## Introduction

AI COPD – Acute Exacerbation of COPD & Asthma Risk Score is a novel artificial intelligence-based risk score system that provides the individual's risk of having Acute Exacerbation of COPD or related events in the next 3 months. The risk is developed by Apollo Hospitals and undergoing further validation. The methodology helps to stratify the patient's risk and provide individualized protocol using a Clinical Decision Support System on the next best actions with an AUC above 0.9.

## Why is AICOPD different?
1. Machine Learning Model developed with Clinical Features, Medication History, and Air Quality Data having Higher Accuracy
    a. CART Model with Deep Learning Tool on Cough Sounds (Coming Soon)
    b. Model Built and Validated with Over 800K Medication Purchase Data
    c. Accuracy - AUC – >0.9 (Development)
2. Feedback Loop from the prospective use in patients
3. Comprehensive & Holistic Risk Assessment
4. Ongoing validation at different National Institutions
5. Integrated Clinical Decision Support Tool (What Next to do)

## What is the Interpretation & Adoption Message
1. AI Algorithm + Clinicians - This Risk Assessment tool has been built as an adjunct tool for the physicians to identify the global/holistic risk for the patients of developing Acute Exacerbation of COPD
2. Risk Identification and Prevention - This Risk Assessment Tool is not to be used for diagnosis of Chronic Obstructive Pulmonary Disease or Asthma. Its limitations include use in pediatric asthma and currently under treatment.
3. Where to Use- This Risk Assessment tool has been prepared for use in Preventive Pulmonology Screening programs at Outpatient Clinics, Emergency Rooms, and Health Check Clinics specifically looking at Chronic Obstructive Pulmonary Diseases.

How to Use for (Clinicians Only )-

1. Provide Appropriate –
   a. Patient Details
   b. Obtain Patient Consent

2. Risk Factors Included –

   a. Medication List
      i. Group 1 : Cough Suppressant & Mucolytic Agents | Anti – Histaminic / Anti Allergic – e.g. Ketotitfen | Ebastine | Montelukast Azelastine | Cetrizine | Others
      ii. Group 2 : Inhalers - Budesonide | Formoterol | Ipratropium | (levo) Salbutamol |Salmeterol | Tiotropium | Rotahalers | Others
      iii. Group 3 : Bronchodilator | Lung Surfactant | Nebulizers - Acetylcysteine | Aminophyline | Phospholipid fraction | Others
      iv. Group 4: Other Categories: Drugs on Respiratory System including the Antibiotics

   b. Vaccination History – COVID-19 (Last Dose) | Influenza Vaccine
   c. Personal/VS – Age | Gender | Smoking | History – COPD & Other Respiratory Diseases/ TB / CVD
   d. Clinical Symptoms - Cough with Expectoration | Progressive Breathlessness | Shortness of Breath
   e. Chest Related Attributes - Heart Rate | SpO2 | Chest – Wheeze | Respiratory Rate

3. Output

   a. Risk Categorization – Low – Moderate – High Risk of Acute Exacerbation of COPD in the Next 3 months
   b. COPD Risk Score
   c. Top Modifiable Risk Attributes
   d. Clinical Decision Support System (What Next to Do)
      i. Lab, Imaging and Investigations
      ii. Pulmonology Referral
      iii. Treatment Goals
      iv. Education
      v. Revisit Guidelines

Workflow for AI COPD APP



Figure 1 – Entry of Patient details and Clinical Parameters (At admission & hourly)

Patient details Dashboard: The first step to use the AI-COPD App is to log into the Doctor Dashboard using your unique credentials. After login, Fill in the Patient Details and accept consent.



Figure 2 – Entry of Patient Attributes (Once and when changed)

