

PELICAN: Novel Research to Help Patients with COPD Takes Flight

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Supplemental oxygen therapy is often an essential component of the treatment plans for individuals with advanced COPD. Despite the proven benefits to quality of life, exercise tolerance, survival and reduced risk of hospitalization, rates of adherence are generally below 50%. Patients are frequently faced with many barriers to optimal use of oxygen therapy including policy, education, perception and other clinical issues.

Since its inception in 2007, the COPD Information Line (the COPD Foundation peer-to-peer toll-free number for support, information and referral) has received anxious calls from patients and caregivers struggling with supplemental oxygen and searching for answers to their questions or an empathetic voice. In order to better address the needs from the COPD community, the COPD Foundation has partnered with researchers at the University of Illinois, National Jewish Health, the Los Angeles Biomedical Research Institute, AlphaNet, and Apria Healthcare to develop an ambitious, uniquely patient-centered approach to improve adherence to oxygen therapy.

The COPD Foundation has been a longtime advocate for an increased focus on the patient in research activities. Together with the UIC, NJH and UCLA teams, the COPD Foundation sought to get to the root of the issues surrounding oxygen use in order to inform the research intervention. Who better to tell research teams what issues to study and which outcomes to measure, than those affected by the disease?

Prior to designing our program, we held focus groups and conversations with patients and caregivers. Participants revealed that the prescription of oxygen was seen as a turning point in their experience of living with COPD. Patients and caregivers reported feelings of fear, anxiety, confusion and sense of being overwhelmed, especially when first prescribed oxygen. For many individuals with COPD, supplemental O₂ therapy is first prescribed during a hospitalization for a COPD exacerbation. The transition from hospital to home is particularly important for these individuals, who face the challenge of

establishing new routines that incorporate O₂ therapy into their lives while at the same time recovering from an episode of acute illness.

Patients clearly indicated that they need education on how to use of their oxygen, delivered in a way that they can understand -- and not solely during hurried discharge sessions where oxygen education is just one of many pieces of information. They also need more information and support regarding the expected benefits of supplemental oxygen therapy. Participants also indicated that, during this overwhelming transition, they would welcome support from a peer who understands and has experience living with COPD.

Based on this information, our study team resolved to better understand the needs of patients and their caregivers during this critical transition, and develop an intervention that is tailored to their needs. The PEer-Led O₂ Infoline for patients and CAregivers (PELICAN) project was born.

Our partnership's focus on stakeholder engagement and pragmatic approach to research align with the priorities of the newly-established Patient Centered Outcomes Research Institute (PCORI). PCORI marked an important shift in how research is planned, executed and disseminated. In its first years of existence, PCORI has defined what patient centered research was, identified national priorities for the research it should support and then launched an ambitious multi-year funding effort that so far has resulted in \$548 million in research awards.

In April 2013, PCORI awarded the University of Illinois, Chicago, a contract to fund the collaborative and innovative PELICAN project (contract # CE 1304-6490). Since then, we have activated the broad-based study team, and engaged stakeholder groups in an iterative process to develop the PELICAN intervention and tailor it to the needs of patients with COPD who are newly prescribed oxygen therapy..

We conducted focus groups, where patients and caregivers expressed their concerns about lack of reliable information about O₂, including

benefits of using O₂, social aspects of O₂ use, fear of becoming addicted to O₂, lack of confidence in knowing what to do, and anxiety. Based on their input, we designed a preliminary PELICAN intervention, including written educational materials and an extensive curriculum to help patients and caregivers navigate the post-discharge period and the process of adjusting to O₂.

The intervention will be delivered by trained peer associates of the COPD Information Line over a period of 5 weeks. Peer associates will address the following topics; 1) Oxygen prescription and equipment 2) Doctor's appointment and goals 3) Physical activity and shortness of breath 4) Outcomes expectancy and 5) Reminders and coordinating care.

The intervention will address patient attitudes and beliefs about oxygen, including confidence in their ability to use oxygen and their understanding of the benefits of using oxygen as prescribed. The PELICAN study will test the effectiveness of the information line, and whether it leads to increased oxygen use and positively impacts outcomes important to patients.

PELICAN has the potential to greatly improve appropriate oxygen use and quality of life of COPD patients, by using a non-invasive strategy tailored to their needs. Most importantly, the patient and caregiver voice carries through every part of the study, including study planning (patient and caregiver input shaped the study question, the design of the peer-coaching intervention, selection of endpoints used to assess the effectiveness of the program), conducting the intervention (peer coaches from the COPD information line will deliver the intervention), providing study oversight (COPDF is on the study's Steering Committee), and participation in subsequent dissemination activities.

