STUDY TITLE: Feasibility of Inpatient and At-Home Use of Handheld Spirometry

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BACKGROUND

Chronic Obstructive Pulmonary Disease (COPD) results in nearly 750,000 hospitalizations annually and is the third leading cause of "early" (within 30-day) hospital readmissions in the United States.[1] Curbing preventable early readmissions for acute exacerbations of COPD (AECOPD) has become a national priority, as demonstrated by the Medicare Hospital Readmissions Reduction financial penalty program.[2] One critical barrier in assessing readmission risk is the lack of an easily-measured 'vital sign' for COPD: accurate, timely measurements of lung function. Unlike other medical problems that have validated, easily-obtained measurements of organ function, COPD evaluation often defaults to patient report and physician evaluation without critical physiologic data. This lack of objective pulmonary function data during AECOPD in turn leads to critical errors in disease severity assessment. However, the required, repeated measurements by spirometry that can demonstrate responses to therapy can be time-consuming and expensive to perform in a laboratory,[3] and both equipment and staffing infrastructure for bedside testing is cumbersome and often not prioritized. For these reasons, spirometry frequently is not done for patients with AECOPD.

To monitor patient responses to therapy and to assess risks based on objective measures, we propose to the study the use of a portable, patient-driven device ("SpiroPD") that can be used in both in-patient and outpatient settings, and that reports (via the internet) values collected in real time. While the device has been used in the lung transplant community and for patients with cystic fibrosis,[4] no studies have been done to validate its use in COPD. Our protocol involves in-hospital patient training with the device followed by serial measurements at home in the first 30 days post hospital-discharge.

Demonstration in a pilot, single-center trial of the usefulness of real-time, repeated hand-held spirometry to provide objective measurements of lung function in AECOPD will have a substantial impact on both patient health outcomes and on health care utilization and will set the stage for appropriate next-step studies and NIH grant applications. It is unknown whether this specific technology will be acceptable in our population, though previous research suggests that older patients may be willing to use home monitoring technology.[5] Our multi-disciplinary team includes providers from the Department of Medicine and the UCM COPD Readmissions Program team.

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[1] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. 2009; 360(14):1418-28.

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[3] Mortimer KM, Fallot A, Balmes JR, Tager IB. Evaluating the use of a portable spirometer in a study of pediatric asthma. Chest. 2003 Jun;123(6):1899-907.

[4] Shakkottai A, Nasr SZ. he Use of Home Spirometry in Pediatric Cystic Fibrosis Patients: Results of a Feasibility Study. Glob Pediatr Health. 2017 Feb 2;4:2333794X17690315.

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PURPOSE & HYPOTHESIS

Our central hypotheses are that handheld spirometry is feasible for inpatient and at-home use and is equally efficacious at determining lung function when compared with bedside spirometry measurements. To test these hypotheses, we propose the following specific aims:

Specific Aim 1: Determine the correlation of SpiroPD handheld spirometry measurements with bedside Koko spirometry lung function.

Hypothesis: Correlation between the two lung function tests will be substantial for both hospitalized and ambulatory patients.

Specific Aim 2: To determine the feasibility, adherence, and preliminary management efficacy of home SpiroPD testing.

Hypotheses: (1) Patients will demonstrate substantial adherence to daily home spirometry testing; (2) medication adherence will increase significantly in patients who are adherent to daily home spirometry testing; (3) acute care utilization will decrease significant in adherent patients.

METHODS OVERVIEW

We will enroll patients diagnosed with COPD both in the hospital and clinic setting and follow for 30 days. Participants will complete comparative lung function measurements with both devices while in the hospital or clinic at time of enrollment and at the 30-day follow up visit. Correlation will be assessed using Spearman's correlation coefficient. A high correlation (> 0.8) will demonstrate the usefulness of the SpiroPD device in these patients in both settings. We will use the FDA-cleared (K 103575) SpiroPD device for its intended use.

