHO Data
https://www.who.int/news-room/fact-sheets/detail/asthma

The Burden

Disease Type

Non-communicable, Non-curable, Treatable & Preventable

Death Toll

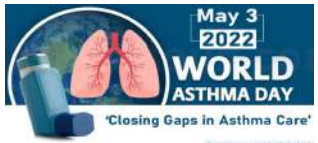
11th deadliest killer in India
“AADR” - 18.49 per 100,000

Case Load

India - 13% of global burden

Experts say

“Asthma causes 4.83 million disability-adjusted life years (DALYs) annually in India, four times more than China”
Sundeep et al., (Lung India Journal - Aug 2022)



Asthma Pathology

Overview

Definition

A

Chronic inflammation of lungs & airways

Triggers

B

Infection, exercise, cold air, dust and dander

Symptoms

C

wheezing and coughing, SOB

Emergency Aspect

F

Prone to “Asthma attacks” Constricts Airways

Diagnosis

E

Standard PFT - NOT Always Accurate for Children.

Treatment

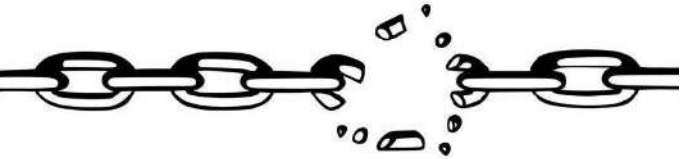
D

Medication.

https://www.researchgate.net/publication/314575331_Prevalence_of_Asthma_in_Urban_School_Children_in_Jaipur_India

https://indianexpress.com/article/lifestyle/health/over-90-of-asthma-patients-in-india-do-not-receive-the-right-medication-7898

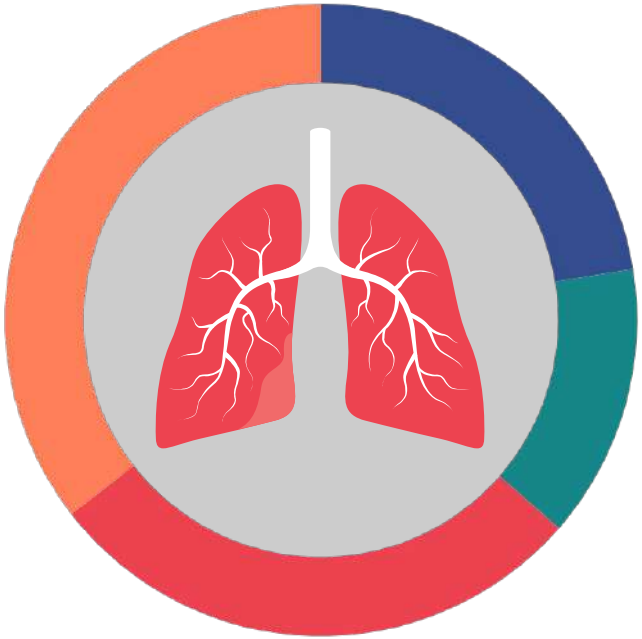
Problem Statement



- **KMN_LB_PUL_070122_002 :** Early Detection and continuous monitoring of Asthma symptoms in Children is a problem, especially in night time.

- “The burden of childhood asthma is considerable and is physically, emotionally and economically taxing on children and their caregivers (who are the main stakeholders). We will look to reduce this burden in Indian children for the next few years/decades.”

Need Statement



There is a need for device that (continuously monitors for signs of asthma symptoms like wheeze especially during the night) in (vulnerable children) to (prevent acute exacerbation which timely notifies caregivers to intervene and provide medicational relief).

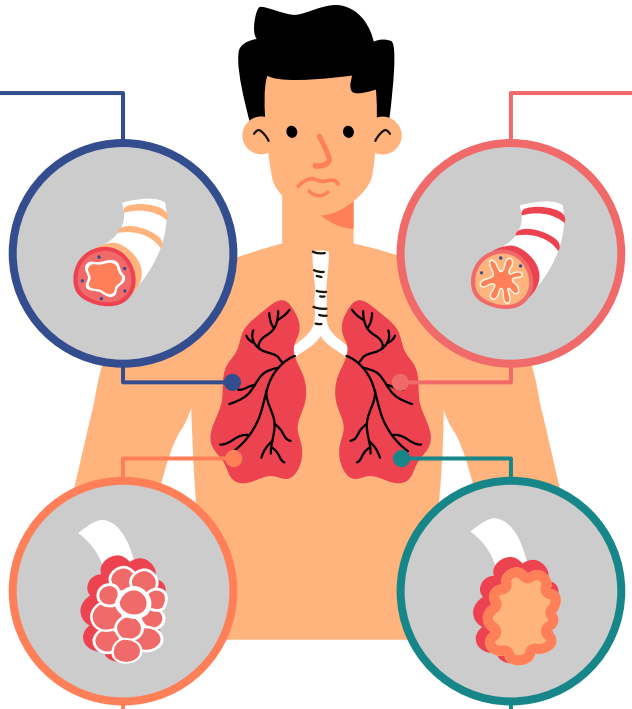
Asthma Attack - Before & After

Normal

Relaxed Smooth Muscles
Normal Airway Patency

Steady Gas-Exchange
Normal Breathing

Normal



Inflammation

Smooth Muscles Tighten
Airway Walls Thicken
Patency reduced

More Air trapped in Alveoli
May Hyperventilate as SOB
Child & Caregiver Panic

Distress

Pain Points - Life with Uncontrolled Asthma

01

Sleep

Night coughing, wheezing disrupt sleep

02

Airway Remodeling

Small airways fibrosed and scarred.

"Twitchy to Triggers"

03

Steroid Resistance

Few respond poorly, Need high doses

Side-effects are serious problem.

Lifestyle Setback

Physical - Academic - Mental

a - b- c - a

"Vicious Cycle"

04

GERD

GERD Asthma

Difficult to control.

"Osler's theory"

05

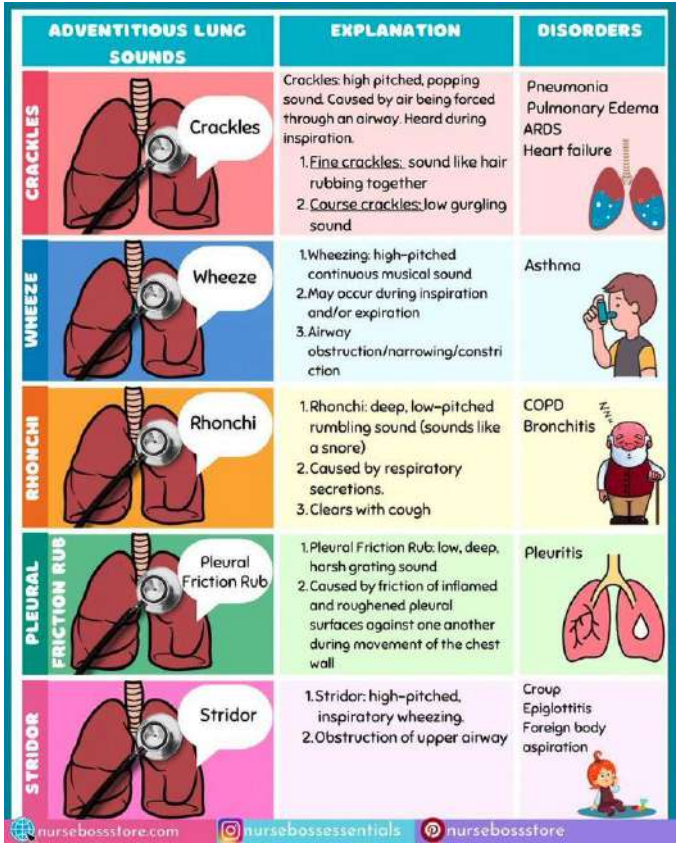
RTI

"Common infections are harder to control."

"Cytokine triggered Bronchoconstriction"

06

Symptoms of Dysfunction



Sign - “popping” - short high pitched - 10-20 ms
frequency range is *between 100 and 200 Hz*

Whistling
100 to 2500Hz with main signal freq at 400 to 1000 Hz

Low pitched sibilant whistle
frequency of <300 Hz - whistling sound

Image courtesy - nursebossessentials

Diagnostic Protocol Flowchart of Asthma

Primary care
Patient presents with acute or sub-acute asthma exacerbations

Assess the patient
Is it asthma?
Factors for asthma related death?
Severity of exacerbations?