An Apollo Hospitals Document

Patient Attributes: The following categories are used to collect the patient attributes data: Location Details to Calculate Air Quality Index (AQI), Clinical Parameters such as Tobacco & Smoking Habits & History of Tuberculosis, Breathlessness, Cough with Sputum Etc.
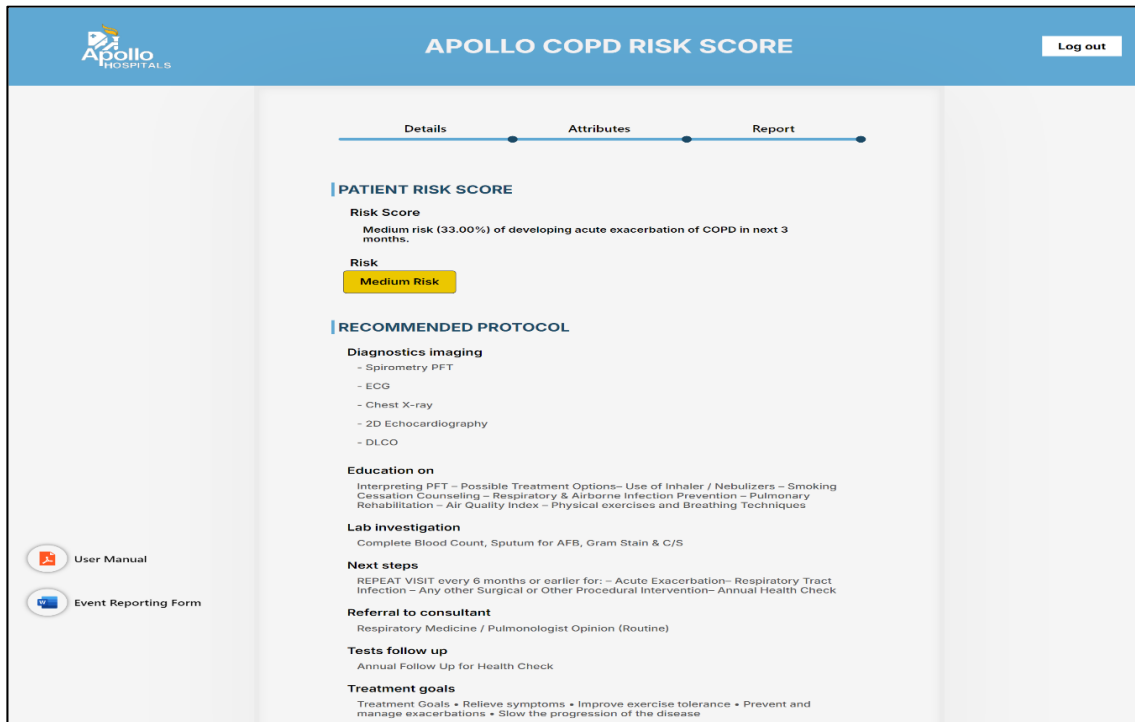


Figure 3 – Generation Risk Score Report of Patient

Output

    a. Risk Categorization – Low – Moderate – High Risk of Acute Exacerbation of COPD in the Next 3 months

    b. COPD Risk Score

    c. Top Modifiable Risk Attributes

    d. Clinical Decision Support System (What Next to Do)

Printed Report

## COPD RISK SCORE

| NAME: JOHN DOE | AGE: 44 | LOCATION: GAYA |
|---|---|---|
| UHID: APJ1324354657 | GENDER: MALE | DATE OF REPORT: 3-5-2024 |

### PATIENT RISK SCORE

**Risk Category**

Low Risk

**Risk Score**

Low risk (24.00%) of developing acute exacerbation of COPD in next 3 months.

### PAST HISTORY

| INFORMED CONSENT OBTAINED ✓ | |
|---|---|
| Allergies | POLLEN - GRASS AND TREE POLLEN – AN ALLERGY TO THESE IS KNOWN AS HAY FEVER (ALLERGIC RHINITIS) |
| Pulmonary History | COPD - CHRONIC OBSTRUCTIVE PULMONARY DISEASE |
| Medication | GROUP 1 : COUGH SUPPRESSANT & MUCOLYTIC AGENTS \| ADULT VACCINES\| ANTI-HISTAMINIC / ANTI ALLERGIC |
| COVID-19 (Vaccination) | (DATE) 2023-11-11 — (BRAND) COVISHIELD |
| Influenza (Vaccination) | (DATE) 2023-11-11 |

### CLINICAL FEATURES

| | | | |
|---|---|---|---|
| Air quality index (Gaya) | 116 | Does the patient use any one the drugs listed below? | NO |
| Smoking | NO | Patient Respiration Rate | 18 |
| Tobacco | NO | Has the patient's pulse rate increased by 10% from baseline recently? | NO |
| Does the patient have history of Asthma/ Tuberculosis or Heart Disease ? | NO | Oxygen Saturation | 98 |
| Does the patient feel progressive breathlessness during normal activity, exercise or at night ? | NO | On patient's chest auscultation, are there presents of wheezes ? | NO |
| Does the patient have cough with sputum production? | NO | | |

