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ORIGINAL RESEARCH ARTICLE

Patient Involvement in the Design of a Patient-Centered Clinical Trial to Promote Adherence to Supplemental Oxygen Therapy in COPD

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Abstract

Background Patients are increasingly viewed as key stakeholders who can contribute in meaningful ways to clinical research and are emphasized in research funded by the Patient-Centered Outcomes Research Institute (PCORI). We are not aware of other peer-reviewed publications that report methods and outcomes of patient engagement to refine study design for a PCORI-sponsored clinical effectiveness trial.

Objective The aim of this report was to describe the process and outcomes of involving patients in the design of a clinical trial to promote adherence to supplemental oxygen therapy among patients with chronic obstructive pulmonary disease.

Methods In-person focus groups and individual discussions via telephone and email were used to elicit feedback to refine the intervention and clarify outcomes of highest importance to patients.

Results A total of 25 patients and five caregivers provided feedback. Their feedback has informed decisions regarding the length of intervention sessions (20 min and in some cases longer was acceptable), the importance of including caregivers, and discussion topics (e.g., social discomfort about using oxygen in public, identifying personally relevant reasons to use oxygen, pulmonary rehabilitation). Multiple outcomes were rated as highly important to patients (physical function, fatigue, sleep, anxiety, depression, and ability to participate in social roles and activities), and the outcome that was ranked as most important varied by individual. Therefore, multiple patient-reported outcomes will be used as endpoints for the clinical trial.

Conclusions Patient involvement led to refinements of the intervention and clinical trial endpoints to better address the expressed needs and concerns of patients and caregivers.

Key Points for Decision Makers

Patient involvement in the design of clinical trials can lead to interventions that are more responsive to the needs of patients.

Use of multiple methods of patient engagement (e.g., in-person focus groups and individual discussions via telephone and email) makes it possible to involve a broader range of patients when soliciting feedback to inform the design of a clinical trial.

Establishing collaborative relationships with patient advocacy groups greatly facilitates patient engagement in the design of clinical trials.

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1 Introduction

The social context in which clinical research is conducted has been changing rapidly. One major change is an increased emphasis on including patients in the process of developing and implementing research projects. This increased emphasis is reflected in the proliferation of peer-reviewed journals that focus on patient involvement in research (e.g., The Patient, Health Expectations), funding that is designated exclusively for patient-centered outcomes research [e.g., Patient-Centered Outcomes Research Institute (PCORI)], and businesses that specialize in gathering patient feedback on protocols for clinical trials (e.g., HealthiVibe). Patient involvement in clinical research has multiple benefits, including the development of interventions and evaluation of outcomes that are more responsive to the needs of patients [1–8].

This report describes patient involvement in the design of a clinical trial to promote adherence to supplemental oxygen therapy among patients with chronic obstructive pulmonary disease (COPD). Supplemental oxygen (O_2) therapy improves survival [9, 10], increases exercise tolerance [11, 12], improves quality of life [13, 14], and reduces hospitalizations [15–17] in patients with COPD and resting hypoxemia. Despite these benefits, rates of O_2 adherence are generally below 50 % [18–20]. The objective of this report is to describe the process and outcomes of involving patients and caregivers in the design of a trial funded by PCORI. Our goal was to utilize patient feedback to design an intervention that is highly relevant to patients, and to select outcomes that are important to patients.

The Peer-led O_2 InfoLine for Patients and Caregivers (PELICAN) intervention is grounded on social cognitive theory and motivational interviewing. This intervention leverages the COPD Foundation's existing Information Line, which is staffed by patients and caregivers who are affected by COPD (known as Information Line Associates). PELICAN is a randomized clinical trial to test the effectiveness of proactive peer coaching versus reactive peer coaching versus usual care. Comparative effectiveness will be evaluated by examining adherence and patient-reported outcomes at 2 months post-randomization (see Table 1 for additional information).