Mild or moderate
- Talks in phrases
- Prefers sitting to lying
- Not agitated
- Respiratory rate increased
- Accessory muscle
- Pulse rate 100–120 bpm
- O_2 saturation (on air) 90–95%
- PEF >50% predicted or best

Severe
- Talks in words
- Sits hunched
- Agitated
- Respiratory rate >30/min
- Accessory muscles used
- Pulse rate >120/min
- O_2 saturation (on air) <90%
- PEF <50% predicted or best

Life threatening
- Drowsy
- Confused
- Silent chest

Start treatment
- SABA 4–10 puffs by pMDI + spacer
- Repeat after every 20 mins for 1 hr
- Prednisolone—adults 40–50 mg
- Children 1–2 mg/kg, max 40 mg
- Controlled O_2 (if available)—target saturation 93–95% (children 94–98%)

Worsening

Transfer to acute care facility
- While waiting give SABA
- Ipratropium bromide O_2
- Systemic corticosteroids

Improving

Worsening

Continue treatment with SABA as needed
Assess response at 1 hr (or earlier)

Assess for discharge
- Symptoms improved, not needing SABA
- PEF improving and >60–80% of personal best or predicted
- Oxygen saturation >94% on room air
- Resources at home adequate

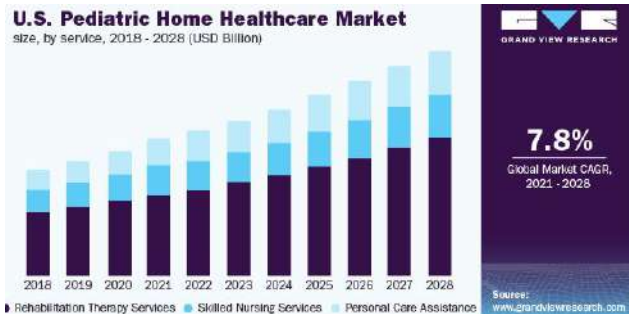
Arrange at discharge
- Reliever: continue as needed
- Check inhaler technique, adherence
- Prednisolone: Continue, usually for 5–7 days (3–5 days for children)
- Follow up: within 2–7 days (12 days for children)

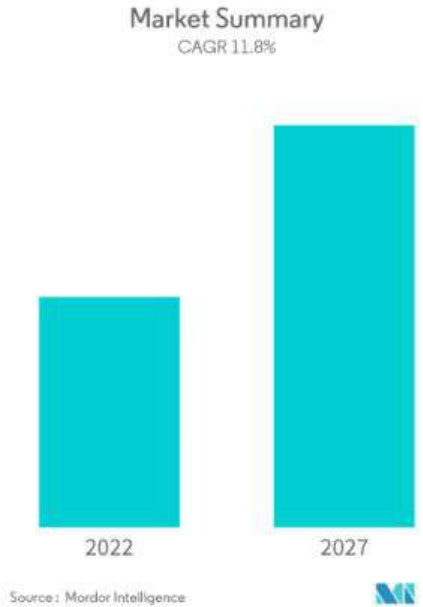
Follow-up
- Review symptoms and signs: Is the exacerbation resolving? Should prednisolone be continued ?
- Reliever: reduce as needed. Controller: continue high dose for short term (1–2 weeks) or long term (3 months) depending on background to exacerbations
- Risk factors: check and correct modifiable risk factors that may have contributed to exacerbations, including inhaler technique and adherence refer if >1–2 exacerbations

Courtesy: https://iapindia.org/pdf/Ch-035-STG-bronchial-asthma.pdf

Market Size - Increasing Demand

- The pediatric medical devices market - CAGR **8.7%** from during **2021–2028.**
- The global respiratory monitoring device market size - CAGR of **11.8%** from 2021-**2026**
- **Fastest Growing Market: Asia-Pacific**
- Robust Demand of Growing population country like India





Market Size - Estimating our End-Users

The population of India in 2021 - **1.4 Billion**

No of Children in India in Age Group **0 -14** years :

The World Bank estimates that Population ages 0 -14 (% of total population) India in 2021 is - **26%**

26% of total population - **364 Million**

RA Daniel et al., (Lung India) found the prevalence of Asthma among Children in India to be **6.5%*** **in 2022**

By this calculation, **at least 1 in every 15 children are suffering from Asthma** at any point in India alone. (TAM - 25 million)

The prevalence was found to be **higher in young boys from urban areas.**

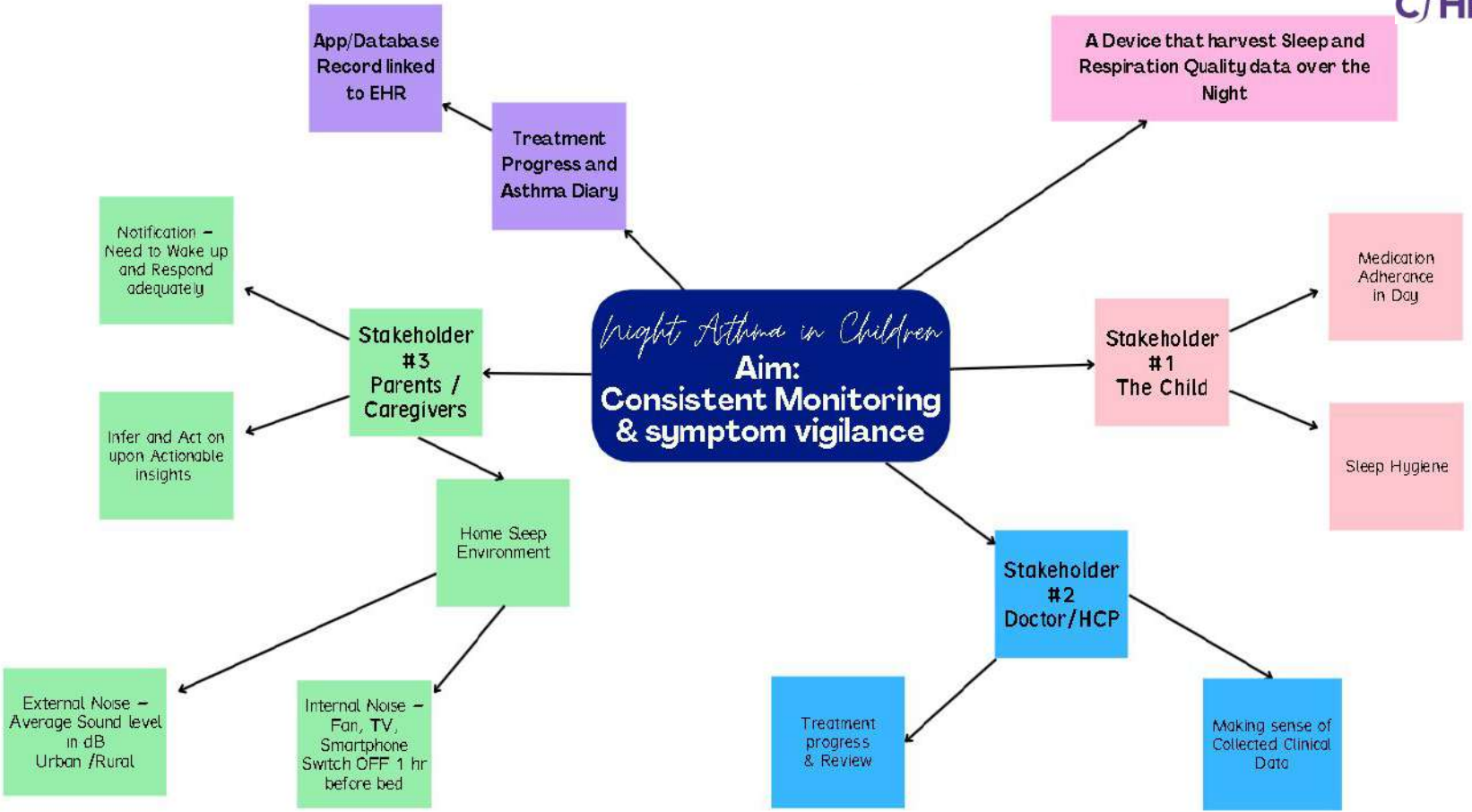
Conclusion - For next few years, Market scope for devices/service addressing 'Gaps in Care' for Pediatric Asthma Care in India are optimistic, entrepreneurially speaking.

