The development and first validation of a Patient Reported Experience Measure in Chronic Obstructive Pulmonary Disease (PREM-C9)

Online Supplement

Detailed Methods

Stage 1

Participants with COPD were recruited from a number of NHS secondary and integrated care organisations which included pulmonary rehabilitation, respiratory clinics and wards. Also British Lung Foundation Breathe Easy groups (self supported groups for people affected by lung disease) from various locations across England and the Channel Islands.

Inclusion criteria included:

- A confirmed diagnosis of COPD (mild to very severe COPD (FEV_1 <100% with symptoms);
- Able to consent and sign a consent form;
- Able to follow written and verbal instructions in English (Due to the availability of advocacy services, those whose first language is not English and who are unable to read or understand verbal English will not be able to participate in the study, unless a family member is available to support and translate during the study period);

Exclusion criteria included:

- Other respiratory conditions such as Asthma/pulmonary fibrosis;
- Who are nearing end of life;
- Had significant other co-morbidities such as severe heart failure.

Stage 2

Participants with COPD were recruited from a singular NHS integrated care organisation which had a number of pulmonary rehabilitation sites across the hospital and community.

Inclusion criteria included:

- A confirmed diagnosis of COPD (mild to very severe COPD (FEV_1 <100% with symptoms);
- Able to consent and sign a consent form
- Completed Pulmonary Rehabilitation by end of May 2016
- Completed a full PR pre-data set
- Met the City and Hackney Pulmonary Rehabilitation (CHPR) inclusion criteria

Exclusion criteria included:

- Other respiratory conditions such as Asthma/pulmonary fibrosis

- Required full assistance to complete questionnaires i.e.: prompting
- Did not speak English and advocacy not available
- Incomplete set of post-data

Date Collection

Stage 1

A healthcare professional conducted daily screening (Monday to Friday) of all patients admitted to the hospital with an acute exacerbation of COPD. They also conducted screening of outpatients attending pulmonary rehabilitation clinics (time and days varied dependent on activity), as well as the hospital PR group, who were not inpatients at the time of recruitment, and community COPD patients and PR groups. The healthcare professional approached eligible patients and their families prior to discharge, or earlier, dependent on how unwell the patient was. They described the study and invited the potential participant to take part in the study. If, during screening, the patient did not fit the inclusion criteria the patient was not entered on to the study. The healthcare professional administered and signed a consent form along with the participant. Patients were informed to read each statement of the question (Table one) and rate their answer which they felt reflected their own experience over the last year from a good experience (0) to a poor experience (5). Pack A included a COPD PREM instrument, CAT & HAD questionnaires which was given to the consenting patient.

Participants then had three options to do the following:

a. take Pack A home with them and return the questionnaires in a stamped address envelope to the participating NHS organisation, or, where it was a Breathe Easy Group, send all instruments back to the Chief Investigator of the study;
b. take Pack A home and return the completed pack to the pulmonary rehabilitation or COPD clinic from where they were recruited;
c. complete Pack A 'there and then' (preferred option).

Pack B consisting of a COPD-PREM instrument and a global rate of change questionnaire was administered to all participants and completed and sent back to the Chief Investigator one week later in the provided self-addressed envelope.

Throughout the process, regardless of which option of completing the instrument packs, the consent, spirometry and demographic data where completed at the time of recruitment. All instruments were labelled with the participants' unique letter and number code. All patients recruited from the Breathe Easy group followed the same process named above.

Stage 2 - Pulmonary Rehabilitation

The NHS Integrated care organisation pulmonary rehabilitation service database was searched for patient data meeting the study inclusion criteria and who completed pulmonary rehabilitation between June 2015 and May 2016. All patient data meeting the inclusion criteria and within the study period was extracted from the database for the purpose of this study. Every patient referred to the CHPR service completed an initial assessment and if no contraindication to exercise was identified, the patient enrolled onto the PR programme of choice. The outcomes completed pre and post PR were:

The primary outcome measure:

- PREM-C9

The secondary outcome measures:

- COPD Assessment Test (CAT)
- Hospital Anxiety Depression Score (HADS)

For participants who were unable to complete the questionnaires independently due to literacy or language barriers, assistance was provided with read only assistance from either the CHPR staff or an advocate, all answers however had to be the participants alone.

