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# Multisensor Non-invasive Telemonitoring System for Prediction of Chronic Obstructive Pulmonary Disease Exacerbation: Trial Design

Louis Kananowicz  
curtkananowicz1@hotmail.com

Karen Larimer PhD, ACNP-BC, FAHA  
klarimer@depaul.edu

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# Multisensor Non-invasive Telemonitoring System for Prediction of Chronic Obstructive Pulmonary Disease Exacerbation: Trial Design

Louis C. Kananowicz, Karen Larimer PhD, ACNP-BC, FAHA  
DePaul School of Nursing

## Background

Chronic Obstructive Pulmonary Disease (COPD) is a debilitating lung disease costing \$32.1 billion in 2010 and projected to increase to \$49 billion by 2020 (CDC, 2014). Quality of life is also significantly impacted. In 2010 it was estimated within the US that 16.4 million days of work were lost to COPD associated absenteeism.

Pulmonary rehabilitation can be added to pharmacotherapy for patient treatment and ranks as one of the most cost-effective treatment strategies.

Current methods of measuring patient progress in pulmonary irrespective of the method is suboptimal given A) the relative infrequency of tests and paucity of data sets, B) the challenge of consistent and accurate test administration, and C) the risk of invalid results from extrinsic factors.

In order to explore a potential biomarker for early identification of worsening COPD during a pulmonary rehabilitation program we propose to evaluate the clinical utility of including the accelerateIQ System in the management of patients in a pulmonary rehabilitation program.

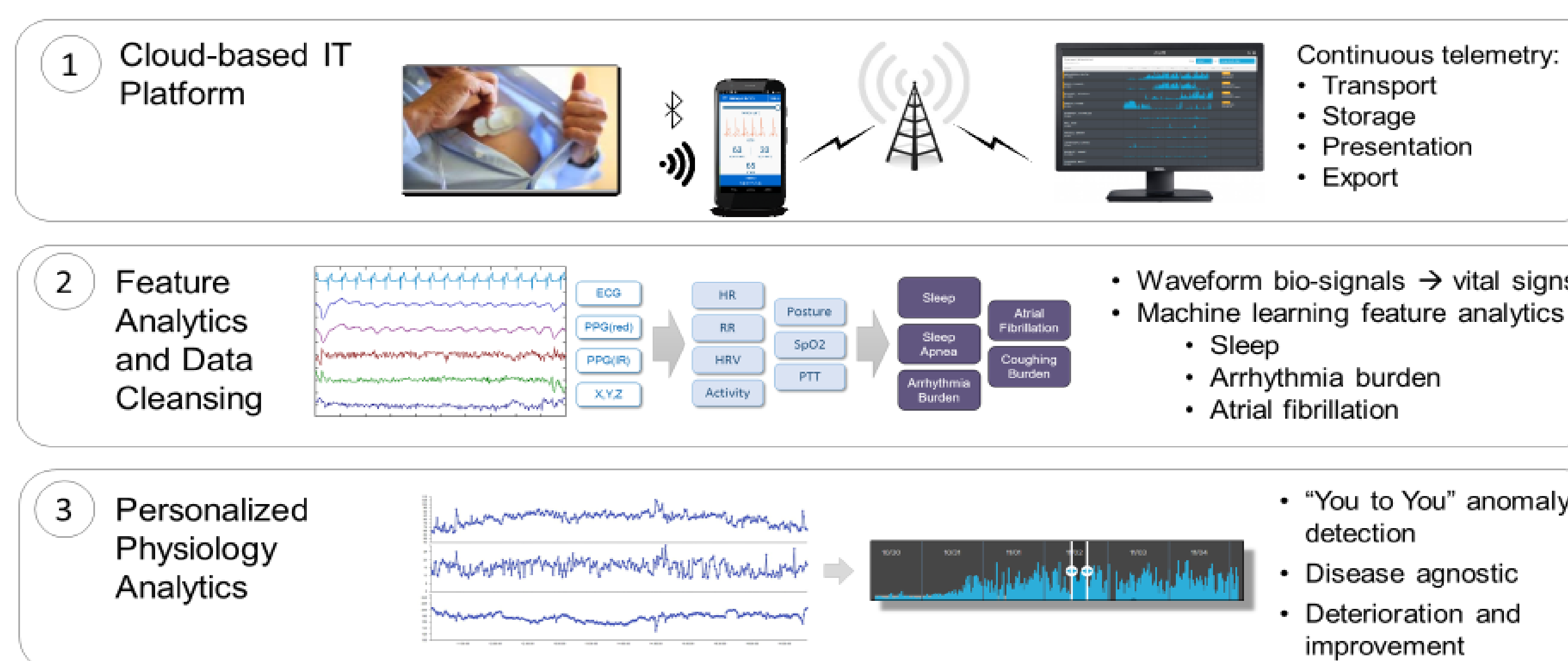
## References

Center for Disease Control and Prevention. (2018,October). *Chronic Obstructive Pulmonary Disease (COPD)*. Retrieved from Center for Disease Control and Prevention:

## Study Design

This is single-center, non-randomized, non-interventional study to evaluate the accuracy of a remote monitoring and analytical platform for prediction of COPD exacerbation. The platform acquires continuous multivariate vital signs from COPD patients participating in a pulmonary rehabilitation program using an ambulatory wearable biosensor and analyzes the data using a novel machine learning algorithm.