https://data.worldbank.org/indicator/SP.POP.0014.TO.ZS?locations=IN

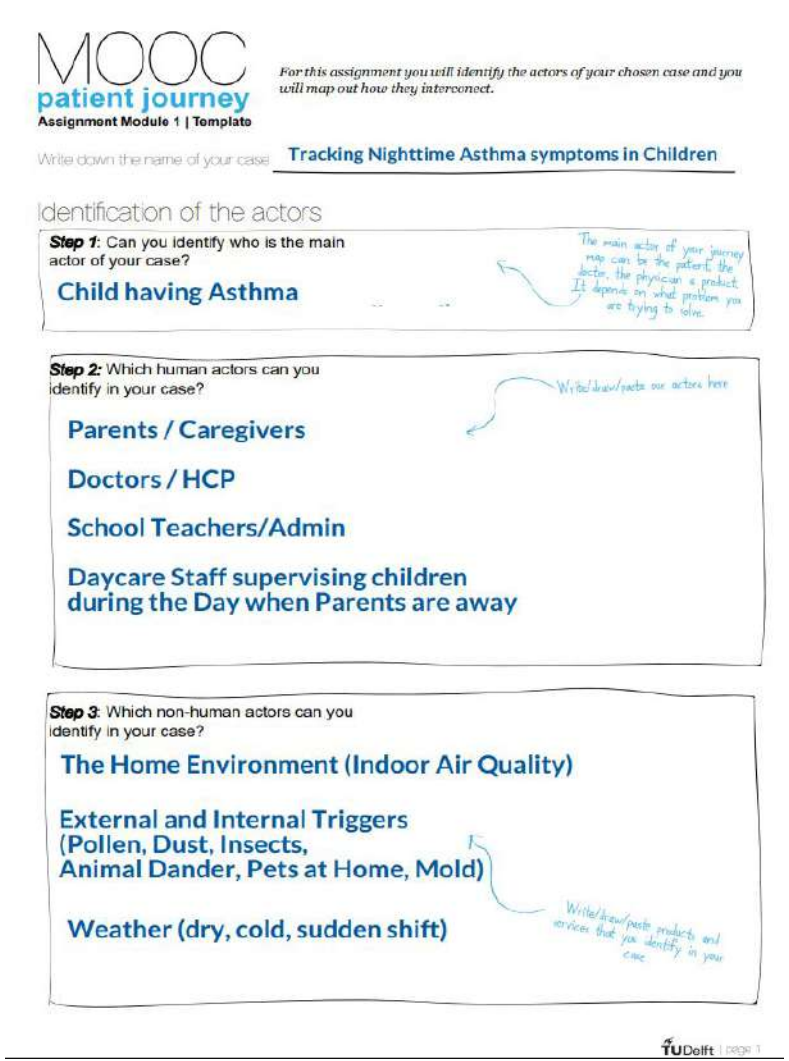
https://data.worldbank.org/indicator/SP.POP.0014.TO.ZS?locations=IN

Daniel, Ret al., 2022 - doi: 10.4103/lungindia.lungindia_706_21

Mindmap of Stakeholders



Mapping the Stakeholders & Actors Based on Delft Design Guide →



MOOC
patient journey
Assignment Module 1 | Template

For this assignment you will identify the actors of your chosen case and you will map out how they interconect.

Write down the name of your case: **Tracking Nighttime Asthma symptoms in Children**

Identification of the actors

Step 1: Can you identify who is the main actor of your case?

Child having Asthma

The main actor of your journey map can be the patient, the doctor, the physician a product. It depends on what problem you are trying to solve.

Step 2: Which human actors can you identify in your case?

Write/draw/paste our actors here

Parents / Caregivers

Doctors / HCP

School Teachers/Admin

Daycare Staff supervising children during the Day when Parents are away

Step 3: Which non-human actors can you identify in your case?

The Home Environment (Indoor Air Quality)

External and Internal Triggers (Pollen, Dust, Insects, Animal Dander, Pets at Home, Mold)

Weather (dry, cold, sudden shift)

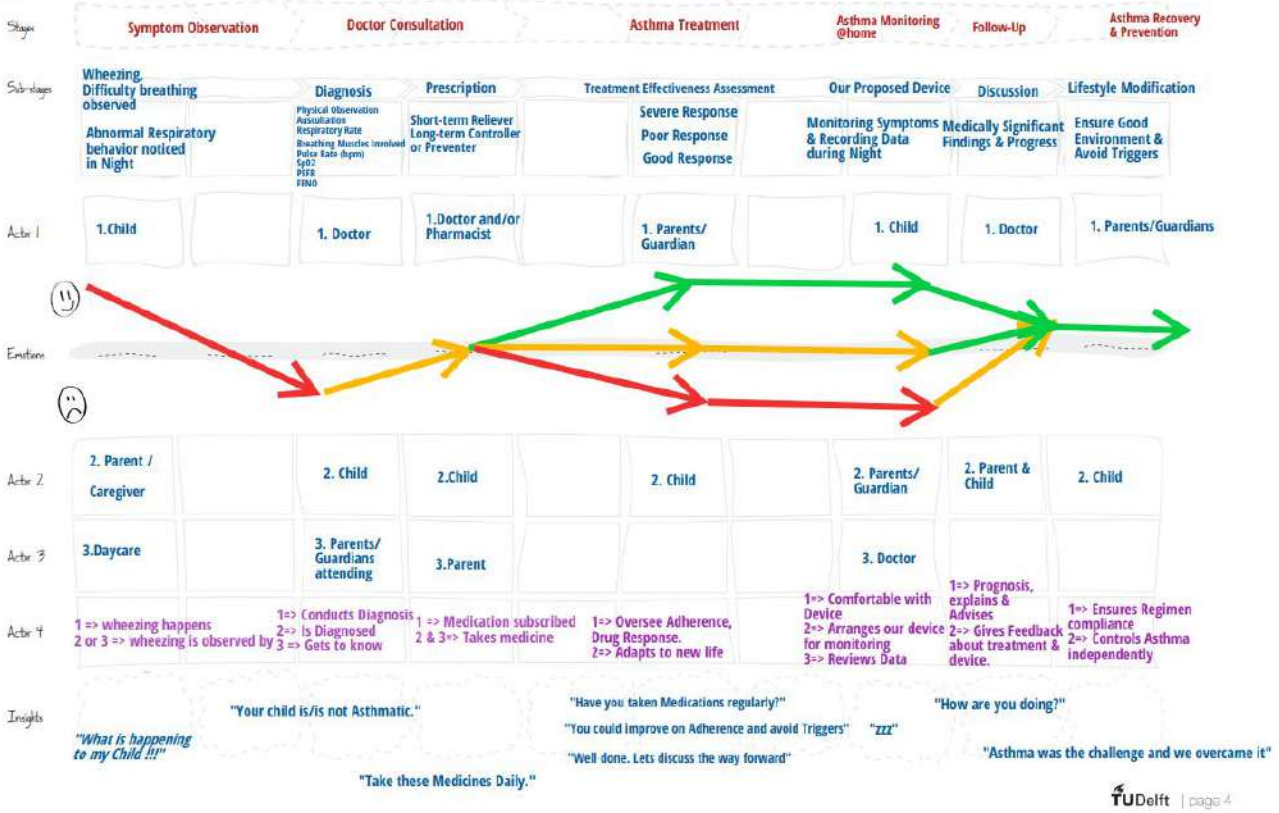
Write/draw/paste products and services that you identify in your case

TUDelft | page 1

Patient Journey Mapping - TU Delft Model

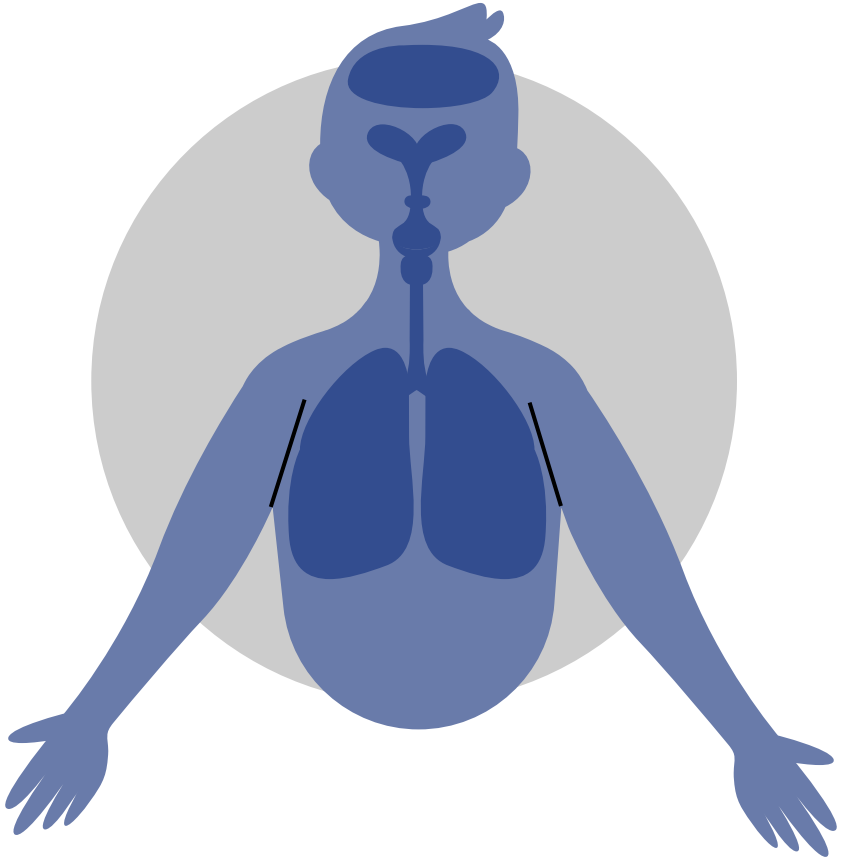
MOOC
patient journey
Assignment Module 4 | Template