2 Methods

When a single method of patient engagement is utilized (e.g., an exclusive reliance on focus groups), the feedback obtained may be biased due to the physical limitations and individual preferences of patients who prefer and can participate in that method of engagement [21, 22]. To promote access to diverse viewpoints, our research team utilized multiple methods of patient engagement, including in-person focus groups (Phase 1), individual discussions via telephone (Phase 2), and email (Phases 2 and 3). Key areas in which we sought input included length of sessions, the role of caregivers in the intervention, and topics covered in the intervention sessions. In addition, patient input was sought to select patient-reported outcomes. Research was reviewed by the Institutional Review Board of the University of Illinois at Chicago (UIC) and written informed consent was obtained from focus group participants (protocol #2013-0999).

2.1 Focus Groups

Phase 1 consisted of three in-person focus groups conducted at UIC: two for COPD patients with an O_2 prescription, and one for caregivers of a COPD patient with an O_2 prescription. All focus groups lasted 2 h. Participants were identified via UIC's Pulmonary Research Registry and review of hospital and outpatient clinic records at UIC. Participants were recruited via mail and phone. One of the patient focus groups was conducted in Spanish (moderated by VPC); the remaining focus groups were conducted in English (moderated by KEH). The goal of the focus groups was to get patient and caregiver feedback regarding how to improve the planned intervention and the importance of various patient-reported outcomes.

Demographic information about participating patients and caregivers was gathered and focus groups were audiotaped. Participants were compensated for their time. See Table 2 for the questions that were used in the patient focus groups. See Table 3 for the handout that focused on learning which outcomes are most important to patients. The ten outcomes listed in this handout encompass the PROMIS (Patient Reported Outcomes Measurement Information System) profile domains for adult self-reported health [23]. PROMIS profile domains were selected to assess physical health (e.g., pain), mental health (e.g., depression) and social health (e.g., ability to do daily routines). In addition, focus group participants were invited to discuss outcomes beyond those specifically listed.

The focus groups were conducted over a 2-day period. Immediately after each focus group, the main findings were summarized (i.e., challenges to using O_2 and feedback regarding the planned intervention, inclusion of caregivers, and outcomes). The day after the focus groups were completed, the research team convened to discuss implications for the planned intervention.

2.2 Additional Feedback Via Telephone and Email

Phase 2 consisted of soliciting feedback from a broader patient base to refine the proposed intervention. At this time, the most pressing task was to finalize the plan for the intervention and develop the curriculum for the pro-active arm of

Table 1 PELICAN intervention

Population	Eligibility criteria
	Age >18 years
	Primary language English or Spanish
	Has a physician diagnosis of COPD
	Prescribed supplemental O_2 24 h/day, 7 days/week
	Working telephone number
	Exclusion criteria
	Expected survival <6 months
	Enrollment target
	450 participants over 18 months ($n = 150$ per arm)
Intervention	Two active comparators
	Proactive PELICAN: 5 phone calls initiated by COPD Foundation Information Line at 2, 7, 14, 30, and 60 days post-randomization
	Reactive PELICAN: 1 phone call initiated by COPD Foundation Information Line at 2 days post-randomization; additional calls initiated by participants
Control	Usual care
Outcomes	Primary outcome: adherence to supplemental O_2
	In all participants, measured via run-time estimates based on number of O_2 tanks used, concentrator gauge, etc. (rough estimate)
	In subset of 50 participants, measured via an innovative objective monitoring system [28] (to validate rough estimate)
	Secondary outcomes: patient-reported outcomes
	The following PROMIS short-form measures will be used: Anxiety, Physical Function, Depression, Sleep, Fatigue, Satisfaction with Social Roles and Activities, Ability to Participate in Social Roles and Activities [29]
	Acute care utilization (hospitalization, emergency room visits)
Timing	Intervention lasts 60 days post-randomization
	Primary outcome assessment: 60 days post-randomization
	Intermediate/additional assessments: 0 (baseline), 30, 60, and 90 days post-randomization
Setting	Nationwide recruitment through web and network of clinicians and durable medical equipment providers
	Delivery of intervention at home, via telephone

This table is an initial draft of the study design; the final study design might be updated once pilot studies are conducted

COPD chronic obstructive pulmonary disease, *O_2* oxygen, *PELICAN* Peer-led O_2 InfoLine for Patients and Caregivers, *PROMIS* Patient Reported Outcomes Measurement Information System

the trial. As such, this phase focused on refining the intervention rather than selecting outcomes. Given that Phase 1 focused exclusively on face-to-face discussions with individuals who lived in the Chicago area, we next sought feedback from O_2 users from a broader geographic area who were willing to provide feedback via phone or email.

