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Original article

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The living with pulmonary fibrosis questionnaire in progressive fibrosing interstitial lung disease

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Take-home message (198/256 characters): The living with pulmonary fibrosis questionnaire contains relevant and important concepts that are understood by patients with all forms of progressive fibrosing interstitial lung disease.

Keywords: pulmonary fibrosis, qualitative research, QoL, questionnaire, symptom evaluation and management

Abstract (249/250 words)

The Living with Idiopathic Pulmonary Fibrosis (L-IPF) questionnaire was developed with substantial input from patients with IPF to assess symptoms and health-related quality of life (HRQoL). Because IPF is the prototypical chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype, we expanded applicability of the L-IPF by deleting the word “idiopathic”, creating the L-PF (Living with Pulmonary Fibrosis) questionnaire, and then assessed its relevance among patients with progressive fibrosing ILDs in one-to-one interviews.

Patients in the USA and Germany with any progressive fibrosing ILD other than IPF were asked about their disease and symptoms, completed the 44-item L-PF questionnaire (comprising two modules that assess symptoms and impacts of disease) and then answered a series of debriefing questions. Interviews were recorded, transcribed and coded for qualitative content analysis.

Twenty patients were interviewed, but time constraints meant not all were asked about all items. The most frequent diagnoses were rheumatoid arthritis-associated ILD (25%) and mixed connective tissue disease-associated ILD (20%). Almost all patients endorsed the symptoms assessed by the L-PF: shortness of breath (19/20), cough (19/20 patients) and fatigue (18/20). Most patients endorsed impacts of progressive fibrosing ILD on activities of daily living, physical well-being, sleep, emotional well-being, and social aspects of their lives. Most patients had an overall positive impression of the Symptoms module and understood items as intended. All seven patients asked understood the items of the Impacts module.

The L-PF contains concepts relevant and important to patients with progressive fibrosing ILD, and items are understood as intended.

Plain language summary

Patients who have fibrosing interstitial lung diseases, or ILDs, may have a type of disease that worsens over time called “progressive fibrosing ILD”. We wanted to find out how suitable a questionnaire called the Living with Pulmonary Fibrosis (L-PF) questionnaire is in these patients. The questionnaire asks about three symptoms – shortness of breath, cough and tiredness – and the impact of disease on patients’ lives. Twenty patients took part in the interviews. Most patients reported experiencing cough, shortness of breath and tiredness, and most understood the items as intended. This suggests that the L-PF questionnaire is suitable for assessing symptoms and the effects of progressive fibrosing ILD on patients’ lives, but additional research is needed to further confirm this suggestion.

Introduction

Interstitial lung diseases (ILD) are a large group of diffuse, parenchymal lung disorders. A proportion of patients with chronic fibrosing ILD develop a progressive phenotype associated with increasing fibrosis on chest imaging, greater symptom burden, deteriorating lung function, declining physical functional capacity, worsening health-related quality of life (HRQoL) and often early death [1, 2]. Idiopathic pulmonary fibrosis (IPF) is the archetypal progressive fibrosing ILD [3]. Patients with any form of ILD, including those caused by environmental or occupational exposures, systemic autoimmune diseases or idiopathic interstitial pneumonias, may develop a progressive fibrosing phenotype [2]. Progressive fibrosing ILDs other than IPF have pathogenetic mechanisms and disease behaviour similar to IPF, including progressive symptoms, effects on HRQoL, risk for early mortality, and response to antifibrotic drugs [2, 4]. Given the commonalities among the progressive fibrosing ILDs (IPF and others), it is useful to study them as a group rather than by individual aetiologies [5].

The most common and burdensome symptoms of progressive fibrosing ILD – dyspnoea, cough and fatigue – are strong drivers of HRQoL impairment [6, 7]. Patient-reported outcome measures (PROMs) are useful for assessing how a condition or its treatment affects the way patients feel and function in their daily lives [7]. PROMs are also important for assessing certain effects of therapies. Thus, PROMs yield patient-centred information that other metrics of disease severity (e.g. pulmonary physiology, imaging) cannot. Various PROMs that assess symptoms and health status have been validated in patients with IPF, including the Cough and Sputum Assessment Questionnaire (CASA-Q) [8], the UCSD Shortness of Breath Questionnaire (SOBQ) [8], the original St. George's Respiratory Questionnaire (SGRQ) [9] and its IPF-specific version (the SGRQ-I) [10], and the King's Brief Interstitial Lung Disease Questionnaire (K-BILD) [11]. However, none of these, nor any other PROM, was developed specifically for assessing patients with progressive fibrosing ILD; the K-BILD was developed to measure health status in patients with a wide range of inflammatory or fibrosing ILDs, including IPF.