Title: **Asthma in Children**

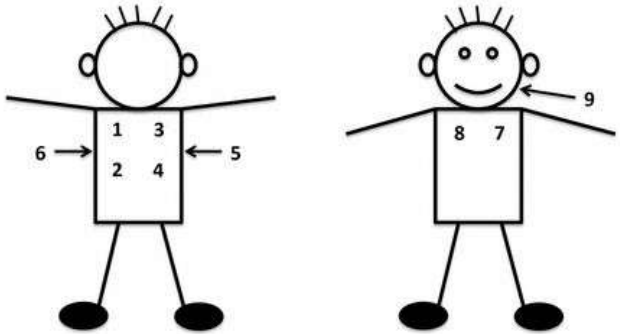


Proposed Solution

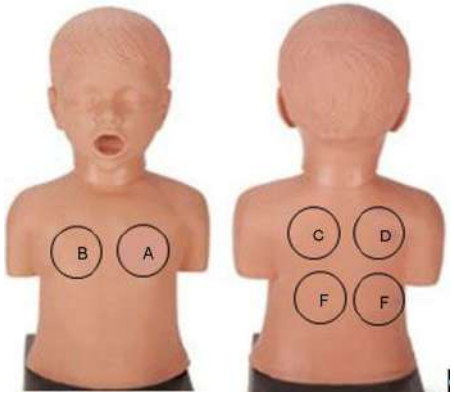
- **A device based system to monitor and record the relevant vital parameters of Asthmatic children.**
- 1. Analyze the characteristics
- 2. Monitor to Detect Patterns
- 3. ALERT the Guardian if Emergency
- 4. Store Patient's Data
- 5. Display key insights to Parent - Live Status
- Other planned features - Gamification
- "Nice to Have" - Live Location



Pediatric Lung Auscultation - Gross Anatomic Locations

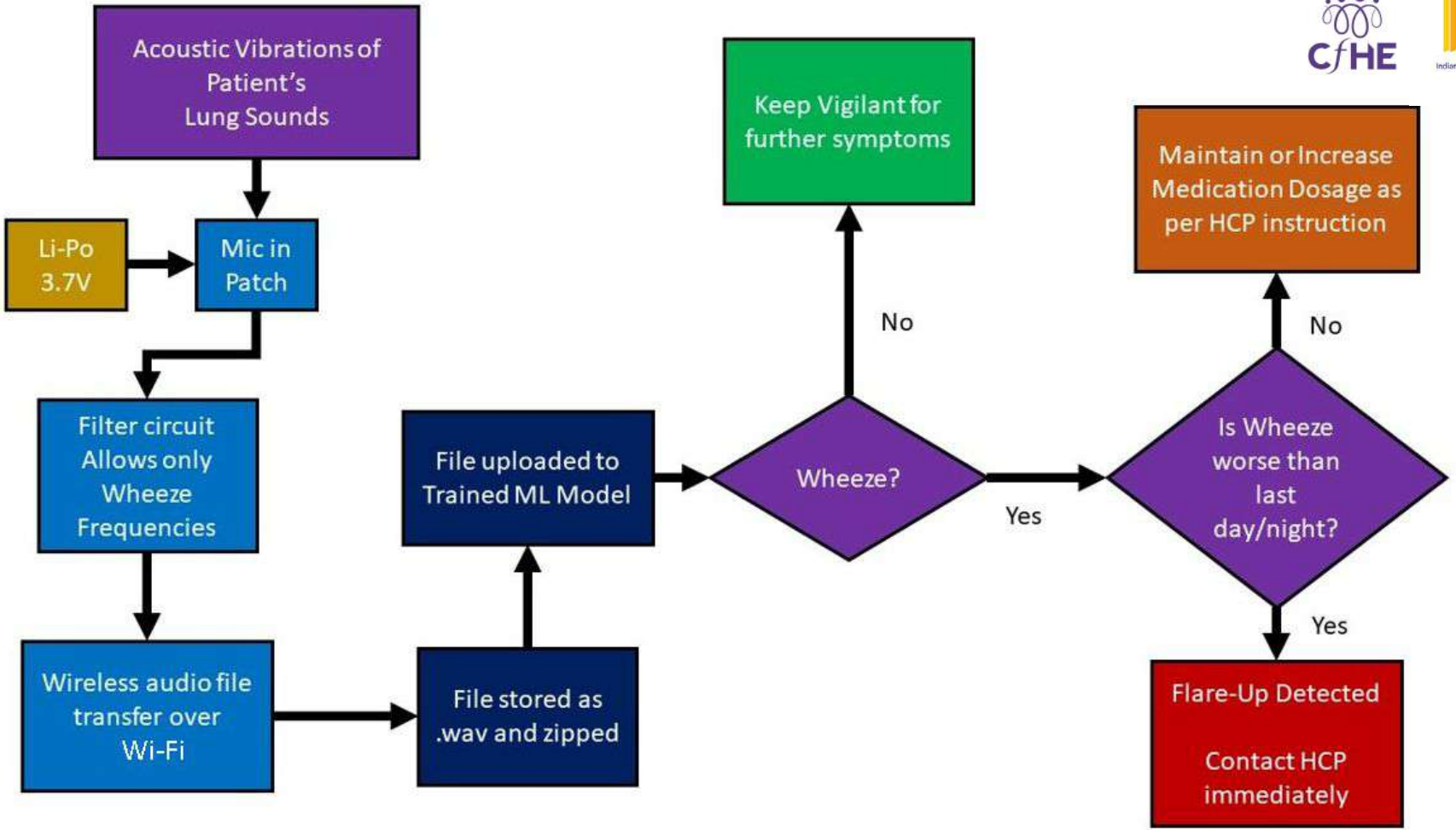


Recommended Location and sequence of listening positions for digitally recorded lung sounds. [1]

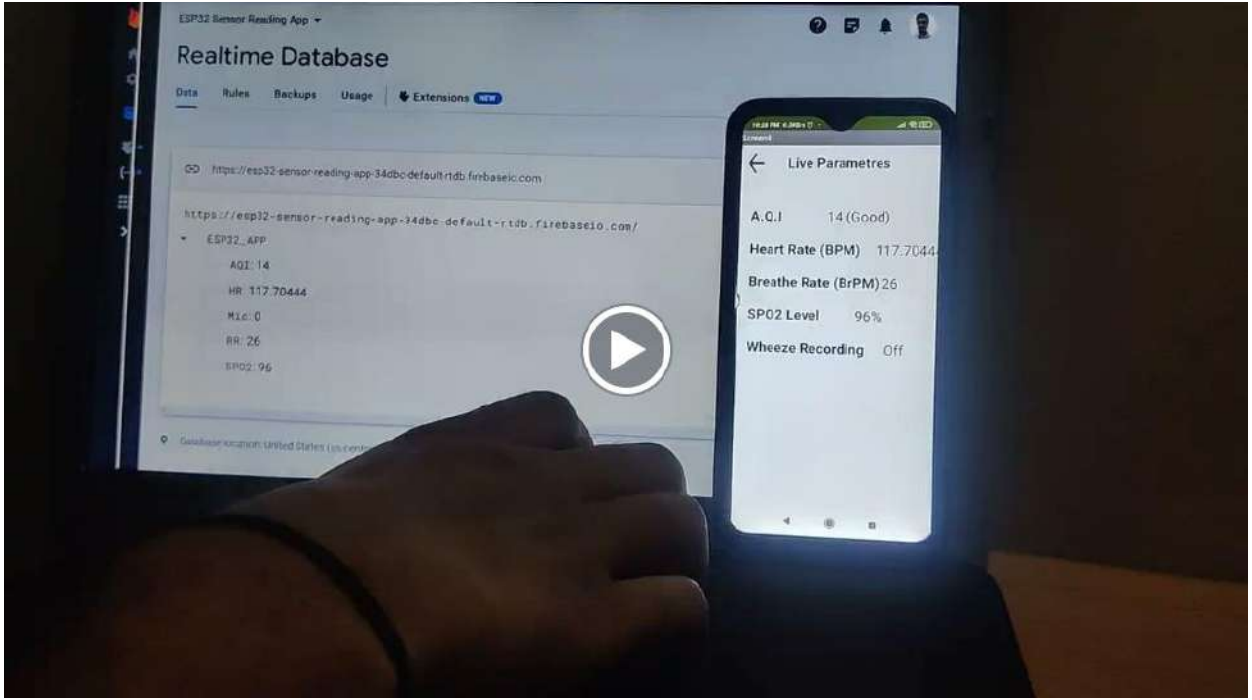


Order of auscultation recording by digital stethoscope[2]