This report is accessed by Dr. Sujoy

Date: 3-5-2024
Time: 5:48:51 pm

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## COPD RISK SCORE

| NAME: JOHN DOE | AGE: 44 | LOCATION: GAYA |
| --- | --- | --- |
| UHID: APJ1324354657 | GENDER: MALE | DATE OF REPORT: 3-5-2024 |

### RECOMMENDED PROTOCOL

**Diagnostics imaging**

- Chest X-ray

- Spirometry PFT

- ECG (optional)

**Educate on**

Interpreting PFT – Possible Treatment Options– Smoking Cessation Counseling – Respiratory & Airborne Infection Prevention – Pulmonary Rehabilitation – Air Quality Index – Physical exercises and Breathing Techniques

**Lab investigation**

Complete Blood Count

**Next steps**

REPEAT TESTING every year or earlier for: – Adults of any age if Symptomatic – Use of Group 2 & 3 Medications – Annual Health Check

**Referral to consultant**

Not Required

**Tests follow up**

Annual Follow Up for Health Check

**Treatment goals**

Relieve symptoms → Improve exercise tolerance→ Slow the progression of the disease

To consult our Pulmonologists dial 1860 500 1066 or download the Apollo 24/7 app (available for both Apple and Android devices)

The Research

Introduction:
Strong evidence exists regarding the links between air pollution and non-infectious respiratory diseases [1]. Exposure to various air pollutants has been related to asthma, chronic obstructive pulmonary disease (COPD), interstitial pulmonary fibrosis, cystic fibrosis, and lung cancers. Less evidence exists for respiratory infections, as most studies have been observational and very few have measured exposure directly. However, there is consistent evidence that indoor air pollution increases the risk of acute

respiratory infection in childhood, which is the most important cause of death among children under 5 years of age in developing countries [2].

Furthermore, outdoor air pollution-related lower respiratory infections (LRIs) caused approximately 237,000 (192,000–277,000) excess child deaths worldwide in 2015, thus contributing about 5% of total air pollution–attributable deaths for that year[3]. In terms of COPD exacerbations, a meta-analysis of 59 studies showed a significant short-term effect for all gaseous and particulate pollutants [4]. These studies have shown a consistent association between elevated ambient oxides of nitrogen (NOx), namely, nitrogen dioxide and nitric oxide, and an increased incidence of COPD exacerbations [5]. Stronger results were seen during winter, in India particularly from the period of October to March. A significant air pollution impact was reproduced in subsequent analyses of exacerbations associated with healthcare use. Similar results, although not always significant, were also observed for particulate matter [6].
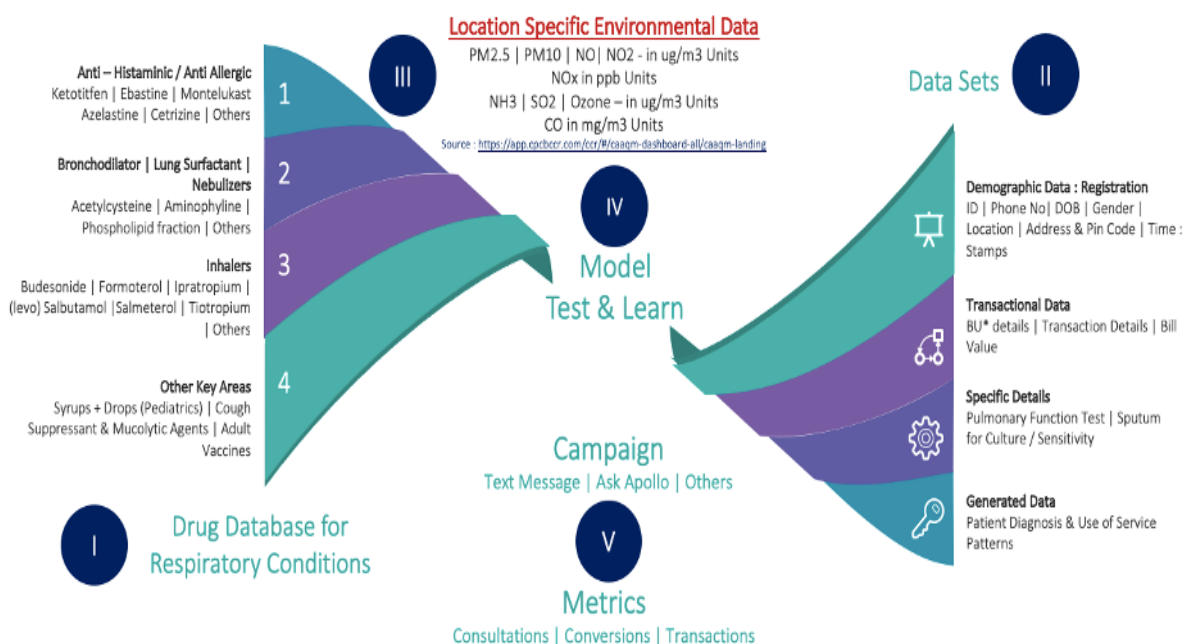
Statistics at a glance:
1. An estimated 1 Billion people worldwide suffer from lung disease
2. 1 million hospitalizations annually in the US for Asthma and COPD
3. 3rd Most Common Cause of Death – according to WHO
4. Most Expensive Chronic Disease in Elderly Patients