The COPD Foundation identified Information Line Associates who are prescribed O_2 and individuals who had contacted the Information Line with questions regarding O_2. The COPD Foundation sent an email to these individuals on behalf of the research team. Of note, the COPD Foundation did not provide names or contact information to other members of the research team. Rather, the COPD Foundation directed people to contact a designated member of the research team (KEH) by phone or email if interested in providing feedback. A single email invitation was sent without any reminder emails. See Table 4 for questions that were used to facilitate discussion with individuals who contacted the research team via phone to provide feedback.

Individuals who contacted the research team were treated as consultants who volunteered to provide their expertise to the research team. Demographic information was not collected about these consultants, and individuals who chose to provide feedback were not compensated for their time. Phone conversations were not audiotaped, based on the assumption that individuals would be more comfortable providing feedback if they were not audiotaped. Handwritten notes were taken during the phone conversations to document the feedback that was provided. The handwritten notes were then summarized in a document that captured the feedback from Phase 2, which was subsequently incorporated with the feedback from Phase 1.

Phase 3 focused on finalizing which patient-reported outcomes to measure. The research team sought additional

Table 2 Discussion guide for patient focus groups

Introduction
Please tell us your name and how long ago oxygen was first prescribed for you
Experience around the time of initial oxygen prescription
Think back to when you were first prescribed oxygen
What were the biggest challenges you had with your oxygen when it was first prescribed?
What would have helped you deal with those challenges at that time?
Ideas for the program that we are developing
As I briefly mentioned earlier, we are developing a program to help people with COPD when they are first prescribed oxygen. We have some initial ideas for this program, listed on the handout we are distributing right now. We need your help to make the program better
Are these the most important topics to cover?
Are we leaving out any important topics?
Timing of the sessions: pros and cons of the schedule we have chosen
Pros and cons of 15 min sessions
By phone versus in person: pros and cons of plan to do the program by phone
What type of materials would you want? Handouts, booklets, DVD, pulse oximeter?
Pros and cons of having a peer call you versus having a medical professional call you?
Involvement of family members/caregivers
What do you think family members/caregivers should know about oxygen?
How can we help family members/caregivers to better support people with COPD in using their oxygen?
Outcomes
Thinking about when you were first prescribed oxygen, what aspects of your life were most important to you at that time?
Distribute handout and ask each person to complete it (see Table 3 for copy of this handout)
Then discuss: Does anyone want to talk about the two or three things that they listed as most important?
General follow-up questions
The moderator will give a brief 2–3 min summary of the discussion
Did that summary include the most important things you said?
Is there anything important that we haven't talked about yet?

patient feedback to determine whether all outcomes identified by the focus groups should be used as clinical trial endpoints. To help the research team make this decision, the COPD Foundation sent an email to Information Line Associates who are prescribed O_2. This email asked Associates to rank the following potential outcomes from 1 (most important) to 6 (least important): physical function, fatigue, sleep, anxiety, depression, ability to participate in social roles and activities. The email from the COPD Foundation directed Associates to email their response to a designated member of the research team (KEH). A single email invitation was sent without any reminder emails. Demographic information was not collected about the Associates who chose to provide feedback and Associates were not compensated for providing feedback.

