Cognita Labs: Precision CareCOPD Platform

Home monitoring of respiratory mechanics for identifying and effectively managing COPD patients

Introduction

250M+ people suffer from Chronic Obstructive Pulmonary Disease (COPD) and are at highest risk of contracting severe COVID-19 complications. Effective home management is more important than ever before.

The COPD Telehealth Challenge:

- No **accurate and scalable** remote data-driven monitoring solution for COPD.
- At-home clinical tests are **difficult to perform** (e.g.spirometry), inaccurate (e.g.symptoms-diary), or too-late-to-be-useful (e.g.PulseOx, Peak flow measurements).
- Need relevant bio and behavioral information that. **seamlessly collects small airway lung function, medication**

CareCOPD Solution

Predictive Analytics

PulmoScan measures Oscillometry Lung Function

CapMedic measures Rescue Medication Use

CareCOPD collects Symptoms Data

CareCOPD for home monitoring	• Easy, simple breathing test • Small airway obstruction • Suitable for elderly patients and home use	• Fully automatic, passive • Medication adherence and technique (efficacy) • Live coaching to improve dosage efficiency	• Text/SMS based interaction – easier for seniors + low-income. • Easy numeric responses to symptoms assessment questions (CAT, mMRC standard)

CareCOPD Objectives – Remote monitoring

CareCOPD Innovations:
- **Data Innovation**- Bringing three most relevant COPD health parameters never captured before remotely
  1. Lung function (from PulmoScan): Respiratory impedance is very sensitive to small airway changes
  2. Medication adherence and competence (from CapMedic): Inhaler use is directly linked with exacerbations
  3. Symptoms assessment: CAT and mMRC questionnaires are standard practice for COPD assessment
- **Innovation in approach**- Portable intuitive devices, automatic cloud upload, text-based symptoms collection
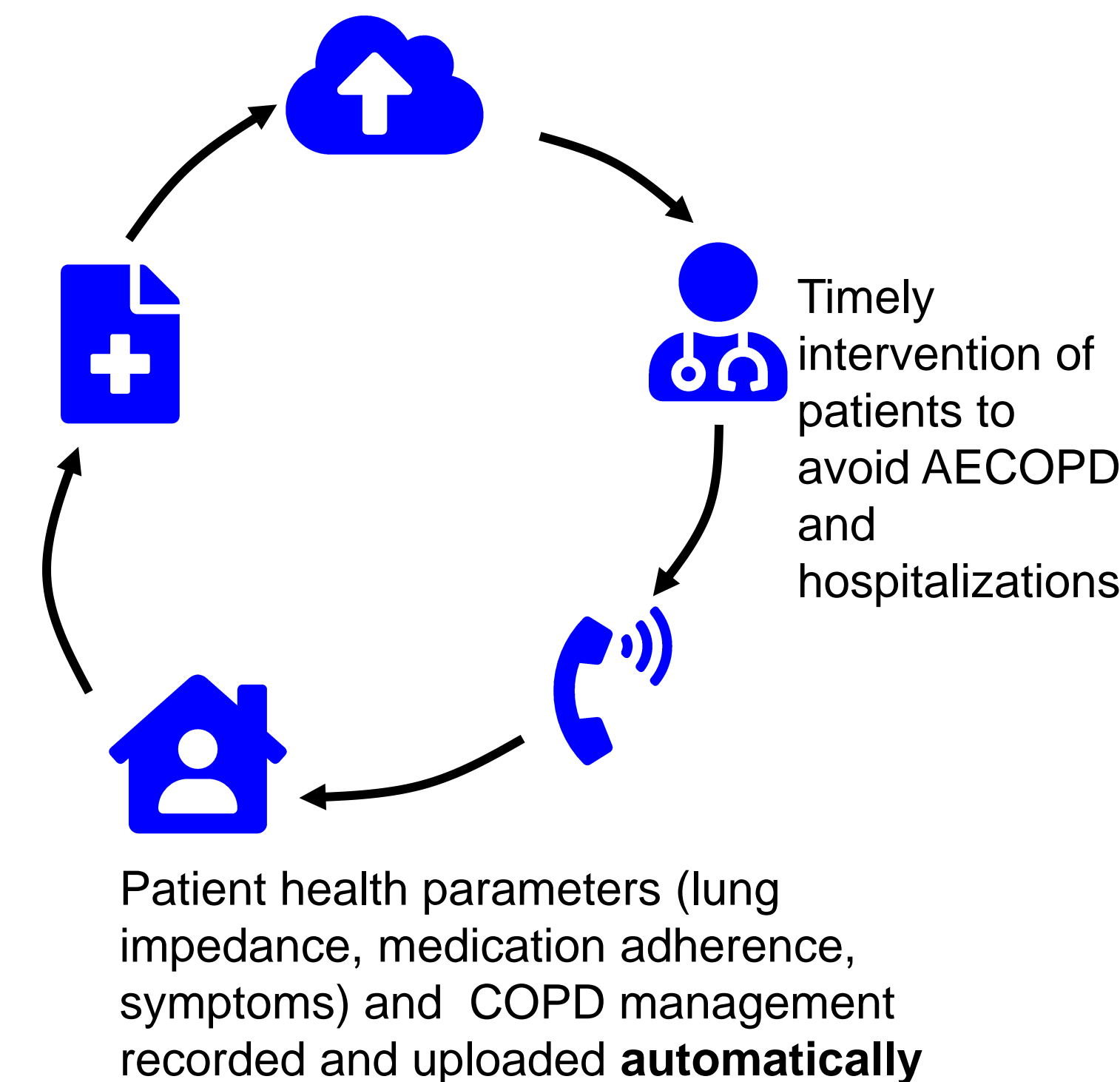
Hypothesis: Home monitoring of COPD patients using CareCOPD mature and validated devices results in **early detection of AECOPD** (acute exacerbation events).

The primary outcomes variables are:
1. Detection of AECOPD in the multivariate temporal data consisting of lung function, medication, and symptoms corresponding to AECOPD events.
2. Detection of AECOPD one day prior to the standard of care.

Goal: **Risk stratification of COPD patients** based on temporal CareCOPD data for early intervention

Relevant data metrics analyzed. CareCOPD performs risk stratification of patients.

Timely intervention of patients to avoid AECOPD and hospitalizations

Patient health parameters (lung impedance, medication adherence, symptoms) and COPD management recorded and uploaded **automatically**

Deliverables

CLINICAL- Pilot validation: Deploy CareCOPD devices to a group of 50 COPD patients (moderate-severe and poorly controlled, aged 40 and over) for 6 months from October to April (winter season) when AECOPDs are more frequent.

The outputs of the clinical trials are as follows:

1. **Predictive power**: Percentage of AECOPDs detected by CareCOPD platform
2. **Percentage** of AECOPDs detected 1 day prior to standard of care
3. **False positives**
4. **Critical variables** governing AECOPD detection – lung function parameters, medication, and symptoms.

Success will be based on improved detection of AECOPD, at least 1 day earlier than patient-reported assessment, false positives of <20%.

MARKET- Successful CAPCaT sponsored pilot - adoption in Ventura County Medical Center (the primary study site) and seven hospitals in Ventura and Santa Barbara counties.

REGULATORY- PulmoScan, CapMedic are FDA cleared. Cognita will pursue expedited FDA clearance for CareCOPD platform post-CAPCaT validation study to fulfill the urgent need of telemonitoring during COVID- 19.

TECHNOLOGY- The data analytics and risk stratification strategy will be finalized using patient data for at- home management plan and intervention methods. The platform uses the HL7 protocol for EHR integration which will also include intervention post- CAPCaT validation study.