Background:
The study looks at the background data of the Air Quality Index of several cities in India and their effect on the exacerbation of COPD / Asthma / ACOS. The study also looks at the current usage of respiratory medication, classified into 4 groups, and how individuals purchase (and use) them. Using the patient demographics, and available medical records, a model is prepared to detect the risk of Acute Exacerbation of chronic airflow diseases.



Artificial Intelligence based Care Pathway Design for Individuals at Risk of Acute Exacerbation of COPD, Asthma and Chronic Respiratory Diseases
Dr Sai Praveen, Dr Suresh Ramasubban, Dr Sujoy Kar

## Ethics Perspective

| | | | |
|---|---|---|---|
| Title | Development and Validation of a Multivariable prediction model using Machine learning to predict the Acute Exacerbation of Asthma, COPD Related events(AICOPD) | Centers | India – Apollo Hospitals |
| Principal Investigators | Dr Sujoy Kar, Dr. Sai Praveen Haranath, Dr Suresh Ramasubban | Institutional Ethics Committee Approval | Obtained |
| Data | Model Built and Validated with Over 800K Medication Purchase Data | Safety | Model advocates risk scores that are interpreted by clinicians through safe Machine (API) – Human (Clinician) Interaction |
| Sample Size + Missing Data | 800k Medication Purchase Data | No imputations | Inclusiveness & Fairness | At admission data includes clinical comorbidities & conditions | No socioeconomic discrimination |
| Personal Health information | De-identified all PHI during analysis, model building, API hosting and Prospective Use | Privacy & Confidentiality | Data secured at Apollo Azure Tenant with all relevant compliance + conforming to laws |
| Addressing Bias (Geographical / Ethnic / Temporal / Gender etc.) | Multiethnic – All Adult Population Group| Automation Bias addressed at API Clinical Use | Accuracy + Efficacy | Metrics -Accuracy - AUC – >0.9 (Development) |
| Risk Groups | Low – Moderate – High Risk of Asthma, COPD related Events Exacerbation in next 3 Months | Informed Consent | Yes – Template & Protocol (Prototype Attached) |
| Model Specification | CART Model | API – Ease of Use + Interpretation | Flows to Clinical Algorithm Standard Clinical Definitions + Lab Units Used |
| Clinical Algorithm Update (Version) | September 2022 | Validation + Peer Review | Ongoing |
| Intellectual Property Rights (IPR) | Patent No|202441065933 | Certifications & Compliance | ISO 13485:2016 Certification | MD 763515 CDSCO Application No | Apollo-Hyder-TE/M/MD/007509 |

**Patient appropriate for SCREENING following**
**Medication Use History + Local Environmental Factors.**

| Medication List | Environmental Factors |
|---|---|
| **Group 1 : Cough Suppressant & Mucolytic Agents | Adult Vaccines| Anti – Histaminic / Anti Allergic** <br> Ketotitfen | Ebastine | Montelukast Azelastine | Cetrizine | Others <br><br> **Group 2: Inhalers** <br> Budesonide | Formoterol | Ipratropium | (levo) Salbutamol |Salmeterol | Tiotropium | Rotahalers | Others <br><br> **Group 3 : Bronchodilator | Lung Surfactant | Nebulizers** <br> Acetylcysteine | Aminophyline | Phospholipid fraction | Others <br><br> **Group 4: Other Categories:** Drugs on Respiratory System | (In ug/m3 Units) <br> o  PM2.5  > 25 (24 hours) <br> o  PM10  > 50 (24 hours) <br> o  NO2 > 80 (24 hours) <br> o  NH3 > 400 (24 hours) <br> o  SO2  >80 (24 hours) <br> o  AQI : > 150 - *AQI Calculation: Each pollutant "safe level" is expressed as 100. If there is an unsafe level of a single pollutant, the AQI number will be over 100.* <br><br> Value Source : <br> 1.  National Ambient Air Quality Standards 18 November 2009 by the Central Pollution Control Board <br> 2.  WHO 2005 & 2014 <br><br> Daily Data Source <br> https://app.cpcbccr.com/ccr/#/caaqm-dashboard-all/caaqm-landing |