At the time of their initial study visit, study participants will be given a SpiroPD device for use at home following instruction in the hospital or clinic. Patient adherence to daily testing over one-month will be monitored using real-time capture Wi-Fi-data from the SpiroPD data portal. Participant surveys will ascertain barriers and facilitators of daily spirometry lung function testing, and subject attitudes and beliefs about the usefulness of this testing for self-management. Adherence to medication use and utilization outcomes will be measured using patient logs. Acute care utilization will be measured via tracking of ED visits, hospitalizations, and urgent care calls. Information will be collected at the 30 day (+/- 1 week) visit through in-person (preferred) or phone call visits (if do not show for in person visit).

Inpatient enrollment

Hospitalized patients with COPD will be screened using medical records. A member of the patients' inpatient care time (e.g., primary team, pulmonary consult service, COPD service) will be contacted for assent prior to approaching the patient. After consent, a trained research assistant will approach the patient and do the screening visit (V0) to ensure the patient has wireless internet and sufficient vision to see if they are eligible to continue with the remaining study visits. The research assistant will conduct both KoKo and SpiroPD spirometry with the participant no earlier than day 2 of the hospitalization. During this assessment, the research assistant will also provide the participant with training on use and function of the SpiroPD

device. They will return for a research visit at 30 days (+/- 1 week) if no clinic visit is scheduled during the 30 day research visit window. The patient will be offered a CTA/bus pass to return for their 30 day follow up. If the study participant is unable to attend the study visit in-person, we will arrange a phone call.

Outpatient enrollment

Patients being seen in the Pulmonary Clinic will be approached for participation following their clinic visit. As with the inpatient study, a trained research assistant will do a preliminary screening (wireless internet, vision) to see if the patient is eligible for the study. The research assistant will conduct obtain KoKo data from the clinical visit the patient just completed and SpiroPD spirometry with the participant. During this assessment, the research assistant will also provide the participant with training on use and function of the SpiroPD device. Outpatients will be offered a CTA/parking pass, if they decide to enroll but cannot complete the visit on the day of enrollment to return for the first visit. They will return for a research visit at 30 days (+/- 1 week) if no clinic visit is scheduled during the 30 day research visit window. The patient will be offered a CTA/bus pass to return for their 30 day follow up. If the study participant is unable to attend the study visit in-person, we will arrange a phone call.

V0

A trained research assistant will screen potentially eligible patient's in-person to see if they further qualify to participate. Every patient will be asked if they have access to wireless internet at home and their vision will be tested. A patient must be able to see at least 20/50 in one eye to be eligible to participate.

- Vision Assessment with Snellen Chart
    - Chart should be two chart lengths away from participant
    - Ask participant to cover their right eye and use their left eye to read the smallest line they can from the chart
    - Ask participant to cover their left eye and read the smallest line they can with their right eye
    - Administrator should follow patient's reading on a copy of the chart included in forms
    - Record acuity in right and left eyes
    - If vision is not better than 20/50 in at least one eye, the patient is ineligible to participate in the study.

Study Schema

	Screening V0	**Baseline (in person)**	**Ongoing (30d)**	**30d Follow-Up (in-person or phone call)**	**90d Post-Enrollment**
Informed Consent	**X**				
Vision Assessment	X				
Participant Data Collection:					
Self-reported demographics		X			
Self-reported health care utilization		X		X	
Respiratory symptoms/morbidity		X		X	
Quality of Life		X		X	

Health Literacy Assessment		X			
Spirometry		X		X	
SpiroPD device education		X			
SpiroPD use survey		X		X	
Reminder Text/Phone calls			X		
Device Data Collection			X		
Medical Record Data Collection		X	X	X	X

Texting and Phone Calls

A trained research assistant will use a study specific cell phone to communicate with patients. Patients will only be contacted by phone or text if they have given research staff permission during enrollment and provide the number to call and/or text. Patients will able to call us directly if they need additional assistant with the device or have any questions. In addition, if the patient had been seen by our COPD APNs in the hospital and make us aware that he or she is not feeling well the research assistant will get in touch with the APN from our COPD program to ensure this information gets communicated to them. We will reach out to patients to offer additional technical support (at 7 days) and to remind them of their 30 day follow up (prior to their appointment). Patient phone numbers will be stored in the phone using a study ID number. We will not store any other identifiable information in the cell phone..