Dr. Jerry Krishnan (Associate Vice President for Health Affairs, University of Illinois Hospital & Health Sciences System and member of the COPD Foundation Medical and Scientific Advisory Committee) is the Principal Investigator of the PELICAN study. Co-investigators include Mr. Scott Cerreta, Director of Education and Ms. Jamie Sullivan, Senior Director of Public Policy and Outcomes (COPD Foundation); Dr. Robert Sandhaus (AlphaNet and National Jewish Health); Dr. Kristen Holm

(National Jewish Health); Drs. Richard Casaburi and Janos Porszasz (LA BioMed-UCLA); and Dr. Julian Husbands (Apria Healthcare).

The COPD Foundation and the Patient-Centered Outcomes Institute (PCORI): putting patients first.

It is essential for the lung health community to get to know PCORI and for PCORI to get to know the pressing unmet needs and opportunities for improvement that can be realized in lung disease patients.

PCORI was formed through language in the 2010 Affordable Care Act, but is not actually a government agency, rather it is an independent nonprofit corporation. PCORI's mission is to *"help people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community."*

Despite the promise of increasing research expenditures in an era of decreased pay lines from most funding agencies, many still feel they are unequipped to participate in this critical opportunity to advance patient centered research in lung disease. The hesitations are understandable; PCORI is NOT just looking to fund business as usual. It is imperative that the COPD community gain a better understanding of PCORI's priorities and use the opportunity to help improve the lives of those living with COPD.

What makes PCORI different and how can you join with the lung health community to help ensure that PCORI becomes a key partner in improving outcomes for COPD patients?

What is patient centered research?

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options.*

This research answers patient-centered questions such as:

1. "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"
2. "What are my options and what are the potential benefits and harms of those options?"

3. “What can I do to improve the outcomes that are most important to me?”
4. “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?”

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual’s preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health related quality of life;
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives.

In order to design and execute successful PCOR projects you may have to step outside the processes you are used to and consider patients and other stakeholders as both key drivers of your work and equal partners in the research team. For you to be successful, you must;

- ✓ Attempt to answer questions that patients and caregivers themselves identify as important to them.
- ✓ Measure outcomes that patients and caregivers would say are important to them such as how well they feel and how well they can function in their daily life
- ✓ Propose interventions and comparators that patients and caregivers want more information about
- ✓ Engage patients and stakeholders early and often and include them as part of your research team. The COPD Foundation can help you identify and connect with great candidates
- ✓ Involve patients, caregivers and patient advocacy organizations in developing methods to disseminate the findings from your research.

What Issues Are Most Important to COPD?

Developing new therapies, slowing the progression of the disease and ultimately finding a cure for COPD are critical endeavors that the community must continue to pursue aggressively. However, in the present, we can and must do better for the 15 million diagnosed and up to 12 million undiagnosed COPD patients in the U.S. Last year, after soliciting stakeholder input and using a process called analytical hierarchy, the CONCERT Network (COPD Outcomes-Based Network for Clinical Effectiveness & Research Translation) published a paper detailing the multitude of priority issues for comparative effectiveness research in COPD. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3603554/>

Topics were identified in the areas of chronic care, care coordination, acute care and transitions in care between healthcare settings. The types of questions identified in the CONCERT paper can serve as a guide to launch your patient and stakeholder engagement efforts. What are the issues that your health system struggle the most with, what do your patients and family members identify as challenges or outcomes that they wish to improve? Understanding their priorities is the first step to a successful PCORI application. You can help make sure that PCORI hears the issues most important to COPD patients by submitting PCOR questions directly to their online form at <http://www.pcori.org/content/suggest-patient-centered-research-question>.

The COPD Foundation is committed to facilitating patient engagement in your research efforts. Count on us to help you find the patient and caregiver voice in your community and to add a unique perspective to your PCOR projects. Let’s come together to ensure this unprecedented focus on improving outcomes is not lost and that COPD gets the respect it deserves from funding agencies. 🌸

Catch up on the other PCORI funded COPD related projects by visiting PCORI’s funding center and searching “COPD.”
<http://www.pcori.org/research-results>

**This information was extracted from: <http://www.pcori.org/content/research-we-support>*