When a patient completed 16 sessions of PR, the measured outcomes were repeated at a final assessment.

Data Analysis

Stage 1

The response rate for questionnaire completion was 81% (n = 174). Those who declined to participate in the study cited reasons such as not enough time to complete the study (i.e. read patient information sheet), feeling too unwell and English not being their first language. All statistical analyses were conducted using SPSS Statistics for Windows, Version 20.0 or RUMM2030. Rasch is recommended by the FDA and enables development of a concise scale with a minimal number of items needed to capture the underlying trait 'experience' – without jeopardising its scaling properties.

This study adopted a test-retest questionnaire development design. Demographics including age, gender, FEV_1%, MRC and the results of the questionnaires and preliminary COPD-PREM were recorded (Table 2) and entered into SPSS initially. A formal approach to the first stage of item reduction was used following a series of different statistical approaches and

following a traditional psychometric theory[1]. A number of statistical tests were undertaken to formulate a structured plan of item reduction.

Following the hierarchical item reduction a pool of items remained. Items were identified for removal based on a combination of panel review, similarity with other items, grammatical challenges, and statistical fit. The expert panel consisted of respiratory physicians and nurses as well as question design expertise. The items removed at this stage were considered to have borderline fit only in relation to these criteria and were removed in favour of items with better overall fit to the item-list as a whole.

The remaining items went through a series of comprehensive tests to explore the data and to understand the current fit to the model. With the overall aim to test how well the observed data fit the expectations of the measurement model.

Stage 2

Statistical analysis was performed using IBM Statistical Package for Social Sciences (SPSS) Version 22. The data in this study was presented in either a table or a side by side bar chart.

Using descriptive analysis, all patient baseline data (Table 2) was analysed for normality via a histogram plot. Where normality was assumed the data was summarised as Mean and Standard Deviation (M SD); if the data were asymmetrical, via Median and range or percentiles. All categorical data was summarised as percentages[2].

The data from the primary and secondary measured outcomes were analysed for normality, and if assumed a paired t-test and 95% confidence interval (95% CI) was used to compare the difference in pre and post PR scores. For all statistical analysis, significance was set as a p value <0.05. If normality was not assumed the relevant non parametric test was used.

Correlation between the primary and secondary outcomes was analysed using a Pearson product-moment correlation co-efficient (r=)[2] test, where normality was assumed. If normality was not assumed, a Spearman's Rank Order correlation test for non-parametric data was performed (rho=) instead.

Between groups, analysis was performed to measure the impact of either gender, age, smoking status, MRC grade and disease severity on the primary outcome scores. The test performed depended upon the number in each group. If there were two groups and normality assumed, an independent t-test or a Mann Whitney U-test when the data was asymmetrical was performed. For more than two groups, the relevant ANOVA test was used dependant on whether the data was parametric or not[2].

Conclusion:

We have summarised the development and preliminary validation of the first published PREM in COPD (PREM-C9). The instrument was designed to present what patients consider is important to them and in relation to their care. We suggest this instrument should be used in routine practice to aid clinicians to understand the patient perspective and to form patient prioritised goals in co-designed management programmes.

Table 1: Reason for item removal stage 1

Q No	Question (Low Score Answer)	Missing >15%	Floor > 40%	Age	Gender	Other	Correlation
1	I am not shocked by my COPD diagnosis					Expert	
2	I have come to terms with my diagnosis of COPD					Rasch	
3	I have given up smoking and I am confident that I will not start	X					
4	I want to stop smoking and I believe I can	X					
5	It was a relief to have a diagnosis for my symptoms	X					
6	I understand my diagnosis		X				
7	I am confident that my GP will listen to my point of view**						
8	I am very pleased with health care workers		X				
9	I am happy with the length of time to see GP					Rasch	
10	I really enjoyed pulmonary rehabilitation	X					
11	I found pulmonary rehabilitation useful	X					
12	I understand my condition and this helps me to manage my fear			X			
13	The information I have been given is consistent		X				
14	I have enough information about my condition**		X*				
15	I understand about my COPD tablets	X					
16	I am confused about how to use my COPD inhalers					Rasch	
17	I understand how my COPD treatments work**		X*				
18	I don't find going to a hospital outpatient clinic frustrating						X
19	I know how to use my inhaler properly		X				
20	I have accepted the limitations to my lifestyle caused by COPD**						
21	I feel that I have good support from others**						
22	Overall I am satisfied with my life					Rasch	
23	I am not depressed		X				
24	Overall I am satisfied with the care given to me		X				
25	I am not embarrassed to tell others about my condition		X				
26	I feel that I am in control of my condition**						
27	I am motivated to keep going and to not give up		X				
28	I am happy to talk about the future**		X*				