The Living with IPF (L-IPF) questionnaire was developed to assess symptoms and HRQoL specifically in patients with IPF [12] and incorporated direct input from patients with IPF at each stage of development. Some of the qualitative data used to develop the ATAQ-IPF (A Tool to Assess Quality of life in IPF) [13] informed the development of the L-IPF, together with additional data and analyses conducted for the L-IPF [14]. Because IPF is a subset of progressive fibrosing ILD, and because all forms of progressive fibrosing ILD have similar symptoms, natural history and risk of death, we expect the L-IPF to be equally relevant to patients with any form of progressive fibrosing ILD. To improve inclusivity and broaden its target population, the L-IPF was very slightly modified to create the Living with Pulmonary Fibrosis (L-PF) questionnaire; it is identical to the L-IPF, except that the two mentions of the word "idiopathic" in the L-IPF were removed. The L-PF has been used to assess symptoms and HRQoL in a multicentre clinical trial of nintedanib in patients with progressive fibrosing ILD (INBUILD), and analyses of the L-PF data are underway [5].

The aim of this study was to interview patients with progressive fibrosing ILDs other than IPF, to gather qualitative data on their perceptions of how the condition affects their lives, to debrief after completion of the L-PF, and, ultimately, to assess the relevance of the L-PF and its fitness for the purpose of evaluating the symptoms and impacts of progressive fibrosing ILD.

Methods

Study design

This was a qualitative study involving one-on-one interviews with adult patients with progressive fibrosing ILD from two clinic sites in the USA and one in Germany. Clinical site staff identified potential patients and invited them in person or via telephone. All patients provided written informed consent. Prior to initiation, the study protocol received institutional review board approval in the USA and Germany (US Advarra Study Number: Pro00023847; Approval: December 19, 2017; Germany EC Study Number: 8053_BO_K_2018; Approval: August 7, 2018).

Patients

Patients were aged ≥18 years with a confirmed diagnosis of progressive fibrosing ILD. They were required to have fibrosis in >10% of the lung on high-resolution computed tomography (HRCT), diffusing capacity of the lungs for carbon monoxide (DL_{CO}) corrected for haemoglobin (Hb) ≥30% and <80% of predicted normal, and forced vital capacity (FVC) ≥45% predicted. Patients also needed to fulfil one of the following criteria for progressive fibrosing ILD within 24 months of screening despite previous ILD treatment: clinically significant decline in FVC % predicted based on a relative decline of ≥10%; marginal decline in FVC % predicted based on a relative decline of 5–<10% combined with worsening of respiratory symptoms or increasing extent of fibrotic changes on chest imaging; or worsening respiratory symptoms as well as increasing extent of fibrotic changes on HRCT. Patients also had to be willing and able to attend an interview either in person or via telephone.

Patients were excluded if they had pre-existing medical conditions that might confound reporting (in the opinion of the investigator; e.g. acute coronary syndrome), had a clinical diagnosis of IPF based on the 2011 guidelines of the American Thoracic Society, European Respiratory Society, Japanese Respiratory Society, and the Latin American Thoracic Association, were currently taking nintedanib or pirfenidone, had a history of alcohol or drug abuse (unless in full remission for >6 months prior to interview), had confirmed cognitive impairment or were otherwise judged to be unable to participate by the study principal investigator(s).

Interviews

Interviews were conducted at clinical sites or, if it was not possible to do so in person, via telephone. Three interviewers experienced in qualitative interview methodology led the discussion using a standardised, semi-structured guide (see Appendix) that was developed in collaboration with clinical experts and translated into German.

