Development of a Novel COPD-Specific Patient-Reported Quality of Life Questionnaire for Pulmonary Rehabilitation

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Introduction

- Outcome assessment is integral to comprehensive pulmonary rehabilitation (PR)
- PR improves health-related quality of life (HRQL)
- To date, only respiratory-specific or generic HRQL instruments are available
- The COPD patient referred to PR may have unique medical or psychosocial impairments that may not be captured by these available HRQL instruments
- Accordingly, we created, revised, and tested a self-administered HRQL instrument for COPD patients in PR
- Our goal is to produce a short, easy-to-use, self-administered questionnaire that is valid, reliable, responsive to the PR intervention

Development of the Questionnaire

- Our research was funded by the Gawlicki Family Foundation and approved by our IRB
- We named this patient-reported outcome assessment the PRO-PR
- A medical anthropologist conducted one-on-one, semi-structured interviews of 9 patients with COPD who participated in, were eligible for, or were referred to PR
- Questions addressed experiences with PR, reasons for participation or non-participation, goals from treatment, expectations and satisfaction with treatment
- 45 potential questionnaire items were initially created
- A study team of patients, caregivers and researchers discussed the above questions and reduced their number to 30, based on perceived importance
- Two focus group sessions comprised of patients and researchers revised or eliminated some items and added others, resulting in a 25-item, self-administered instrument
- Researchers then edited the wording, and created 7 subscores (# items): Activity (5), Social (5), Psych (7), Self-Care (4), Fatigue (3), Dyspnea (3), and Sleep (1)

Testing the Instrument

- A consortium of PR centers (SFH, Gaylord, Hospital for Special Care, Nuvance Norwalk) was organized
- Each center did PR as usual, but added the PRO-PR, and (if not already using) the Chronic Respiratory Questionnaire (CRQ), COPD Assessment Test (CAT), and the modified Medical Research Council (mMRC) dyspnea rating, and the six-minute walk test
- These outcomes were obtained before and shortly after completing PR
- Patient characteristics included age, sex, FEV1, supplemental oxygen status, Charlson Comorbidity Index, and socioeconomic status (SES) defined by Medicaid or no insurance
- 91 of 100 patients recruited to date

COPD Patient Reported Outcomes Questionnaire

Based on your experience with COPD in the last two weeks, please rate each of the following statements using the scale below.

	None of the time	Some of the time (1-5 days)	Half of the time (6-8 days)	Most of the time (9-13 days)	All the time (14 days)	Does not apply
1. I have difficulty doing things with my loved ones.	☐	☐	☐	☐	☐	☐
2. I avoid exercise.	☐	☐	☐	☐	☐	☐
3. I cannot do things that I enjoy.	☐	☐	☐	☐	☐	☐
4. I tend to avoid leaving my home.	☐	☐	☐	☐	☐	☐
5. I can't walk as much or as far as I would like.	☐	☐	☐	☐	☐	☐
6. I feel held back from doing things I want to do.	☐	☐	☐	☐	☐	☐
7. I spend too much time alone.	☐	☐	☐	☐	☐	☐
8. I do not spend as much time with friends and family as I would like.	☐	☐	☐	☐	☐	☐
9. I feel trapped.	☐	☐	☐	☐	☐	☐
10. I feel helpless.	☐	☐	☐	☐	☐	☐
11. I am nervous about having lung flare-ups.	☐	☐	☐	☐	☐	☐
12. I am anxious about not being able to catch my breath.	☐	☐	☐	☐	☐	☐
13. I am not very confident in my physical capabilities.	☐	☐	☐	☐	☐	☐
14. I have a negative outlook for the future.	☐	☐	☐	☐	☐	☐
15. I do not get enjoyment out of activities that I use to enjoy.	☐	☐	☐	☐	☐	☐
16. I am afraid of trying new things.	☐	☐	☐	☐	☐	☐
17. I'm frustrated with my limitations.	☐	☐	☐	☐	☐	☐
18. I must rely on others more than I would like.	☐	☐	☐	☐	☐	☐
19. I am not able to manage my everyday breathing problems.	☐	☐	☐	☐	☐	☐
20. I do not have enough energy for dressing or showering.	☐	☐	☐	☐	☐	☐
21. I do not have enough energy for cooking or shopping.	☐	☐	☐	☐	☐	☐
22. I feel fatigued throughout the day.	☐	☐	☐	☐	☐	☐
23. Physical activity wears me out quickly.	☐	☐	☐	☐	☐	☐
24. I get worn out or exhausted easily.	☐	☐	☐	☐	☐	☐
25. Breathlessness is a major problem for me.	☐	☐	☐	☐	☐	☐
26. I get too breathless walking up a set of stairs.	☐	☐	☐	☐	☐	☐
27. I get short of breath while bending over.	☐	☐	☐	☐	☐	☐
28. I do not sleep well.	☐	☐	☐	☐	☐	☐

Baseline Characteristics

Variable	Mean	SD	n.
Age (years)	71.85	9.72	91
FEV1 (% pred)	55.99	19.42	89
6MWD (m)	286	101	91
Charlson	3.52	2.11	90
mMRC (0-4)	2.54	1.14	91
CAT	17.21	7.26	91
CRQ Total	4.35	1.10	61
PRO-PR Total	2.38	0.88	91

Spearman correlations (r. and p.)

PRO-PR	Age	FEV1	mMRC	CAT	CRQ	6MWD
Total	-0.22	0.08	0.31	0.63	-0.83	-0.47
	0.04	0.46	0.00	<.0001	<.0001	<.0001
Activity	-0.13	0.14	0.31	0.57	-0.74	-0.42
	0.23	0.21	0.00	<.0001	<.0001	<.0001
Social	-0.24	0.09	0.23	0.45	-0.66	-0.46
	0.02	0.40	0.03	<.0001	<.0001	<.0001
Psych	-0.23	0.06	0.22	0.51	-0.77	-0.44
	0.03	0.58	0.04	<.0001	<.0001	<.0001
Self-Care	-0.19	0.00	0.25	0.55	-0.72	-0.45
	0.06	0.99	0.02	<.0001	<.0001	<.0001
Fatigue	-0.24	0.04	0.27	0.59	-0.71	-0.40
	0.02	0.72	0.01	<.0001	<.0001	<.0001
Dyspnea	-0.16	0.00	0.33	0.53	-0.60	-0.28
	0.13	0.98	0.00	<.0001	<.0001	0.01
Sleep	-0.12	-0.03	0.24	0.45	-0.41	-0.11
	0.27	0.78	0.03	<.0001	0.00	0.30

Change with PR (Responsiveness

Change (Δ)	Mean	N	SD	p.	ES
6MWD (m)	51	37	59	<.0001	0.86
CAT	-1.79	28	5.98	0.1259	-0.30
mMRC	-0.93	27	1.07	0.0001	-0.87
CRQ	0.99	45	0.92	<.0001	1.08
PRO-PR	-0.59	46	0.71	<.0001	-0.83

ES: Effect size = Δ/SD; >|0.8|: large

Summary and Plan

- The PRO-PR demonstrates good validity and responsiveness on a par with the CRQ and 6MWD, and better than the CAT
- Plan:
  - Finish recruitment
  - Modify its subscores, if necessary
  - Shorten the instrument to 10-12 questions, if possible
  - Determine its minimal, clinically-important difference (MCID) from pre- to post-PR