3 Results

A total of 30 individuals (including 14 patients, five caregivers, and 11 Information Line Associates) provided feedback. Eleven individuals participated in focus groups (Phase 1; see Table 5). None of the participants had a prior relationship with the focus group moderators (KEH and VPC). In Phase 2, eight of 37 individuals contacted the research team in response to the email sent by the COPD Foundation. Of these eight individuals, seven were patients and one was a caregiver. In Phase 3, 11 of 13 Information Line Associates who were invited provided feedback via email. None of the individuals in Phases 2 or 3 had a prior relationship with KEH, to whom they provided feedback.

3.1 Refining the Intervention

Feedback from patients and caregivers helped our research team refine our plans regarding the length of intervention sessions, the inclusion of caregivers in the intervention, and topics discussed in the intervention.

3.1.1 Length of Intervention Sessions

To minimize the potential burden of participating in the intervention, we originally planned to limit each session to 20 min or less. While patients and caregivers appreciated our desire to minimize burden, they indicated that

Table 3 Handout from patient focus groups regarding outcomes

Thinking back to when you were first prescribed oxygen, what aspects of your life were most important to you at that time?
For each area listed below, rate how important it was to you, using a number between 1 and 10.
1 = not at all important
10 = extremely important

Area of Life	Importance (1 to 10)
Physical function (ability to carry out activities that require physical actions)	
Fatigue (tiredness or exhaustion)	
Pain (intensity of pain, pain interfering with life activities)	
Sleep (ability to sleep, satisfaction with sleep)	
Anxiety (fear, worry, dread)	
Depression (negative mood)	
Ability to do daily routines, including work	
Sexual function (ability and interest in sex)	
Social support	
Anger (angry mood)	
Other (list):	
Other (list):	
Other (list):	
Other (list):	
Other (list):	

participants in the intervention may prefer longer sessions that allow more time to discuss their questions and concerns. Given this feedback, we plan to limit prepared content to 20 min per session while providing access to the peer coach after the prepared content has been discussed. The Information Line Associates who deliver the intervention will block their schedule for at least 45 min per session to ensure that they are available to engage in longer discussions.

3.1.2 Inclusion of Caregivers in the Intervention

The caregivers who participated in the focus groups indicated that they would like to be included in the intervention. However, not all patients have a caregiver. We hope to meet the needs of patients across the spectrum, including those who have a highly engaged caregiver and those who do not have a caregiver. As such, caregivers will be invited to join each intervention phone call, but caregiver participation will not be required.

3.1.3 Topics Discussed in the Intervention

Patients underscored the importance of conveying positive messages about supplemental O_2, especially in the first session. They stated that positive messages about O_2 are important because patients often focus more on negative feelings and beliefs about O_2. This feedback guided the development of the first session, which has been carefully crafted to ensure that peer coaches make positive statements about O_2 throughout the session. For example, the

Table 4 Questions to facilitate discussion via telephone

Do you agree with the topics for each phone session?
Are there any topics you feel are important that we have not included?
Do you think five phone calls is the right number of calls to make?
Is the time we are allocating to each call too much, not enough, just right?
Do you have feedback regarding the length of time between each call?
Pros and cons of delivering the intervention by phone versus in person?
What types of materials would you want—handouts, booklets, DVDs, pulse oximeter?
Pros and cons of having a peer do the phone call?
Do you have any other feedback to share?

Table 5 Descriptive information regarding focus group participants

Characteristic	Patients, *n* (%)	Caregivers, *n* (%)
Gender		
Male	2 (28.6)	0 (0.0)
Female	5 (71.4)	4 (100.0)
Racial/ethnic background		
Black, non-Hispanic	3 (42.9)	3 (75.0)
Hispanic	3 (42.9)	1 (25.0)
White, non-Hispanic	1 (14.3)	0 (0.0)
Age (mean, SD)	65.4 (7.5)	56.5 (17.7)
Annual household income (US$)		
Less than $10,000	3 (42.9)	0 (0.0)
$10,000 to $19,999	3 (42.9)	1 (25.0)
$20,000 to $49,999	1 (14.3)	0 (0.0)
$50,000 to $74,999	0 (0.0)	1 (25.0)
$75,000 or more	0 (0.0)	1 (25.0)
Would rather not say	0 (0.0)	1 (25.0)
Highest level of education		
Grammar school	3 (42.9)	1 (25.0)
High school or equivalent	2 (28.6)	1 (25.0)
Some college	2 (28.6)	1 (25.0)
Bachelor's degree	0 (0.0)	1 (25.0)
Marital status		
Single	4 (57.1)	1 (25.0)
Married	2 (28.6)	3 (75.0)
Would rather not say	1 (14.3)	0 (0.0)
Relationship to the patient		
Spouse	n/a	2 (50.0)
Child	n/a	1 (25.0)
Grandchild	n/a	1 (25.0)