Firstly, in the concept elicitation phase of the interview, patients were asked about their disease and whether they had any symptoms that day in order to help assess whether the symptoms included in the L-PF were commonly reported in this group. If patients did not spontaneously mention shortness of breath, cough or fatigue, they were asked about each symptom specifically. Patients were then asked a series of questions about the frequency and severity of each symptom. Following the open-ended discussion, patients were asked to complete the paper version of the L-PF questionnaire and then answer a series of questions about the L-PF to assess their understanding and interpretation of items, thoughts about the recall period, and gather feedback on the relevance of its content. Interviewees were also asked to complete the K-BILD and answer questions about it, but in this article, we focus only on the L-PF. All interview sessions were audio recorded and transcribed using a professional transcription service. Transcripts were reviewed for content and participant-identifying information was removed.

The entire process took approximately 90 minutes, including consent, interview, and sociodemographic questionnaire. If interviews began to run out of time, the L-PF Symptoms measure was prioritised.

L-PF questionnaire

The questionnaire consists of 44 items divided into two modules: Symptoms (23 items) and Impacts (21 items). The Symptoms module assesses shortness of breath, cough and fatigue in the past 24 hours. For each of the shortness of breath items, respondents are asked to rate shortness of breath resulting from doing activities of varying intensities that span a range of metabolic demands. Because some respondents may not perform certain activities, each item first asks whether the respondent performed the activity in the last 24 hours; if they did, they proceed to rating their shortness of breath; if they did not perform the activity in the last 24 hours, they are asked whether they did not have the opportunity to do it (e.g. a respondent who does not have stairs in their home may not have had the opportunity to climb a flight of stairs in the last 24 hours) or whether they

avoided the activity because it was too difficult to perform. The Impacts module assesses multiple aspects of HRQoL with a recall period of 1 week. Items in both modules have response options on a five-option numeric rating score with an anchor of 0 “Not at all” to 4 “Extremely”. Overall scores range from 0 to 100, with higher numbers indicating a greater impairment. The L-PF questionnaire was translated into German by the MAPI Research Trust using a rigorous translation process [15, 16] and patients in Germany completed a German version of the questionnaire.

Analysis

The interviews were coded for qualitative content analysis using ATLAS.ti software (version 8.0) and using methodology described by Willis [17]. A coding dictionary of key concepts was developed, and investigators tested the concepts by coding several transcripts and comparing between investigators. The dictionary was refined until the coding was consistent. One coder then completed the coding of all transcripts using the constant comparative method, an iterative coding approach moving between consecutive transcripts and any new codes that emerge [18].

Quotations from interviews are included in this article to illustrate patient responses.

Results

Patients

In total, 20 patients were included; 15 in the USA and five in Germany. All interviews were conducted in person apart from four in the US that were conducted by telephone. The mean age was 70.1 years (median 72.5; range 48–81); 50% of patients were female, and 85% of patients were white (Table 1). Mean time since ILD diagnosis based on imaging was 4.3 years (median 3.0; range 1.8–12.5). Median FVC % predicted was 66.5% (range 47–95) and median DL_{CO} % predicted was 53% (range 35–66). The most frequent diagnoses were rheumatoid arthritis-associated ILD (25% of patients), mixed connective tissue disease-associated ILD (20%), and hypersensitivity pneumonitis (15%) (Table 1).

Concept elicitation

Almost all patients spontaneously reported shortness of breath (19/20), with one endorsing it when probed. When asked about the frequency of shortness of breath, three patients said it was constant, three described it as occurring a few times a day, two as occurring almost every day/when active, and four patients when exerting themselves. Four patients described their shortness of breath as severe and not good, one as between moderate and severe, two as not bad/not very severe, and one as mild to medium (see quotation in Table 3).

Cough was reported by the majority of patients (19/20) either spontaneously (9) or when probed (10) (Table 2). Nine patients described their cough as occurring daily. When asked about the severity of their cough, one participant described it as severe, one as affecting activities, three as not severe but nagging/annoying, and two as "usually not bad". See example quotation in Table 3.

Fatigue was reported by the majority of patients (18/20) either spontaneously (9) or when probed (9). Three patients described it as being constant (Table 3), three as occurring at least once a day, and three as occurring when pushing or exerting themselves or doing activities.

Other symptoms mentioned included heavy breathing, joint pain, weight loss, loss of appetite, chest rattling and heaviness (two participants each), trouble swallowing (one participant), body aches and feeling a heavy weight on their body (one participant), and light-headedness, nail clubbing, pain, weakness, chest pressure, numbness, headaches, hoarseness, disorientation, and chest pain (one patient each).