Device Data Collection

The SpiroPD device will record participant use and lung function scores. These measurements are stored in a HIPAA compliant server over wifi and are available to the participant and research team.

Survey Data Collection

Trained research staff will assess the following at the initial enrollment, post-discharge follow-up visit (for hospitalized patients), and at the 30-day follow-up:

- Demographics
- Self-reported health care utilization
- respiratory symptoms/morbidity
    - Modified Borg Dyspnea Scale
    - Modified Medical Research Council (MMRC) Dyspnea Scale
    - COPD Assessment Tool
- Self-reported medication adherence
    - MARS
- Quality of Life
    - St. George's Respiratory Questionnaire-COPD
- Health Literacy: Ask brief health literacy screen questions for all participants
    - Brief Health Literacy Screen (BHLS) – three questions
        - How often do you have problems learning about your medical condition because of difficulty understanding written information?
        - How confident are you filling out medical forms by yourself?

    - How often do you have someone help you read hospital material?

- SpiroPD use
    - SpiroPD Pre-Education Survey
    - SpiroPD Post-Education Survey
    - SpiroPD Follow-Up Survey
    -
- Assess vision with Snellen Chart
    - Chart should be two chart lengths away from participant
    - Ask participant to cover their right eye and use their left eye to read the smallest line they can from the chart
    - Ask participant to cover their left eye and read the smallest line they can with their right eye
    - Administrator should follow patient's reading on a copy of the chart included in forms
    - Record acuity in right and left eyes
    - If vision is not better than 20/40 in at least one eye attempt to correct vision with non-prescription glasses
        - 4 strengths of glasses: 2.00, 2.25, 2.75, and 3.25
        - Start with 2.00, and repeat the vision screen, with each eye separately
        - If visual acuity of 20/40 is reached in at least one eye, the patient is eligible to complete the STOHFLA HL evaluation using the readers
    - If vision is not corrected after trying all of the strengths of the readers, the patient is ineligible to complete the STOHFLA HL evaluation

Spirometry

Spirometry will be performedusing the portable KoKo spirometer and the SpiroPD device. We have previously demonstrated that this population has poor perception of airflow obstruction and spirometry is feasible during the inpatient setting.

Medical Record and Administrative Data Collection

The following data will be collected by the CRDW and merged with survey and device data:

- Admission labs (e.g., bicarbonate, hemoglobin, creatinine) (hospitalized patients)
- Admission and discharge medications, inpatient medications (hospitalized patients)
- Admission length of stay (hospitalized patients)
- Admit and discharge service (hospitalized patients)
- Procedures during hospital stay (ICD-10 coded procedure) (hospitalized patients)
- Index admission type (urgent or emergent vs elective) (hospitalized patients)
- Comorbidities, ICD-9 & ICD-10
- Number of ED visits in the 12 months prior to enrollment and during the study period
- Number of hospitalizations in the 12 months prior to enrollment and during the study period
- Number and type of outpatient visits in the 12 months prior to enrollment and during the study period

- Number of observation stays in the 12 months prior to enrollment and during the study period
- PFTs
- Prescriptions for medications
- EPIC Healthy Planet data, including follow up phone calls, medication education, etc
- Consults received
- Insurance types
- Cost accounting system data (eSimon) including expected pay, net expected pay, etc.

These data will be collected from the time of electronic medical record initiation at University of Chicago (11/1/2008) until 90 days past enrollment.

DURATION

Participants will be asked to use the SpiroPD device for 30 days after discharge from the hospital or starting the day after the clinic visit if recruited from clinic. They will be in the study for 30 days (with a window of +/- 1 week for the 30 day visit) from the time of enrollment.

Electronic data will be collected from the time of electronic medical record initiation at University of Chicago (11/1/2008) until 90 days past the day of enrollment.