### PhysIQ Personalized Physiology Analytics platform



physIQ Sample = 50 Patients  
Monitored for 12 weeks (while in pulmonary rehab)



## Study Objective

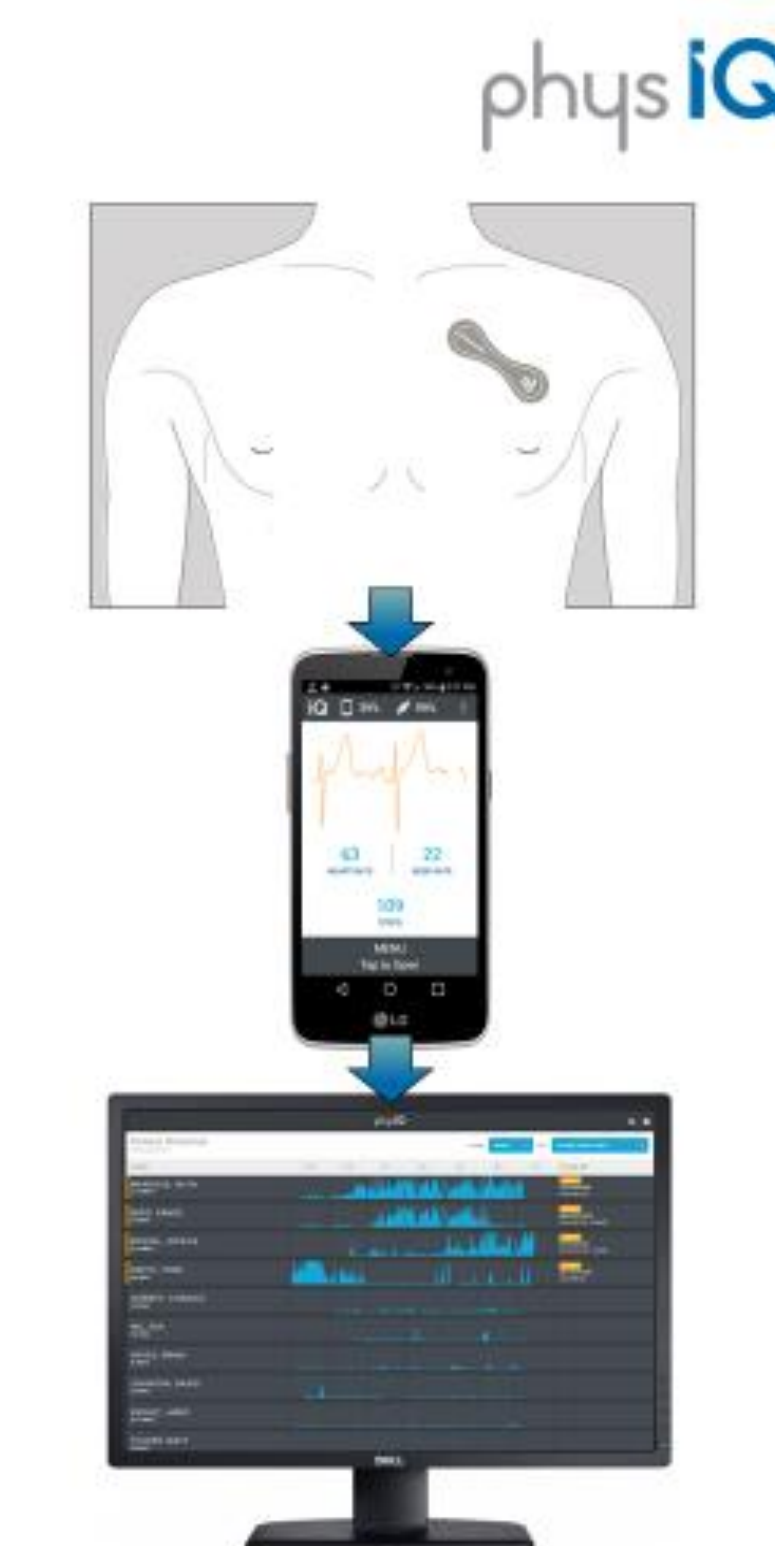
The primary objective of this study is to evaluate the clinical utility of including the accelerateIQ System in the management of patients in a pulmonary rehabilitation program and detection of COPD exacerbations at 90 days.

## How it Works

- VitalPatch worn on chest for 4 days collects vital signs
- VitalPatch sends data via Bluetooth to phone
- Phone transmits data to physIQ cloud platform using a cellular signal
- Subject data is stored on platform website



[www.physiq.com](http://www.physiq.com)



## Major Eligibility Criteria

### Inclusion Criteria

1. Male or female, at least 18 years of age;
2. Diagnosis of (COPD);
3. Enrolled in pulmonary rehabilitation program;
4. Capable of completing a 6-minute walk test;
5. Willing and able to comply with scheduled protocol procedures and follow up.

### Exclusion Criteria

1. Patient has cognitive or physical limitations that, in the opinion of the investigator, limit the patient's ability to fully utilize the System;
2. Patients who have CIED;
3. Patient is allergic to hydrocolloid adhesive.

## Statistical Analysis

Correlation of by algorithmic alerts generated non-invasive telemonitoring system to a verified COPD exacerbation event, measured in percent accuracy. A receiver operating characteristic (ROC) curve, (a graphical plot that illustrates the performance of a binary classifier system as its discrimination threshold is varied) will be generated. The curve is created by plotting the true positive rate (TPR) against the false positive rate (FPR) at various threshold settings resulting in specificity and sensitivity indices, respectively.

## Conclusion

In order to improve the completion rate of pulmonary rehabilitation programs and possibly avoid adverse events experienced by these patients, it is important to explore new methods for monitoring patients through the therapeutic process. The study is expected to begin enrollment in December 2018 at Northshore University Hospital with completion in April 2019.