**Personalized Parameter Review: Clinical Features and Examination**

Review medical history, including baseline FEV1, frequency of previous exacerbations/hospitalizations & comorbidities
**Category 4: Very High-Risk Category - Severe\*  Symptoms – Immediately refer to Emergency Department or Pulmonologist**

Severe underlying COPD (FEV1 <50% of predicted) | Frequent previous exacerbations or hospitalizations ( > 3/year) | Presence of comorbid conditions | Antimicrobial use within the last 3 months | Marked increase in the intensity of symptoms | Use of accessory respiratory muscles | New onset of central cyanosis or peripheral edema | Hemodynamic instability | Signs of right heart failure

| Patient Parameters | Clinical Symptoms | Examination |
|---|---|---|
| o  Age <br> o  Gender <br> o  Smoking <br> o  History – COPD / TB / CVD | o  Cough with Expectoration <br> o  Progressive Breathlessness <br> o  Shortness of Breath | o  Respiratory Rate <br> o  Pulse Rate <br> o  SpO2 <br> o  Chest – Wheeze; <br><br> **Medication History** <br> Mention – Group 1 / 2 / 3 / 4 |

| | | |
|---|---|---|
| o BMI<br>o Smoking<br>o History – COPD / TB / CVD<br>o History of other inhalation exposures (e.g., occupational dust or chemicals, indoor or outdoor air pollution, passive exposure to smoking) | **Mild**: Cough: Productive or Unproductive, Allergic Rhinitis & Dermatitis<br><br>**Moderate**: Progressive Breathlessness & Shortness of Breath (on exercise); Persistent Cough with Chronic Sputum Production & Chest Tightness | o Temperature<br>o Blood Pressure<br>o Expiratory Prolongation |

**Risk Calculation & Stratification**

| <0.26 | 0.26 – 0.31 | >0.31 |
|---|---|---|
| Category 1 | Category 2 | Category 3 |
| **Lab Investigation**<br>Complete Blood Count | **Lab Investigation**<br>Complete Blood Count<br>Sputum for AFB, Gram Stain & C/S | **Lab Investigation**<br>Complete Blood Count<br>Sputum for AFB, Gram Stain & C/S<br>Optional – Aplhia – 1 antitrypsin |
| **Diagnostics & Imaging**<br>Chest X-ray<br>Spirometry PFT<br><br>ECG (optional) | **Diagnostics & Imaging**<br>Spirometry: PFT<br>ECG,<br>Chest X-ray,<br>2D Echocardiography<br>DLCO<br><br>Allergy Tests | **Diagnostics & Imaging**<br>Spirometry: PFT<br>ECG, Chest X-ray, 2D Echocardiography<br>DLCO<br><br>ADVANCED Tests -<br>CECT Chest<br>Arterial Blood Gas<br>Allergy Tests |
| **Referral**<br>None | **Referral**<br>Respiratory Medicine / Pulmonologist  Opinion (Routine) | **Referral**<br>Respiratory Medicine / Pulmonologist Referral (Urgent) |

The choice of treatment/medications is at the discretion of the treating physician.