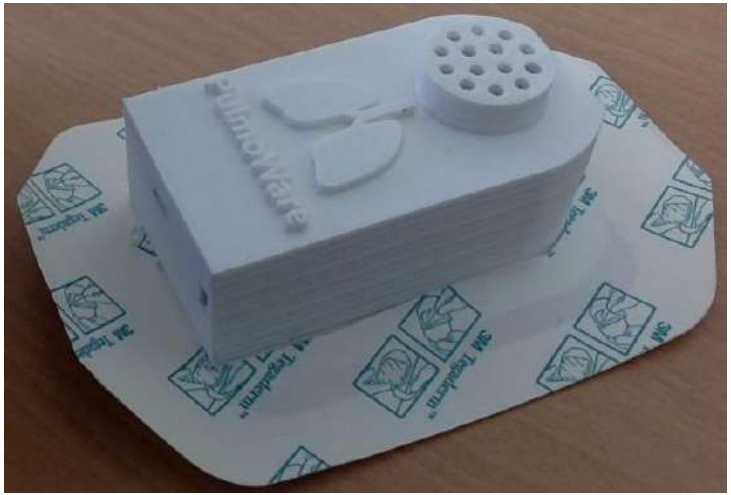
1. https://bmjopenrespres.bmj.com/content/4/1/e000193
2. doi: 10.1055/s-0036-1593749


Acoustic Vibrations of Patient's Lung Sounds
Li-Po 3.7V
Mic in Patch
Filter circuit Allows only Wheeze Frequencies
Wireless audio file transfer over Wi-Fi
File stored as .wav and zipped
File uploaded to Trained ML Model
Wheeze?
No
Keep Vigilant for further symptoms
Yes
Is Wheeze worse than last day/night?
No
Maintain or Increase Medication Dosage as per HCP instruction
Yes
Flare-Up Detected
Contact HCP immediately

Video Demo - Working Prototype 2

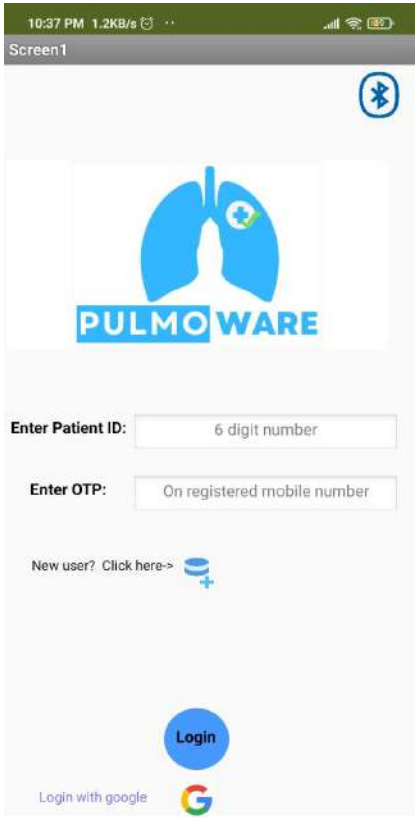


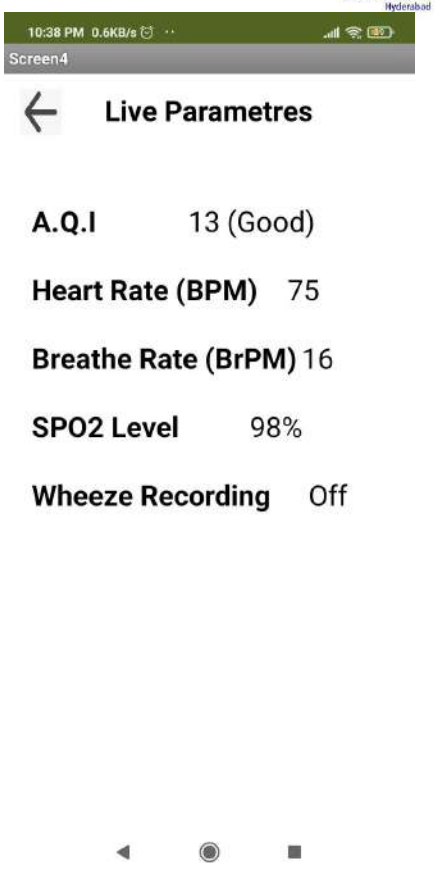
Prototype 2
Wireless Multi sensor patch - Enhanced Functionality



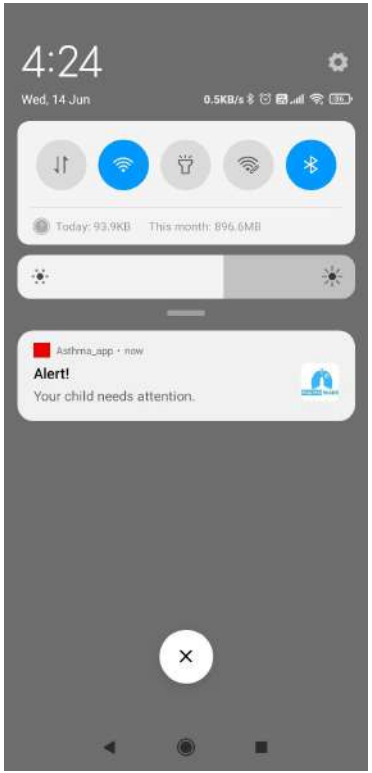
Prototype #2 in Action

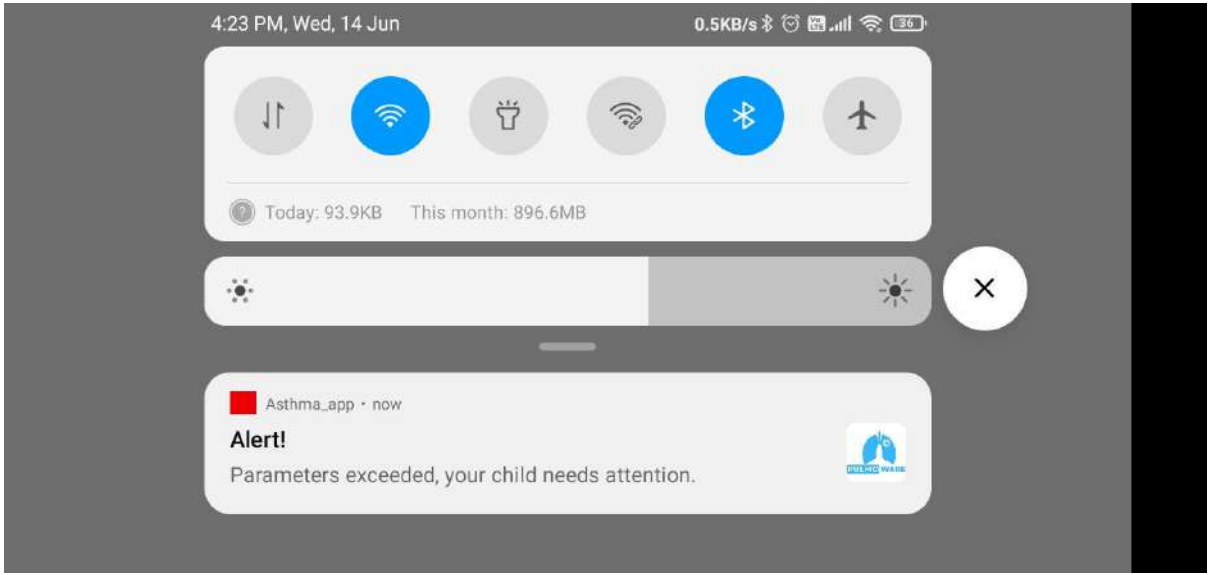
Android Device Companion App - User Enrollment Flow