LOCATION

The study will take place at the University of Chicago Medicine within the hospital and the clinic.

TYPE AND NUMBER OF EXPERIMENTAL SUBJECTS

We will enroll 150 study participants.

Inclusion Criteria

1. Age 18 years and older
2. Physician-diagnosed COPD. We will enroll patients even if the primary reason for admission is not COPD or asthma (e.g., patients admitted for heart failure, but with a physician diagnosis of COPD are eligible).
3. Able to perform spirometry
4. Access to wireless internet at home
5. Visual acuity of at least 20/50 in one eye

Exclusion Criteria

1. Currently in an intensive care unit
2. Physician declines to provide consent
3. Patient unable to provide consent (e.g., history of cognitive impairment, unable to understand English) or declines to provide consent

For our study regarding correlation of the Koko with the SpiroPD devices to measure lung function, we will have power to detect a small to moderate effect size (ρ=0.023) at >80% (87%) power with n=150 participants at an alpha <0.05.

Statistical Test (Spearman)	Sample Size	Power	Correlation	Significance Level
Correlation	193.78	0.8	0.2	0.05
Correlation	145.92	0.8	0.23	0.05
Correlation	123.13	0.8	0.25	0.05
Correlation	84.75	0.8	0.3	0.05

STATISTICAL ANALYSES

SA1: Correlation between KoKo and SpiroPD measurements will be assessed using Spearman's correlation coefficient. A high correlation (> 0.8) will demonstrate the usefulness of the SpiroPD device in these patients.

SA2: Feasiblity process measures such as proportion of participants who adhere to the at-home use of SPiroPD lung function testing, adherence measures to treatment regimens, and estimates of efficacy as denoted by exacerbations and acute care utilization will be analyzed using descriptive statistics. Patient characteristic associated with increased SpiroPD use, treatment adherence, and efficacy of lung function testing will use McNemars, Fishers exact or Chi square testing for categorical variables and rank sum or t-tests for continuous variables.

POTENTIAL RISKS AND BENEFITS

The subject may be uncomfortable answering some interview questions. All subjects will be told that they can refuse to answer any question.

Loss of confidentiality. To help ensure that patients' health information remains private, we will restrict access to data collected for our study to study personnel only (via use of password-protection and locked cabinets for study documents). Study ID numbers will be generated and will be used when discussing and/or reviewing data at study meetings. Also, study reports will report results in aggregate and not contain information that can be used to identify individual patients.

Spirometry is safe and is commonly used to measure disease severity but can cause some minor chest soreness or lightheadedness.

You may not understand the data you see on your Spiro PD device. Use your best clinical judgement and care for your COPD as you normally would. Our research team is always available if you're not feeling well and would like to speak with a member of our COPD team.

DATA SAFETY MONITORING PLAN

The PI will review monthly data reports reviewing recruitment, consent, intervention activities, adverse events, and follow-up. Although few, if any, intervention-related adverse events are anticipated in this observational study, the study population is at risk for poor outcomes, including life-threatening exacerbations and death. The PI will comply with prompt reporting of any unanticipated events to the IRB.

COMPENSATION

Study participants will receive the SpiroPD for use during the study and will be able to keep this device for their personal use upon completion of the study; this device is valued at $500.

INFORMED CONSENT

Medical records at the University of Chicago will be examined each day to screen for potentially eligible patients. The medical team will be contacted for verbal assent using standardized text. Among patients whose medical team provides assent, medical records will be reviewed to ascertain eligibility. Patients will be further screened upon approach to ensure they have sufficient vision (20/50) and wireless access at home. Written informed consent will be sought from eligible patients.

DATA SHARING

A summary final report will be provided to the SpiroPD manufacturer. Individual level data will not be provided. The final report should include de-identified summary data for those receiving a SpiroPD device:

- Used SpiroPD Y/N
- If Y—usage data (# of uses)
- If Y—lung function data from SpiroPD
- If Y-- Medication adherence from SpiroPD
- Gender
- Age
- Pre/post study health care utilization
- Insurance type
- Demographics