**Treatment Goals**
• Relieve symptoms
• Improve exercise tolerance
• Slow the progression of the disease

EDUCATE on
– Interpreting PFT
– Possible Treatment Options
– Smoking Cessation Counseling
– Respiratory & Airborne Infection Prevention
– Allergen & Triggers
– Pulmonary Rehabilitation
– Air Quality Index
– Physical exercises and Breathing Techniques

REPEAT TESTING every year or earlier for:
– Adults of any age if Symptomatic
– Use of Group 2 & 3 Medications
– Annual Health Check

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**Treatment Goals**
• Relieve symptoms
• Improve exercise tolerance
• Prevent and manage exacerbations
• Slow the progression of the disease

EDUCATE on
– Interpreting PFT
– Possible Treatment Options
– Use of Inhalers / Nebulizers
– Smoking Cessation Counseling
– Respiratory & Airborne Infection Prevention
– Allergen & Triggers
– Pulmonary Rehabilitation
– Air Quality Index
– Physical exercises and Breathing Techniques

REPEAT VISIT every 6 months or earlier for:
– Acute Exacerbation
– Respiratory Tract Infection
– Any other Surgical or Other Procedural Intervention
– Annual Health Check

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The choice of treatment/medications is at the discretion of the treating physician.

**Treatment Goals**
• Relieve symptoms
• Improve exercise tolerance
• Prevent and manage exacerbations
• Slow the progression of the disease
• Reduce morbidity and mortality

EDUCATE on
– Interpreting PFT
– Possible Treatment Options
– Use of Inhalers / Nebulizers
– Smoking Cessation Counseling
– Oxygen Therapy
– Pulmonary Rehabilitation
– Respiratory & Airborne Infection Prevention
– Allergen & Triggers
– Air Quality Index
– Physical exercises and Breathing Techniques

REPEAT VISIT every 3 months or earlier for:
– Acute Exacerbation
– Respiratory Tract Infection
– Any other Surgical or Other Procedural Intervention

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*Disclaimer: This **Clinical** Algorithm is a general guideline for Physicians using the COPD Risk Calculation and Stratification. Any additional Laboratory Investigations, Diagnostic Imaging, Treatment, or Patient Education related to lifestyle management is under the Outpatient or ER Physician's or Pulmonologist's discretion.*

Frequently Asked Questions

Introduction.
 AI COPD – Acute Exacerbation of COPD & Asthma Risk Score is a novel artificial intelligence-based risk score system that provides the individual's risk of having Acute Exacerbation of COPD or related events in the next 3 months. The risk is developed by Apollo Hospitals and undergoing further validation. The methodology helps to stratify the patient's risk and provide individualized protocol using a Clinical Decision Support System on the next best actions with an AUC above 0.9.

Why is AICOPD different or What is the advantage of this score?
1. Machine Learning Model developed with Clinical Features, Medication History, and Air Quality Data having Higher Accuracy
    a. CART Model with Deep Learning Tool on Cough Sounds (Coming Soon)
    b. Model Built and Validated with Over 800K Medication Purchase Data
    c. Accuracy - AUC – >0.9 (Development)
2. Feedback Loop from the prospective use in patients
3. Comprehensive & Holistic Risk Assessment
4. Ongoing validation at different National Institutions
5. Integrated Clinical Decision Support Tool (What Next to do)

What is the Interpretation & Adoption Message
1. AI Algorithm + Clinicians - This Risk Assessment tool has been built as an adjunct tool for physicians to identify the global/holistic risk for the patient developing Acute Exacerbation of COPD.
2. Risk Identification and Prevention - This Risk Assessment Tool is not to be used for diagnosis of Chronic Obstructive Pulmonary Disease or Asthma. Its limitations include use in pediatric asthma and currently under treatment.

Where can the physicians use the AICOPD tool –
This Risk Assessment tool has been prepared for use in Preventive Pulmonology Screening programs at Outpatient Clinics, Emergency Rooms, and Health Check Clinics specifically looking at Chronic Obstructive Pulmonary Diseases.

What are the Risk Factors Included –
a. Medication List
    i. Group 1 : Cough Suppressant & Mucolytic Agents | Anti – Histaminic / Anti Allergic – e.g. Ketotitfen | Ebastine | Montelukast Azelastine | Cetrizine | Others
    ii. Group 2 : Inhalers - Budesonide | Formoterol | Ipratropium | (levo) Salbutamol |Salmeterol | Tiotropium | Rotahalers | Others
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    iv. Group 4: Other Categories: Drugs on Respiratory System including the Antibiotics

b. Vaccination History – COVID-19 (Last Dose) | Influenza Vaccine
c. Personal/VS – Age | Gender | Height | Weight | BMI  | Smoking | History – COPD / TB / CVD
d. Clinical Symptoms - Cough with Expectoration | Progressive Breathlessness | Shortness of Breath
e. Chest Related Attributes - Heart Rate | SpO2 | Chest – Wheeze | Respiratory Rate

What are the Output and Follow-Up For the Risk Score

   a. Risk Categorization – Low – Moderate – High Risk of Acute Exacerbation of COPD in the Next 3 months
   b. COPD Risk Score
   c. Top Modifiable Risk Attributes
   d. Clinical Decision Support System (What Next to Do)
        i. Lab, Imaging and Investigations
        ii. Pulmonology Referral
        iii. Treatment Goals
        iv. Education
        v. Revisit Guidelines

Is this a diagnostic tool?
This is not a diagnostic tool and it does not guarantee the accuracy of the result and cannot be independently acted upon.