Push Notification to Alert Caregiver





Model 1 Training

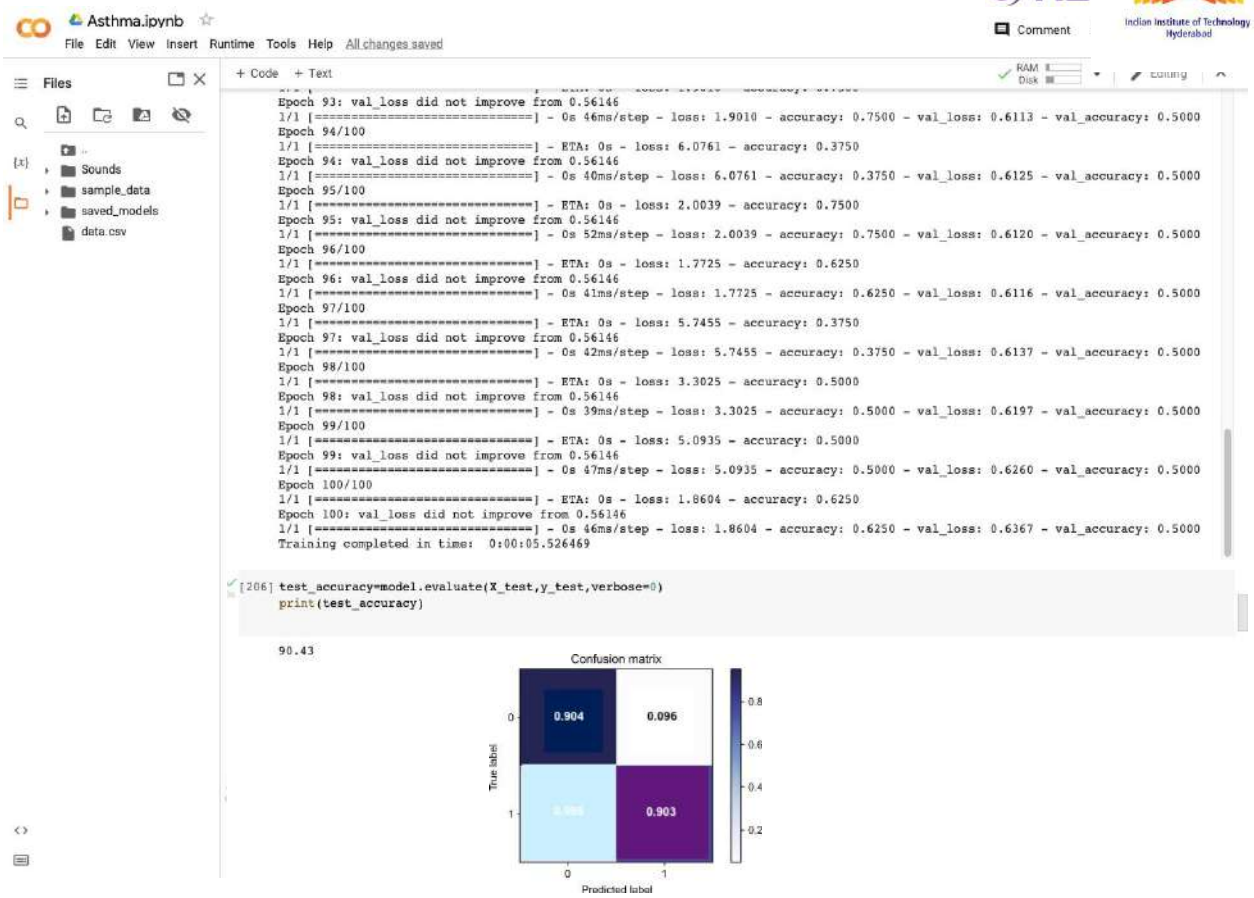
Features considered: MFCC

Dataset Used: Baghel et al., (2022) Vasant Kunj Database consists of 230 samples.

Classification Type: Binary Classification

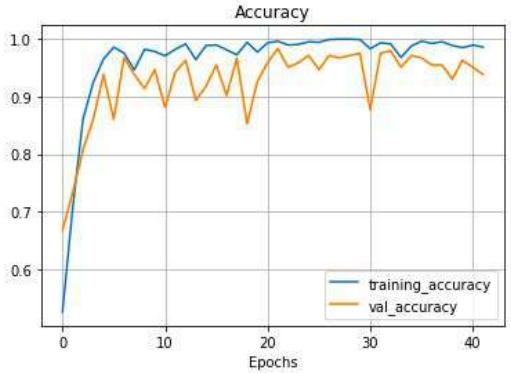
Model used: CNN

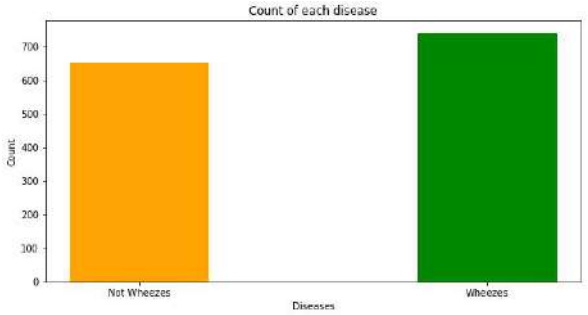
Accuracy: 90.4 %



Model Ver. 2 - Wheeze/NoWheeze ML Classifier

```
8/8 [==============================] - 0s 9ms/step - loss: 0.0701 - accuracy: 0.9836
[0.07011795043945312, 0.9836065769195557]
```






```
{'Not Wheezes': 653, 'Wheezes': 741}
```

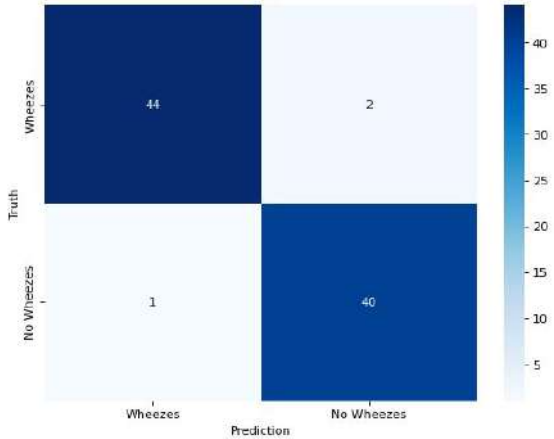
Features considered: MFCC

Datasets Used: ICBHI 2017 Challenge Respiratory Sound Database(920 samples), Vasant Kunj Database(230 samples).

Classification Type: Binary Classification

Model used: RNN(LSTM)

Accuracy: 96.55 %



	precision	recall	f1-score	support
Wheezes	0.94	0.96	0.95	46
No Wheezes	0.95	0.93	0.94	41
accuracy			0.94	87
macro avg	0.94	0.94	0.94	87
weighted avg	0.94	0.94	0.94	87

Sample Analysis

File Name : Sample_1.wav

Channels : 2

Sample Rate : 48000 Samples per second

Precision : 16-bit

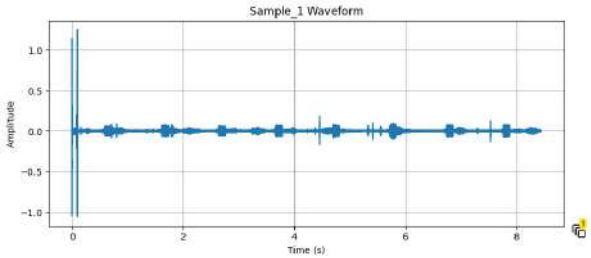
Duration : 00:00:35.26 = 1692288 samples ~ 2644.2 CDDA sectors