Patients were also asked how having progressive fibrosing ILD affected their day-to-day life. Most patients endorsed various impacts related to their physical functioning, including activities of daily living, sleep, emotional well-being and social aspects of their lives. Of the 18 patients who reported effects on daily living; the majority (16/18; 89%) had difficulty with completing housework, yard work, or daily chores. Sixteen patients (16/20; 80%) reported impairments in physical functioning,

most frequently difficulty in walking (5/16; 31%) and exercising (4/16; 25%). Eight patients (8/20; 40%) reported negative impacts of progressive fibrosing ILD on sleep, and 14/20 (70%) reported negative effects on their emotional health, including stress and anxiety (4/14; 29%), getting frustrated easily and feelings of concern/worry and fear (2/14 for each; 14%).

Cognitive debriefing of the L-PF

Due to respondent burden and time constraints, not all patients debriefed on both modules, so items were not discussed individually. The majority of patients (13/15) had an overall positive impression of the Symptoms module of the L-PF (Table 3). One patient reported both positive and negative impressions, and one did not directly answer the question.

Of the 15 patients who were asked about the time period they were thinking of while completing the Symptoms module, six reported they were thinking of the previous 24 hours (as intended in the questionnaire) (Table 3), two reported the "previous 24 hours and 7 days depending on the question". Other time periods mentioned by one patient each were: all the time; the last 2 days; now; morning until now; 2–4 weeks; last few days; and the last 14 days.

Of the patients asked, the majority demonstrated understanding of the items when asked to explain what they meant (cough: 15/16 patients; shortness of breath: 16/17; fatigue: 14/15).

Eighteen patients were asked about the relevancy of the shortness of breath items; 10 patients (56%) reported that all the items were relevant to them, whereas eight patients (44%) said certain items were relevant to their experience (Table 3). Most of these patients named one item that they felt was not relevant, and two patients stated that most were not relevant (Figure 1). One patient responded that they were unsure whether the items were relevant to them.

Seven patients were asked about the meaning of items from the Impacts module. All seven interpreted the items associated with shortness of breath, cough and fatigue as the developer intended by stating that they were asking about how symptoms impacted their daily life and

activities. All seven also interpreted the quality of life items as intended; they described quality of life as being able to do what you wanted throughout the day, including socialising and running errands. The five patients who were asked about the response options for the quality of life items understood the numeric response options and were able to provide detailed explanations for each response on the differing scales. Seven patients were asked about the Global items. They stated that the items were asking about physical health and quality of life as well as the general state of well-being. All seven demonstrated an understanding of the response options for these items.

Discussion

Overall, these data show that the L-PF contains relevant and important concepts and is understood by patients with various forms of progressive fibrosing ILD. The three symptoms addressed by the L-PF – shortness of breath, cough and fatigue – were endorsed by almost all of the patients, supporting their relevance in patients with progressive fibrosing ILD. Other symptoms were mentioned by only a few interviewees, suggesting that they are not important to most patients in the target population, though a larger study would be needed to determine their prevalence. Patients generally interpreted all items in the Symptoms module as the developer intended.

Patients largely understood that the items in the Symptoms module were asking about their symptoms over the previous 24 hours, and there was positive feedback about the length of the recall period. Although symptoms may vary day to day, the rationale for the shorter-than-typical recall is that it likely decreases the bias of responses, and short recall periods are encouraged by regulatory agencies (e.g. the U.S. Food & Drug Administration). This is one key difference between the L-PF and the K-BILD questionnaire, which has a 2-week recall [11].

Although a smaller number of patients were interviewed about the Impacts module, they all interpreted the items as intended and showed an understanding of the response options for the items.

The vast majority of clinical trials in ILDs have used FVC as the primary endpoint, either alone or as one facet of a composite endpoint. While FVC is regarded as an easily collected, valid and reproducible measure of physiological impairment, with very good performance characteristics, it does not capture (with any degree of granularity) many aspects of disease relevant to patients, such as how they feel and function in their daily lives [2]. Hence the addition of a validated PROM can provide extremely useful information alongside spirometry measurement.