curriculum for the first session now explicitly includes statements about the health benefits of using O_2 and the fact that many patients notice over time that O_2 helps them to feel better. In addition, patients and caregivers indicated that several important topics were missing from the planned intervention, including explicit discussion of social discomfort (e.g., embarrassment) related to using O_2. Patients indicated that the peer coaches should initiate discussions about social discomfort related to using O_2. To address this feedback, the peer coaches will initiate conversations in several sessions regarding the participants' feelings about using O_2 in public, and will state that feelings such as being embarrassed are common.

Patients indicated that in order to overcome social discomfort and other barriers to O_2 use, they needed to find personally relevant reasons to use their O_2. They stated that it is important for the peer coaches to help each participant identify the unique factors that will motivate him/her to use O_2. We have addressed this feedback by extending the planned discussions regarding the medical benefits of using supplemental O_2. After describing the medical benefits of supplemental O_2, peer coaches will ask each participant to consider which benefits of O_2 are most personally relevant.

Patients also indicated that pulmonary rehabilitation was an important setting in which they learned about the benefits of O_2 and gained social support for using O_2. They noted that the planned intervention did not include any mention of pulmonary rehabilitation, and they encouraged the research team to add some discussion of pulmonary rehabilitation. Based on this feedback, we have added information about pulmonary rehabilitation to the intervention.

3.2 Selecting Patient-Reported Outcomes

Patient engagement also has influenced the choice of patient-reported outcomes that will be measured in PELICAN. When deciding which outcomes to measure, the research team reviewed quantitative and qualitative feedback from patients who participated in the focus groups. When patients numerically rated the ten potential outcomes listed in Table 3 on a scale from 1 (not at all important) to 10 (extremely important), all outcomes had a mean score above 7.0 except sexual function (which had a mean score of 4.4). This suggests that, with the exception of sexual function, all of the outcomes were important to patients. In the group discussion, patients indicated that the ability to participate in their typical roles and activities was particularly important. Patients also indicated that social support

for using O_2 was important. They stated that they did not want other people to feel awkward around them or treat them differently because of O_2 use.

Based on feedback from the focus groups, sexual function was eliminated as a potential outcome. The research team considered instruments to measure the remaining potential outcomes. We searched for available instruments that were brief, validated for administration via phone, and validated in both English and Spanish. Given these considerations, six outcomes were further considered for use in the study: physical function, fatigue, sleep, anxiety, depression, and ability to participate in social roles and activities. Information Line Associates ranked the importance of these six outcomes from 1 (most important) to 6 (least important). Each outcome was ranked as most important by at least one Associate.

Overall, the feedback from the focus groups and the Information Line Associates suggests that multiple outcomes are important to patients, and there is not any one outcome that is consistently rated as most important. As such, the research team decided to retain all six patient-reported outcomes that were ranked by Associates to complement the primary outcome (O_2 adherence).

It is important to note that social support for using O_2 is important to patients, who voiced concerns about being perceived or treated differently as a result of using O_2. Existing measures of social support do not capture these O_2-specific social concerns. As such, we will not be able to measure this important outcome in the PELICAN project due to the lack of an existing instrument.