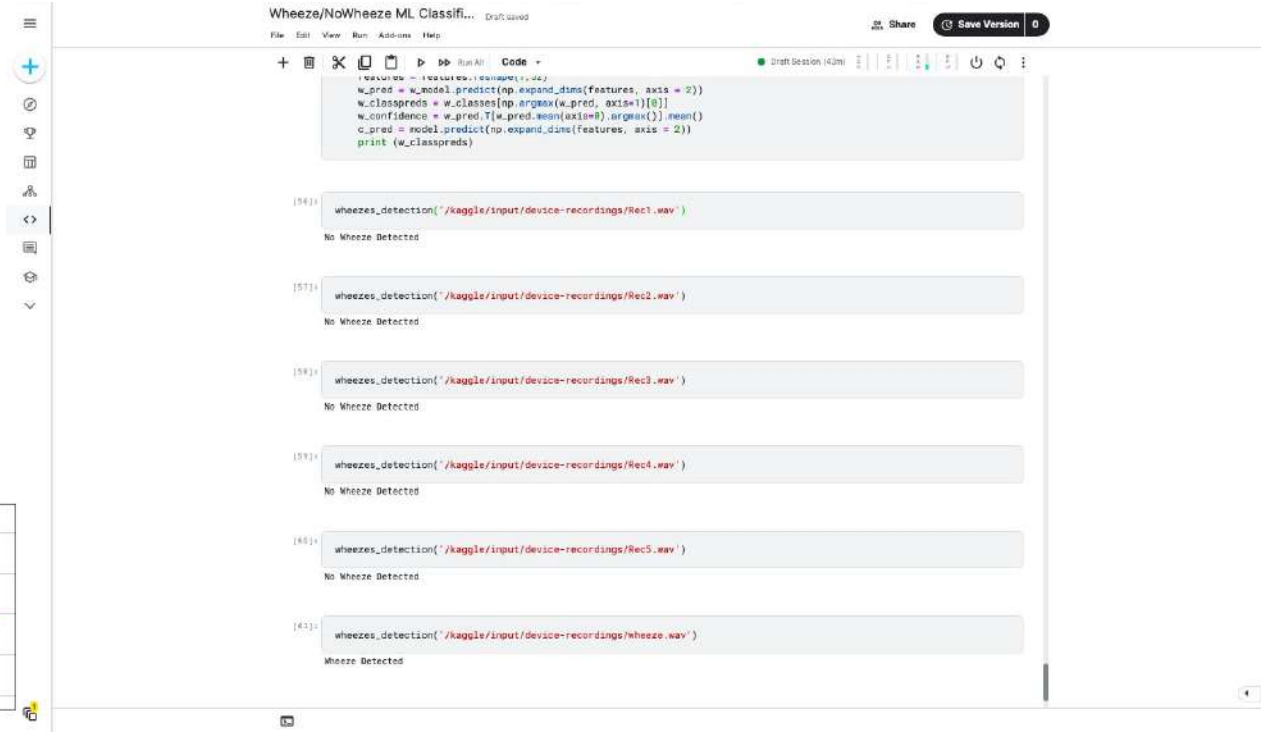
File Size : 6.77M

Bit Rate : 1.54M

Sample Encoding: 16-bit Signed Integer PCM

Signal to Noise Ratio (SNR): 23dB





Conventional Lung Auscultation vs Our Device

Features of Device	Conventional Stethoscope	Electronic Stethoscope	Our Prototype
Can it detect Adventitous Lung sounds/wheezing symptoms of Asthma?	✅	✅	✅
Does it automatically classify Asthmatic activity based on a evolving ML model?	❌	❌	✅
Can Caregiver access chest sounds data over long distance? (Telemedicine-compatible)	❌	✅	✅
Is it able to provide a timestamp when the wheezing symptoms was most intense?	❌	❌	✅
Can a Detailed Report of Asthma specific activity generated after use and linked to patient's medical history and records?	❌	❌	✅
Is the device wearer-friendly and suitable for night monitoring?	❌	❌	✅

Competitive Landscape

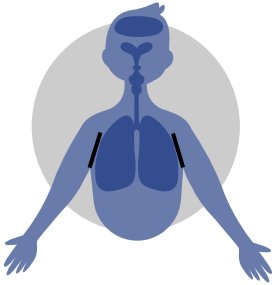
Company	Chest Sounds	EMG	Breath detection/Respiratory Rate	Heart Rate/ HRV	SpO2
Omron WheezeScan	✓	✘	✘	✘	✘
Respiri Wheezo	✓	✘	✘	✘	✘
Aevicehealth AireSone	✘	✘	✓	✓	✘
Asthmaware	✘	✓	✓	✘	✘
Ventica System	✘	✓	✓	✘	✘
AirSonea Device	✓	✘	✘	✘	✘
Respira Labs Sylvee(AR)	✓	✘	✘	✘	✘







Existing Landscape



Market

- User - Asthmatic children in India - 6.5% (1 in every 15 kid)
- Customers - Caregivers of 2.35 Cr asthmatic Indian children
- Early Adopters =
  % of Doctors Recommending our Device * Parents willing to Afford

  Most Important are our First Customers - “Make or Break”
  UX, Testimonials & Word-of-mouth Review
  Loyal Base Customers - Repeat Subscribers to Service
- Main Partner - Pediatricians and specialist healthcare providers
- Partners - Schools and daycare centers
- Partners - Insurance companies and healthcare institutions

Competition

- National Level Competitors - Omron Wheezescan
- Cipla Spirofy® & PEFM
- Alveo.fit (Digital spirometer from Pune)
  - International Competitors -
  - **Respiri Wheezo** from USA
  - **Aevicehealth AireSone Junior** from Singapore
  - AirSonea from USA
  - Respira Labs (Sylvee) from USA.
  - Ventica System from Croatia
  - MIR+ Spirolab from Italy
- Substitutes -
  - eStethoscopes (Ayu Synk, Muse Diagnostics)
  - Exclusive Vitals monitoring Device - Dozee
  - Smart Inhalers that remind adherence (Adherium eHealth, NZ)

Starting Up to Scaling Up

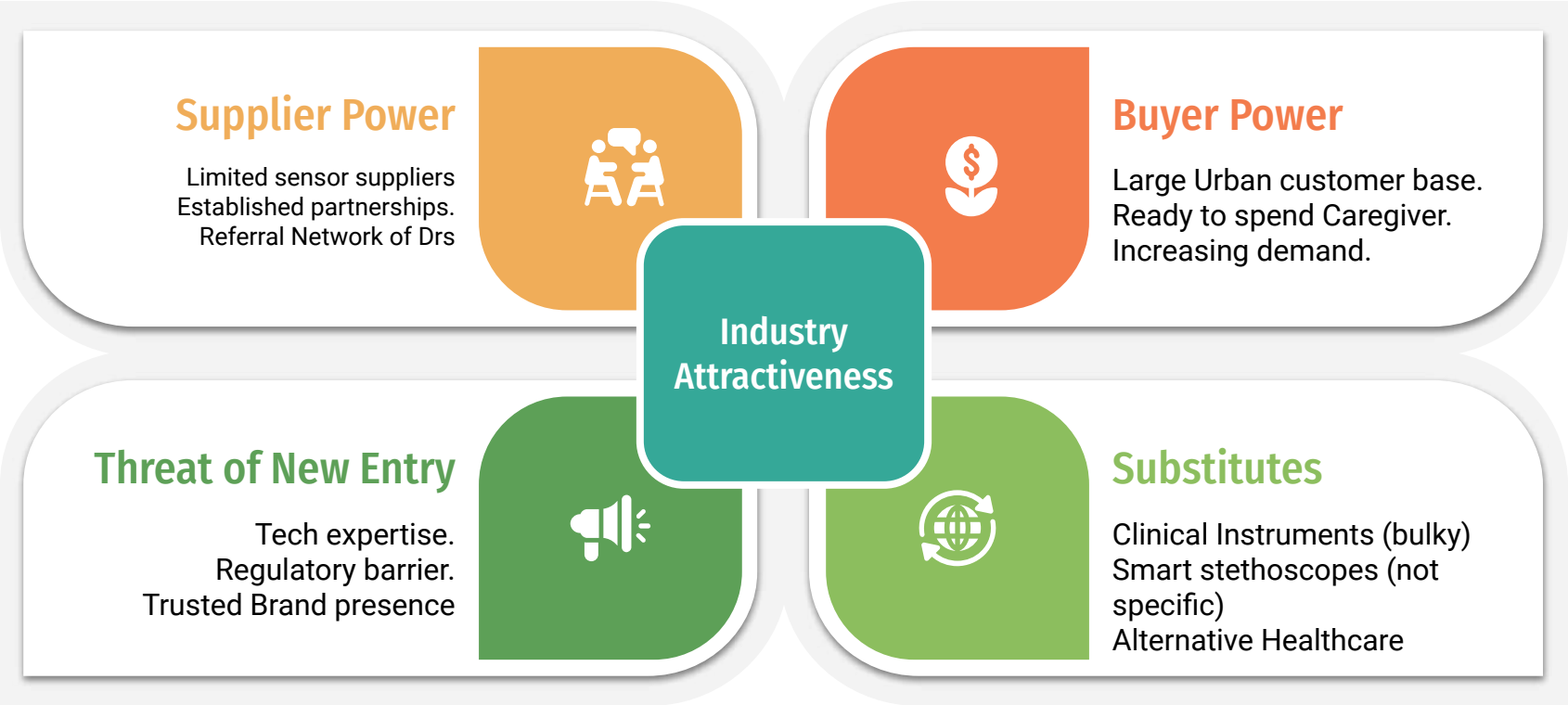
Traction

- Direct approach to **pediatricians** and healthcare providers
- **Word-of-mouth** referrals/Testimonials from satisfied customers
- Partnerships with schools and daycare centers
- Online and offline marketing campaigns
- Participating in Health Conference Events (**NAPCON** / National Conference on Pulmonary Diseases)
- (Inter)national healthcare device **Expos**