The L-PF was included as a patient-reported outcome measure in the INBUILD clinical trial, which tested the effects of nintedanib in patients with progressive fibrosing ILDs [5]. Analyses of L-PF data are currently underway. Patients in the current study met inclusion criteria for the INBUILD trial [5] and had similar demographic and clinical characteristics [4]. Our findings, that the concepts in the L-PF are relevant and important to patients with progressive fibrosing ILD, support the validity of the L-PF results in the INBUILD trial population and the use of this questionnaire to assess symptoms and HRQoL in patients with progressive fibrosing ILD in general. The identical content of the L-IPF and L-PF questionnaires, and the fact that IPF is a subcategory of progressive fibrosing ILD, would suggest that an IPF-specific questionnaire (e.g. the L-IPF) may not be needed, and moving forward, the L-PF could be used in trials, whether enrolment is limited only to patients with IPF or expanded to include patients with any form of progressive fibrosing ILD.

Although healthcare practitioners may not have time in regular visits to use lengthy patient questionnaires, the Symptoms module of the L-PF is relatively short (23 items) and captures the three most relevant and burdensome symptoms in patients with ILDs. Thus, if future validation work confirms acceptable performance in this setting, it could be suitable for use in clinical practice.

Our study has some limitations. Due to the nature of the open-ended discussions and time constraints of the interviews, not every patient responded to every item on the L-PF, so some data are missing; in particular, the cognitive debrief of the Impacts module was only completed in a small proportion of patients. It was important to ascertain what symptoms patients mentioned

spontaneously before using the questionnaire; however, conducting the concept elicitation phase prior to the completion of the questionnaires may have affected patients' responses to the L-PF. It is also possible that completing both the L-PF and the K-BILD questionnaires in the same session may have confounded patients' answers about the time periods.

Despite these limitations, the results suggest that the L-PF is an innovative tool that taps relevant domains and includes items that are understood as the developer intended. Although additional testing and longitudinal validation is needed, we believe that the L-PF provides researchers interested in testing therapies for progressive fibrosing ILD with a disease-specific tool useful for assessing outcomes important to patients.

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Table 1. Patient demographics and disease characteristics

Characteristic	(N=20)
Age (years)	
Mean (SD)	70.1 (9.5)
Median (range)	72.5 (48–81)
Female, n (%)	10 (50%)
Smoking status, n (%)	
Current smoker	1 (5%)
Previous smoker	7 (35%)
Non-smoker	12 (60%)
Duration since ILD diagnosis based on imaging (years)	
Mean (SD)	4.3 (3.1)
Median (range)	3.0 (1.8–12.5)
Underlying ILD diagnosis, n (%)	
Rheumatoid arthritis-associated ILD	5 (25%)
Mixed connective tissue disease	4 (20%)
Hypersensitivity pneumonitis	3 (15%)
Systemic sclerosis-associated ILD	2 (10%)
Respiratory bronchiolitis with ILD	2 (10%)
Other fibrotic ILD[a]	4 (20%)
Diagnosed with usual interstitial pneumonia pattern,[b] n (%)	
Yes	6 (30%)
No	14 (70%)
FVC % predicted	
Mean (SD)	67.0 (13.6)
Median (range)	66.5 (47–95)
DL_{CO} % predicted	
Mean (SD)	51.6 (9.7)

Median (range)	53.0 (35–66)
Comorbidities, n (%)[c]	
History of unstable or deteriorating cardiac disease	1 (5%)
COPD	4 (20%)
Sleep disorders	3 (15%)
GERD	12 (60%)
Articular joint involvement	1 (5%)
Other	15 (75%)
None	2 (10%)
Supplemental oxygen use, n (%)	7 (35%)
BMI	
Mean (SD)	26.8 (4.6)
Median (range)	26.9 (20–36)

[a]Systemic lupus (n=1), byssinosis (n=1), drug toxicity (n=1), inflammatory bowel disease-related ILD (n=1); [b]defined based on the ATS/ERS/JRS/ALAT 2011 guidelines; [c]not mutually exclusive. ALAT: Latin American Thoracic Association; ATS: American Thoracic Society; BMI: body mass index; COPD: chronic obstructive pulmonary disease; DL_{CO}: diffusing capacity of the lungs for carbon monoxide; ERS: European Respiratory Society; FVC: forced vital capacity; GERD: gastroesophageal reflux disease; ILD: interstitial lung disease; JRS: Japanese Respiratory Society; SD: standard deviation.