Does this contradict the Physician's view?
This Risk score and Clinical Algorithm is a general guideline for Physicians. Any additional laboratory investigations, Diagnostic Imaging, Treatment, or Patient Education related to lifestyle management is at the Physician's or Pulmonologist's discretion.

How does one ensure the accuracy of the AI COPD tool
To ensure the information in the report is up to date, accurate, and correct, the Doctor shall be consulted for interpretation of the report. Additionally, the input data should be accurate and as per the conventional metrics used.

Is this a substitute for any diagnostic test or clinician's advice
Absolutely No. This is an adjunct tool made with Clinical Features and History of the Patient. It doesn't substitute for any tests or advice.

What are the disclaimers for the use of this tool?

   a. Apollo Hospitals and its Staff do not offer any assurance on the information made available or be liable for any loss or damage as the said report is based on the AI COPD Risk Score without any intervention from their side.
   b. By usage of the AICOPD Risk Score, it is deemed that the beneficiary of this service has agreed to get the same done at his own risk and further agrees with this disclaimer without any limitation or any clauses or sub-clauses.

Can the report be shared with other clinicians?
Yes, each patient shall get a printed report or PDF copy which can be kept by the patient maintaining privacy and confidentiality.

Is this tool validated for research ethics committees?
Yes. Institutional Ethics Committee Approval for Hyderabad and Kolkata are obtained and annually followed.

How is Safety addressed?
The model advocates risk scores that are interpreted by clinicians through safe Machine (API) – Human (Clinician) Interaction. Informed consent from each individual is obtained before the Risk Score generation.

Current Definitions of asthma and COPD, and clinical description of ACOS:

1. Asthma – Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined as the history of respiratory symptoms such as wheezing, shortness of breath, chest tightness, and cough that vary over time and in intensity, together with variable expiratory airflow limitation [GINA 2015][7].

2. COPD – COPD is a common preventable and treatable disease characterized by persistent airflow limitation that is usually progressive and associated with enhanced chronic inflammatory responses in the airways and the lungs to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients [GOLD 2015] [8].

3. Asthma – COPD Overlap Syndrome (ACOS) - Asthma – COPD Overlap Syndrome (ACOS) is characterized by persistent airflow limitation with several features usually associated with asthma and several features associated with COPD. ACOS is therefore identified in clinical practice by the features that it shares with both Asthma and COPD. The specific definition of ACOS is under development as more evidence is available including the clinical phenotype and underlying mechanisms.

Air Quality Index:
- An air quality index (AQI) is used by government agencies[9] to communicate to the public how polluted the air currently is or how polluted it is forecast to become.[10][11] Public health risks increase as the AQI rises. Different countries have their air quality indices, corresponding to different national air quality standards.
- Computation of the AQI requires an air pollutant concentration over a specified averaging period, obtained from an air monitor or model. Taken together, concentration and time represent the dose of the air pollutant. Health effects corresponding to a given dose are established by epidemiological research. Air pollutants vary in potency, and the function used to convert from air pollutant concentration to AQI varies by pollutant. Its air quality index values are typically grouped into ranges. Each range is assigned a descriptor, a color code, and a standardized public health advisory.
- The AQI can increase due to an increase in air emissions (for example, during rush hour traffic or when there is an upwind forest fire) or from a lack of dilution of air pollutants. Stagnant air, often caused by an anticyclone, temperature inversion, or low wind speeds lets air pollution remain in a local area, leading to high concentrations of pollutants, chemical reactions between air contaminants, and hazy conditions.
- The definition of the AQI in a particular nation reflects the discourse surrounding the development of national air quality standards in that nation. A website allowing government agencies anywhere in the world to submit their real-time air monitoring data for display using a common definition of the air quality index has recently become available.
- The National Air Quality Index (AQI) was launched in New Delhi on September 17, 2014, under the Swachh Bharat Abhiyan.