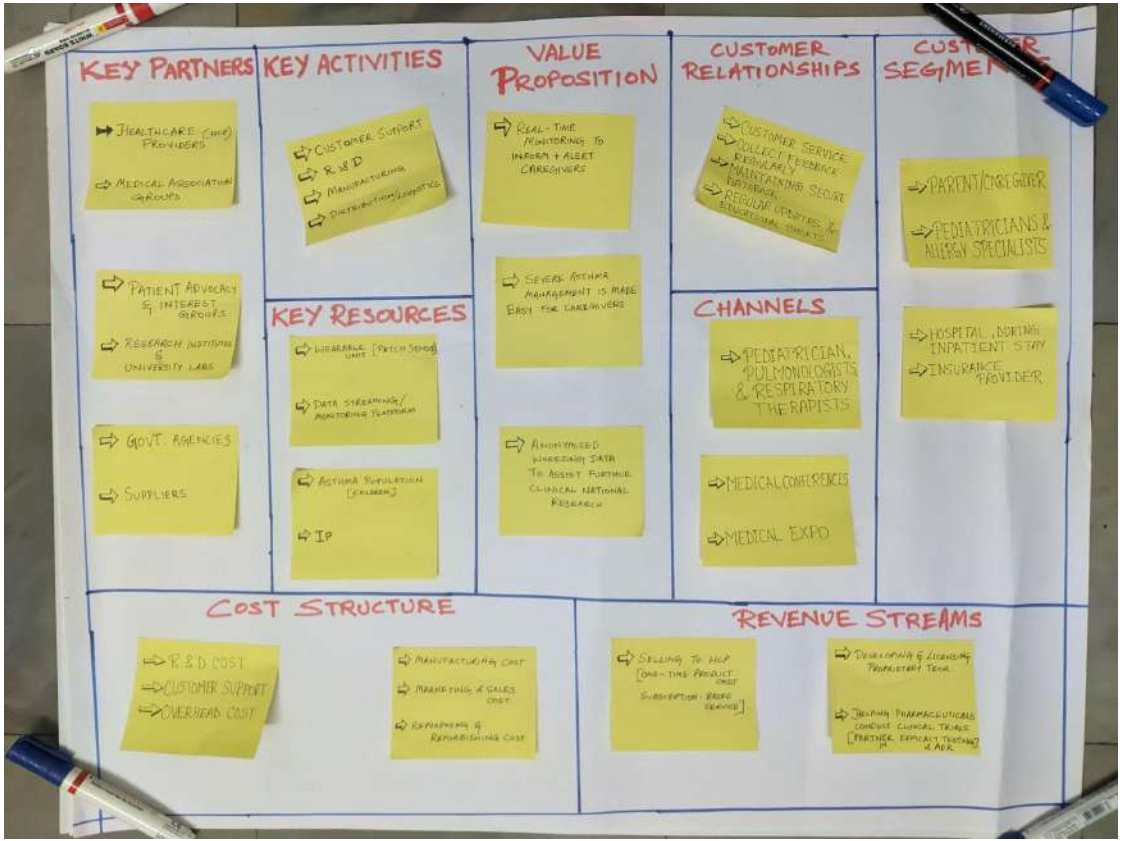
Business Model

Operating Model -	**Revenue Model -**
Directly approaching pediatricians and healthcare providers first Limiting initial sales of D2C to establish credibility Potential for partnerships with insurance companies and healthcare institutions For underserved communities - Licensing to NGOs	• B2B • Subscription based Service • Direct to customers • Offering -%s for long-term subscriptions

Porter's 5 Forces Infographics



Business Model Canvas (the Alex Osterwalder Method)

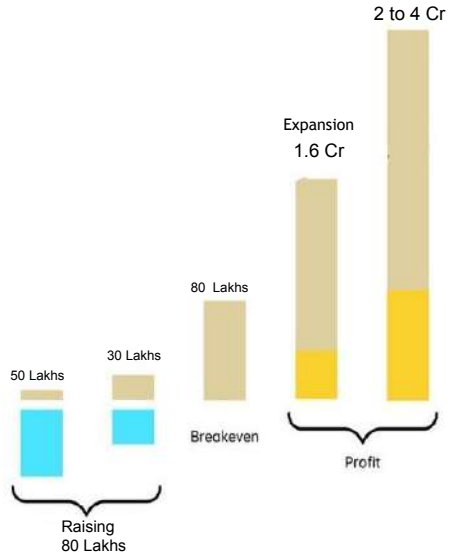


Capital Requirement (Gross Estimates)

Our Projections - 2024 2025 2026 2027 2028

Projected Fund Use of BIG Grant (50 Lakh)

- 10 Lakhs R&D/GTM Product
- 5 Lakhs for CE class 2a certificate
- 5 Lakh for Clinical Testing, Ethical Approval
- 10 lakhs key hires
- 20 lakhs working capital (for OpEx,Mfd)



Funds

- 8.1) Required for?
- M+M+D
- Hiring + team members
- Setting up partnerships

- 8.2) Already Invested -
- Prototyping (5000 Rs)
- Market research & validation of the product
- Legal, administrative out-of-pocket costs

- 8.3) Potential Sources ?
- Grants and government funding - BIG Grant
- Institutional Incubator like itic, CfHE
- Angel investors and venture capital firms
- Partnerships with healthcare providers and insurance companies
- Crowdfunding campaigns

FC • Obtaining certifications • Setting up Mfd facilities • Cost of raw materials & production	**OC** • Rent for office space • Salaries of employees • Cost of Mktg & Advt
CapEx • Investment in R&D • Software development	**OpEx** • Mfd facility Running expenses • Utility bills and maintenance costs.

Novelty in our Product

1. Completely Wireless and Hassle-free.

   Our solution is Specific to Asthma only.
2. Continuous monitoring
3. Comfortable wearable patch -

   Allergic free material. Fully Biodegradable.
4. Dedicated Application for Parents -

   Stress-free 24*7 monitoring
5. Automated AI/ML classification -

   Wheeze/No Wheeze activity classification
6. Parameters Updates Live on Dashboard
7. Made In India for the Indian Market first.

Our Logo and Tagline Resonates with Product

Motto - **Breathe Back to Life**

Means - **Conveys the simple message of**

"Helps get your child back to the Normal way of Breathing, Improving everyday

to embrace a life full of vitality and limitless possibilities."

Brand - **PulmoWare**

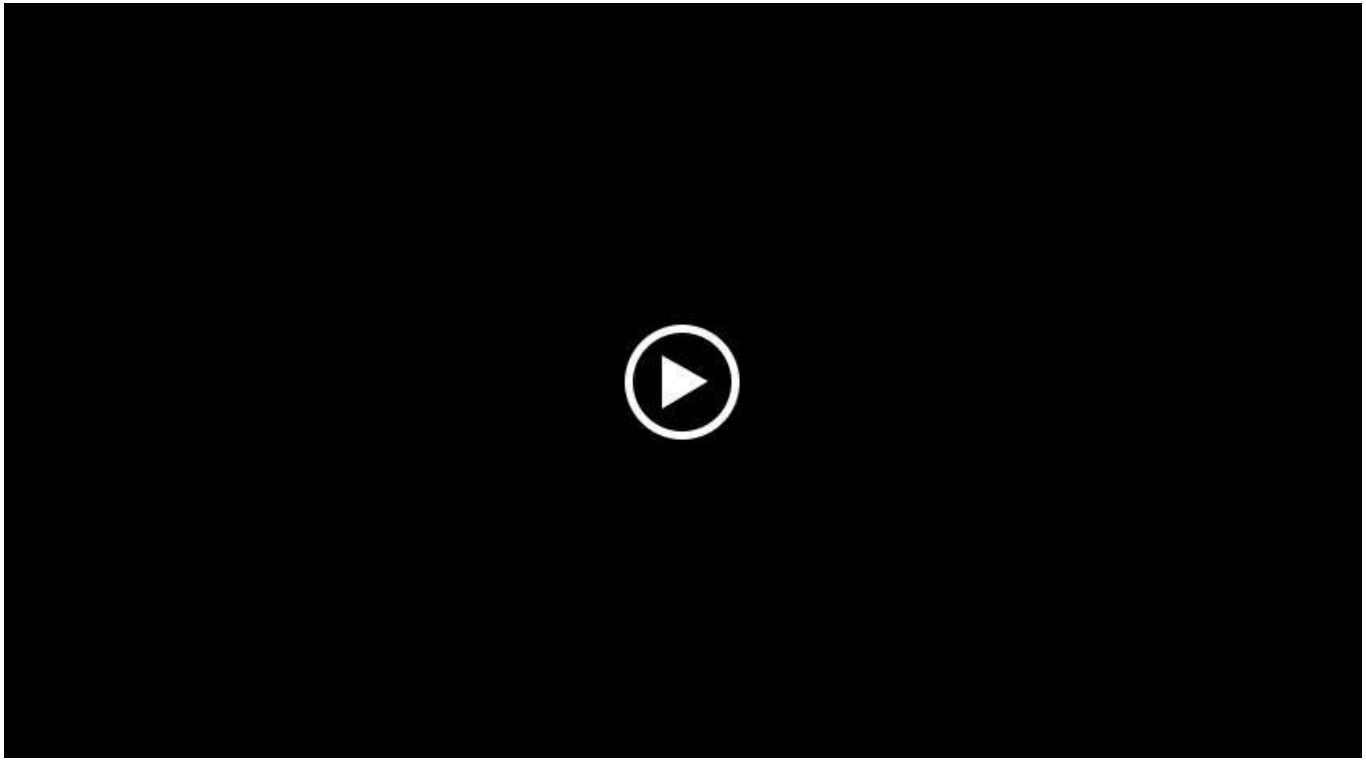
Simple Depiction of our Medical grade Wearable Product

Understandable and Relatable to End Users

PULMOWARE

breathe back to life

Clinical Validation of our Product by
Dr. Vishwanath V Bellad, MD, DM (Pulmonology)
Bengaluru, Karnataka, India



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