Table 2. Number of patients reporting shortness of breath, cough and fatigue in the concept elicitation phase of the interview

Symptom	Brought up spontaneously, n	Endorsed when probed, n	Total (N=20)
Shortness of breath	19	1	20
Cough	9	10	19
Fatigue	9	9	18

Table 3. Illustrative quotations from the interviews

Topic	Patient quotation
Shortness of breath	***INTERVIEWER: How would you describe the severity of the difficulty breathing?*** *Patient: It's not good; it stops me in my tracks. Like I said I have to sit, I have to stop what I'm doing and recover. So it's definitely changed every aspect of my life.*
Cough	***INTERVIEWER: We'll talk about the cough first. How would you describe that cough?*** *Patient: It is most like a dry hacky cough, I don't cough up anything and it's very tiring. I can cough sometimes, like I said, I cough, some days I cough a lot and I have like coughing spells where I cough for it seems forever, but I'm sure it's probably just a minute or so at a time. Like I said, it's just something that's really more like an aggravation and tiring, it tires you out.*
Fatigue	***INTERVIEWER: Okay. You sleep several times a day, but how often would you say you just feel tired, in general?*** *Patient: I would say all the time.* ***INTERVIEWER: Every day?*** *Patient: Other than when I'm sleeping, I'm just tired.*
Overall impression of the Symptoms module	*Patient: You can tell that these questions were written by people who really know what it is like … I have to say. Really well done.*
Time period of the Symptoms module	*Patient: I was thinking about the last 24 hours, because I, as a sick person, you always only think day to day, only on the last 24 hours. The last 24 hours, I have calculated exactly what I did yesterday at this time. So, it worked wonderfully. Fits perfectly.*
Relevance of shortness of breath items	*Patient: I'd have to say they were all relevant, yes, I had some where, no, I did not do, but I would say they would all be relevant.*

Figure 1. Relevancy of the shortness of breath items of the L-PF

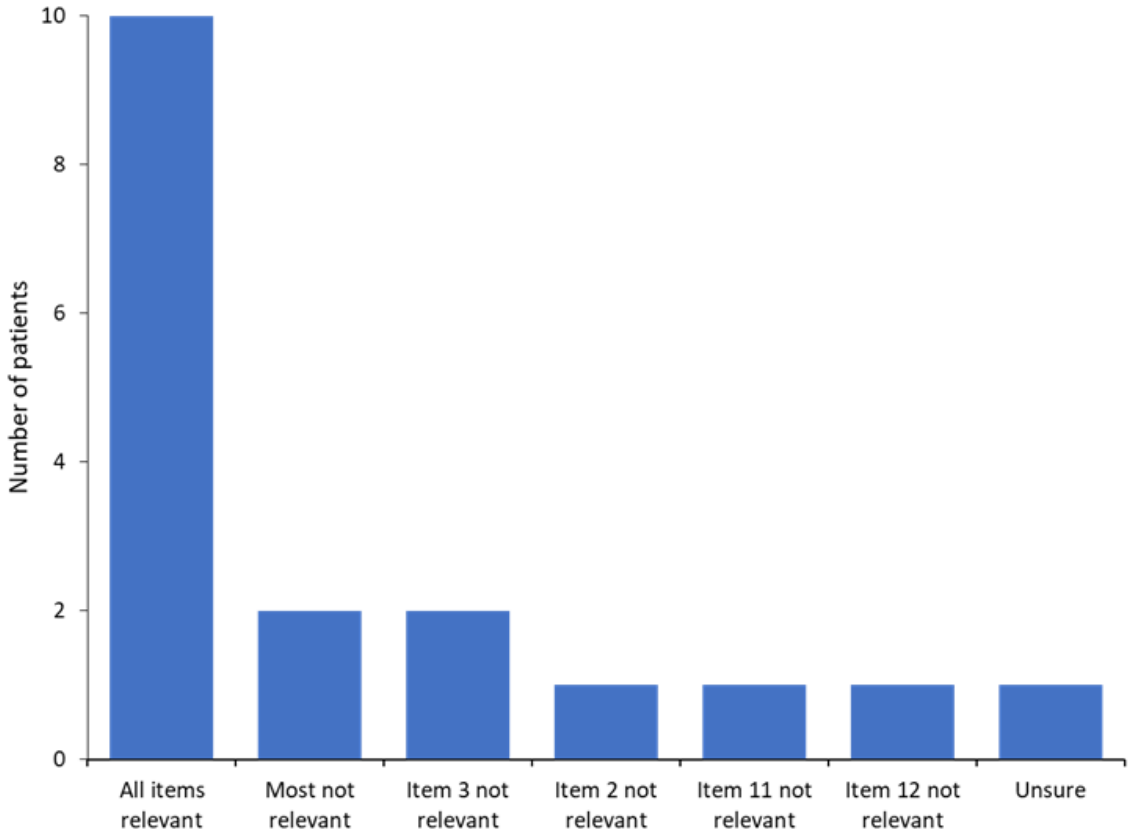
Item 2: Did you walk up one flight of stairs in the last 24 hours? Yes - How short of breath did walking up one flight of stairs make you?