29	I am not concerned about the future		**X**		
30	I am not worried about the season		**X**		
31	I keep going and try to enjoy my life	**X**			
32	I am confident in a 'flare up' I have quick access to treatment**				
33	I do not feel anxious about my current health		**X**		
34	I am not worried about the care I will get with 'flare-up'**				
35	I am not scared of getting a cold or an infection			**X**	
36	I am not frightened of being breathless when I have a 'flare-up'		**X**		
37	I am not frightened to go to sleep when I am having a 'flare up' of my COPD				**Expert**
38	I try not to panic when I have a 'flare up' as it will make my breathlessness worse				**Expert**

* Good face validity meant these items were retained and found to perform well within Rasch and added reliable information to the overall score ** Final COPD PREM-9 item

Table 2: Overall baseline characteristics for patients included in stage1 and 2

	Stage 1 All	**Stage 2 All**
	N = 174	**N = 36**
Age, years (Mean ±SD)	71± 9.1	65.6 ±10.97
Gender		
Male (%)	83 (48%)	22 (61.1%)
Female (%)	91 (52%)	14 (38.9%)
Smoking status, number		
Active smokers	20 (12%)	11 (30.6%)
Ex-smokers	125 (72%)	22 (61.1%)
Not disclosed/Non	29 (16%)	3 (8.3%)
Spirometry		
FEV_1 (% predicted) (Mean ±SD)	59±21.9	53.4±19.39
FEV_1 % /FVC (Ratio) (Mean ±SD)	50±20.4	56±14.0
NICE classification*†	% (n)	
Mild	23 (13)	19.4 (7)
Moderate	46 (26)	2.8 (1)
Severe	50 (29)	30.6 (11)
Very Severe	26 (17)	44.4 (16)
Outcome measures		
Medical Research Council (MRC) (Mean ±SD)	3.4±1.0	3.17±0.7
COPD Assessment Tool (CAT) (Mean ±SD)	20±8.5	23.5±7.7
Anxiety Score (Mean ±SD)	7.6±4.1	8.1±5.1
Depression Score (Mean ±SD)	6.1±3.9	7.4±3.9

Data shown represented mean ± SD unless otherwise indicated

FEV_1: Forced expired volume in one second; FVC: Forced vital capacity

*NICE (2010) Classification

† Only 145 people with spirometry information

Table 3: Final nine PREM C-9 Items

Q	Low Scoring Question (0)	High scoring Question (5)
1	I am confident that my GP will listen to my point of view	I am concerned that my GP won't listen to my point of view
2	I have enough information about my condition	I am frustrated by my lack of information about my condition
3	I understand how my COPD treatments work	I am confused about how my COPD treatments work
4	I have accepted the limitations to my lifestyle caused by COPD	I am frustrated and unhappy by the limitations to my lifestyle caused by COPD
5	I feel that I have good support from others like my family, friends, neighbours or carers	I feel that I don't have any support from others like friends, family, neighbours or carers
6	I feel that I am in control of my condition	I feel that I don't have any control over my condition
7	I am happy to talk about the future	Talking about the future makes me feel depressed
8	I am confident in a 'flare up' I have quick access to treatment e.g. a rescue pack or access to my GP	I am worried that in a 'flare up' I don't have quick access to treatment e.g. a rescue pack or access to my GP
9	I am not worried about the care I will get from health professionals when I get a 'flare-up'	I worry about the care I will get from health professionals when I get a 'flare-up'

Additional References

1. Hand, D. J. (2011). Introduction to Psychometric Theory by Tenko Raykov, George A. Marcoulides. *International Statistical Review*, *79*(2), 298–299. doi:10.1111/j.1751-5823.2011.00149_24.x

2. Pallant, J. (2013). *SPSS survival manual*, McGraw-Hill Education (UK).