4 Discussion

In PELICAN, feedback from patients and caregivers has informed the design of a clinical trial to promote O_2 adherence among COPD patients. We believe that feedback from patients and caregivers has helped us develop an intervention that is highly responsive to the needs of individuals who are struggling to use their O_2. This feedback has influenced decisions regarding the length of intervention sessions, the inclusion of caregivers in the intervention, topics discussed in the intervention, and patient-reported outcomes that will be assessed.

Our research team used an evolving process in which patient feedback was sought in different stages, via different methods in each stage (i.e., focus groups followed by phone and email). We formally recruited focus group participants and provided transportation and reimbursement for their time. We hope that this helped us reach individuals who were affected by supplemental O_2 but not necessarily passionate about O_2. After the focus groups, we were intentional about treating patients and caregivers as consultants rather than as research subjects. Part of this shift was deciding not to formally collect demographic information about these individuals or audiotape our phone calls with them. People who provided feedback via phone and email were not reimbursed for their time, and likely provided feedback because O_2 is an issue in which they are personally invested.

One of the limitations of our process is that we do not know the demographic characteristics of all of the individuals who provided feedback, and therefore do not know the extent to which these individuals are representative of COPD patients who are prescribed O_2. It is worth noting that there is debate in the emerging patient engagement literature regarding how much emphasis should be placed on the extent to which these patients are representative of the broader patient population [24, 25]. An alternative way to think about engaging patients is to seek patients who are qualified to provide feedback. Ultimately, it would have been ideal if we had collected demographic information from all of the individuals who provided feedback, at least to help us understand which patients we were more successful at engaging. We do know that our focus group participants were primarily African-American and Hispanic. Some research indicates that African-American and Hispanic patients prefer to be less involved with medical decision-making [26]; as such, it appears as though the focus groups helped us reach patients who might typically be more difficult to engage. However, Caucasians and males were under-represented in the focus groups. The feedback we received suggests that the patients and caregivers who provided feedback are not representative of the broader population; we consistently heard about the importance of pulmonary rehabilitation, and yet only a minority of patients have access to pulmonary rehabilitation. Ultimately, our decision not to collect demographic information leads to a more limited understanding of who we engaged, and the extent to which these individuals represent the broader population.

Another limitation is that we did not ask patients to comment on our decision to measure six different patient-reported outcomes, nor did we ask patients to review the actual instruments that will be used to measure these outcomes. As such, it is possible that the instruments we selected don't fully capture patients' concerns. In fact, social support for using O_2 is an important outcome for which there are no existing instruments. Of note, our research team is in the process of developing instruments that measure social support for using O_2 in an ancillary study to PELICAN.

Patients are an integral part of the research team as we move forward with delivering the intervention. The intervention will be delivered by trained peers who work for the COPD Foundation's Information Line. All Information

Line Associates participate in 80 h of disease-specific training that also includes motivational interviewing and active listening. Of note, some of the Associates who have already provided feedback will be delivering the intervention. The value of collaborating with Associates can be summarized as follows: "A motivated and vocal patient, especially one who is in contact with other patients and aware of the variety of experiences of disease and its treatments, can be an excellent research partner" (p. 72) [27]. Associates embody this description: they are in an ideal position to deliver the intervention because they can draw on their own experiences as patients, their additional formal training as Associates, and the awareness of other patients' experiences that they have gained through working as Associates. We look forward to a continued partnership with patients as we work with the Associates to implement the PELICAN intervention.

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Author contributions Kristen Holm: involved with all stages of this project. Jerry Krishnan: principal investigator of the PELICAN project and involved with all stages of this project. Richard Casaburi, Scott Cerreta, Hélène Gussin, Julian Husbands, Janos Porszasz, Valentin Prieto-Centurion, Robert Sandhaus, Jamie Sullivan, Linda Walsh assisted in the development of the project and commented on drafts of the paper.

Compliance with Ethical Standards

Ethical approval Research was reviewed by the Institutional Review Board of the University of Illinois at Chicago and written informed consent was obtained from focus group participants (protocol #2013-0999).

Conflict of interest KEH, RC, SC, HAG, JH, JP, VPC, RAS, JLS, LJW and JAK declare that they have no conflict of interest.

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