Item 3: Over the last 24 hours, how short of breath have you been while sitting down, relaxing, reading, or watching TV?

Item 11: Over the last 24 hours, how short of breath were you after eating a meal or snacks?

Item 12: Did you lift and carry a light load (e.g., less than 10 lbs) a short distance (e.g., from one room to another) in the last 24 hours? Yes - How short of breath did lifting and carrying a light load a short distance make you?

L-PF: living with pulmonary fibrosis.



APPENDIX

CONCEPT ELICITATION & COGNITIVE INTERVIEW GUIDE

CONCEPT ELICITATION OF Interstitial Lung Disease Symptoms, Impacts and Progression of Disease

(UP TO 30 MIN)

Let's get started.

1. You qualified for this study because you have a medical condition that affects your lungs. What do you call this condition?

    - Are there any other terms that your doctor has used to describe your medical condition?

2. How long has it been since you were first diagnosed with [lung condition]?

3. Thinking back to before you were diagnosed with [lung condition], what were the first signs that something was wrong? What symptoms were you feeling?

4. What made you decide you needed to go see a doctor?

5. Tell me about the day you received your diagnosis.

    - Did you have to go to many physicians before getting a diagnosis, or were you diagnosed the first time you saw a physician for your lung problem?

    - If not, how long did it take from that first visit with a doctor until the doctor was able to tell you exactly what you had?

    - Did your diagnosis ever change after that first visit? (i.e. they told you had one kind of lung condition, then later they told you had something different).

    - What did the doctor tell you about [lung condition] Was there anything that your doctor told you that day that you remember being very helpful? Anything that was not very helpful?

    - Has your doctor been your only source of information about [lung condition]? Or did you look for other ways to learn about your illness? Please describe

    - Did you see multiple doctors before receiving your diagnosis?

6. Do you have any symptoms today from [your lung condition]? If so, can you describe them?

Sign/Symptoms Currently Experiencing	Spontaneously mentioned?	Probed?
1. Cough		
2. Shortness of Breath/Dyspnea		
3. Fatigue/ tired/ listless/lack of energy/ washed out/ low energy/ weak/ other ways to describe?		
4. Other:		

a. What are the 3 symptoms that have the greatest impact on your daily life?

b. How would you describe [symptom] to someone who does not have [lung condition]?

c. Does the experience of [symptom] impact any of your daily activities? If yes, how?

d. How often do you have [symptom]?
   - *Probe*: Ask about different timeframes – in a day and in a week.

e. Does the severity of [symptom] change day to day?
   - *Probe*: How would you describe your 'usual' severity of [symptom]?
   - *Probe*: How do you know when [symptom] is getting worse or getting better

f. When do you have [symptom]?
   - *Probe*: Do you have [symptom] during the day? At night?
   - *Probe*: Are there times when you are more likely to have [symptom]?
   - *Probe*: What triggers your cough? Do certain things trigger the ouch more than others?

g. When did you first experience [symptom]? Has this symptom changed in any way since you first started experiencing it? If yes, tell me more about how it has changed.

Symptom	a. Description	b. Impact	c. Frequency	d. Usual Severity	e. Timing (i.e. Day? Night?)	f. Start and Change Over Time
Cough						
Shortness of Breath/Dyspnea						
Fatigue/ tired/ listless/lack of energy/ washed out/ low energy/ weak/ other ways to describe?						
Other						

4. How does having [lung condition] affect your day to day life right now? [If the following areas are not mentioned spontaneously, please probe]
    a. Activities of daily living (e.g., taking care of household)
    b. Physical Impacts
    c. Sleep
    d. Emotional Impacts
    e. Social Impacts (e.g., interactions with friends)

5. Is this different from how it affected your life when you were first diagnosed?

COGNITIVE INTERVIEW: DISCUSSION OF THE L–PF (UP TO 20 MIN)

Now, we will ask your input on another specific set of two questionnaires. Please take as much time as you need to complete this questionnaire as you normally would, say in a doctor's office.

[If the interviewer is being conducted over the phone, instruct the participant to say when they are done with the questionnaire so that time can be recorded.]

Time to complete Symptoms: _____

Time to complete Impacts: _____

1. What is your overall impression of these questionnaires?

2. What time period were you thinking about when you answered the questions?

ITEM LEVEL QUESTIONS: Symptoms

Let's go through each of the questions. Let's look at items 1–12

ITEMS 1–12: Short of Breath

1. Can you tell me in your own words what these items are asking about?

2. Are there days you avoid certain activities and days you do not?

3. Can you tell me 0 (not at all); 1; 2; 3; 4 means to you in this context? Can you tell me what marking No means to you in this context? What about "not applicable" (No–b)?

4. Were there any activities listed that stood out to you as not relevant to you? Were there any activities you felt should be included that aren't listed?

5. Is there anything else you would like to add or mention about these items?

ITEMS 13–18: Cough

1. Can you tell me in your own words what these items are asking about?

2. Do you experience coughing every day?

3. What does the phrase "annoying tickle in your throat" make you think of?

4. Can you tell me 0 (not at all); 1; 2; 3; 4 (constantly) means to you in this context?

5. Is there anything else you would like to add or mention about these items?

ITEMS 19–23: Fatigue/Energy

1. Can you tell me in your own words what these items are asking about?

2. Do you experience fatigue daily?

    a. If yes, then ask: If you were describing "fatigue" from [lung condition] to a friend, what would you say?

3. Does coughing impact your energy levels? What about shortness of breath?

4. Can you tell me 0 (extremely low); 1; 2; 3; 4 (excellent) means to you in this context? How about 0 (nothing) – 4 (everything); 0 (no energy) – 4 (a lot); 0 (no effect at all) – 4 (a lot); 0 (no time at all) – 4 (an extremely long time)?

5. Is there anything else you would like to add or mention about these items?

ITEM LEVEL QUESTIONS: Impacts

Let's go through each of the questions. Let's look at items 1–16

ITEMS 1–16: Impacts

1. Can you tell me in your own words what these items are asking about?

2. What does the phrase "exerted physically" mean to you?

3. Are there times when you feel embarrassed about your coughing? What about the coughing is embarrassing?

4. What does "pulmonary fibrosis" mean to you?

5. Can you tell me 0 (not at all); 1; 2; 3; 4 (extremely) means to you in this context? How about 0 (extremely poor) – 4 (excellent)?

6. Is there anything else you would like to add or mention about these items?

ITEMS 17–19: Symptoms on QoL

1. Can you tell me in your own words what these items are asking about?

2. What does quality of life mean to you? What were you thinking about when you answered these items?

3. Can you tell me 0 (made my QoL extremely poor); 1; 2; 3; 4 (no negative effect) means to you in this context?

4. Is there anything else you would like to add or mention about these items?

ITEMS 20–21: Physical Health and QoL

1. Can you tell me in your own words what these items are asking about?

2. What does physical health mean to you? Do you think of all aspects of health or just health related to [lung condition]?

3. Did you have any difficulty understanding these items?

4. Can you tell me 0 (extremely poor); 1; 2; 3; 4 (excellent) means to you in this context?

5. Is there anything else you would like to add or mention about these items?

CONCLUSION OF DISCUSSION ABOUT ILD (UP TO 5 MIN)

1. Do you have any other thoughts about your personal experience that I have not asked about that you would like to share with me?

2. If you were sitting next to someone who was just diagnosed with [lung condition], what would you tell them?