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

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KEY MESSAGES

What is the key question

Living with COPD impacts greatly on a person's everyday life; including experience of living with COPD and as a recipient of healthcare. No currently available instrument captures this experience.

What is the bottom line

We have developed and validated a COPD Patient Reported Experience Measure (PREM-C9). A simple and easy to use 9-item unidimensional measure designed to quantify the experience of people living with COPD.

Why read on?

The article describes the development and validation of the PREM-C9 which will enable measurement of patient experience and help to benchmark across services and tailor healthcare services.

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Introduction

The drive to improve the quality of care for patients requires robust instruments to capture patients' perceptions of the health care that they receive. The experience of patients living with chronic obstructive pulmonary disease (COPD) and their views on the quality of healthcare they receive is not captured in currently available Patient Reported Outcome Measures (PROM)[1]. A new era of measures - Patient Reported Experience Measures (PREM) – is emerging. PREM's assess patient experiences as opposed to outcomes (such as symptoms and quality of life) per se[2]. PREMs are often used as a benchmark for care experience and the experience of living with a disease that complements information obtained with PROMs. Here, we present the development and validation of a COPD specific PREM.

Methods

Study 1: A 38-item list, extracted from our previous qualitative work[3], the COPD Assessment Test (CAT)[4] and Hospital Anxiety and Depression Scale (HADS)[5] were administered to patients with COPD[6]. Hierarchical item reduction and Rasch analysis were applied to our 38 items to identify those with the best measurement properties and potential for inclusion[7]. This iterative process continued until a final item-set that met the Rasch unidimensional measurement model requirements was achieved[8]. Test-retest reliability was assessed in patients who repeated the item-list one-week later and reported that their general health was 'about the same'. Concurrent validity was assessed using correlations between the final item-list (PREM-C9), CAT and HADS (see online supplement).

Study 2: Further concurrent validity of PREM-C9 with the CAT and HAD, and its change scores pre and post pulmonary rehabilitation (PR) were tested in a sub-study (see online supplement).

Data Analysis

Items were flagged for removal due to floor/ceiling effects (>40%), age bias (Pearson's correlation), gender bias (independent t-test), item-item correlation (>0.7), and missing responses (>15%). Fit to the Rasch model was determined by a non-significant chi-square statistic ($p>0.05$) and Person Separation Index (PSI) (>0.7). Test-retest reliability was assessed using the Intra-class correlation coefficient (values >0.7). Construct validity was assessed in both studies using correlations (Pearson's *r*) between PREM-C9, CAT and HAD. Statistical significance was set at $p <0.05$. In study 2, PREM scores pre and post PR were compared using student's paired t-test.

Results

Study 1: PREM development and preliminary validation

In total, 174 patients completed the questionnaire pack (Mean age 71 years, SD 9; Female 52%; Mean FEV_1 59%, SD 21.9) (Table 2 online supplement). Participants were recruited via British Lung Foundation Breathe Easy Groups (n=88, 51%) and hospital and community pulmonary services (n=86, 49%). 40 people declined to participate in the study. Reasons included the time to complete the questions, feeling too unwell and language.

Item reduction

Twenty-two of the 38 items were removed in hierarchical reduction: age bias (n=6), gender bias (n=1), missing data (n=6), floor effect (n=12), item-to-item correlation (n=4), and three items due to expert opinion (Table 1 online supplement). The remaining 13 items underwent Rasch analysis. Four items were removed due to poor fit to the Rasch unidimensional model. The final 9-item solution (PREM-C9) demonstrated good fit to Rasch (xp=0.33; PSI = 0.75) and good distribution of item scores (logit range: -0.1 to +0.2) (Figure 1 and Figure 2). Each PREM-C9 item is scored 0 (good experience) to 5 (bad experience); total score ranges from 0 to 45 (Table 3 online supplement). PREM-C9 scores moderately correlated with CAT (r =0.42), HAD-anxiety (r =0.30) and HAD-depression (r =0.41) ($p<0.05$).

Test-retest reliability was assessed in 88 (49%) participants and was acceptable (ICC=0.7).

Study 2: PREM validation and change scores

36 patients with confirmed COPD (Mean age 65 years, SD 10.97; Male 61%; Mean FEV_1 53.4%, SD:19.4) completed questionnaires pre and post PR. PREM-C9 demonstrated very similar correlations to those seen in Study 1: CAT (r=0.48) HAD-Anxiety (r=0.44) and HAD-Depression (r=0.46). A significant difference in PREM-C9 scores pre and post PR was found (20.08±8.43 and 14.72±10.59, respectively; mean change 5.36±9.70, 95% CI: 2.08 to 8.64, p=0.002), indicating improved experience.

Discussion

We report the development and validation of the first COPD PREM. The PREM-C9 offers a new approach by capturing patient experience and their interactions with healthcare systems and clinicians in three main areas of COPD: ‘usual care in COPD’ (items 1-3); ‘my everyday day life with COPD (items 4-7); and ‘self-management and exacerbations’ (items 8-9). These sections draw upon important patient-centred aspects of COPD.

PREM-C9 demonstrated good fit to the Rasch model confirming that its items relate to the same underlying structure – patient experience; enabling simple item summation to obtain an overall experience score, from good to bad. The PREM-C9 correlated moderately with

other PROM's suggesting that the PREM captures a related but somewhat different patient perspective.

The focus on ensuring that patients remain at the heart of healthcare and reporting patient experience is becoming an essential part of quality improvement. Evaluation of healthcare experience is continuously evolving with the patient perspective increasingly sought[9]. This approach differs from the measurement of symptoms and quality of life. Current satisfaction surveys are also limited as they are normally generic and loosely constructed[1]. Assessment using PROMS is important but they do not capture the experiential views of patients[1].

This short instrument should complement the range of instruments currently used within the COPD population when used alongside clinical audit and quality improvement strategies [10]. Measuring and benchmarking patients experience in a systematic way pre and post healthcare intervention may be a powerful way to demonstrate quality improvement and outcomes for healthcare professionals and patients.

Our study does have limitations. Patients recruited indicated they attended Breathe Easy specifically for their COPD condition as advised by medical/nurse practitioner and had spirometry at time of recruitment but we did not confirm this through accessing medical records. We conducted questionnaires in English only and results may not be applicable linguistically across a diverse patient group. Patients who did not have a good knowledge of English declined to participate as subjects from which the PREM was derived.

Conclusions

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 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.

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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 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 also completed and sent back to the Chief Investigator one week later in the provided SAE.

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 'the time to complete the questions', 'feeling unwell' and 'language (comprehension)'. 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:

The instrument was designed to present what patients consider is important to them in relation to their care. We envisage the instrument being used by a nurse/therapy led clinics and Pulmonary Rehabilitation to assist dialogue interactions with patients to understand the patient perspective and to improve the quality of care for patients from the patient perspective.

Table 1: Reason for item removal stage 1

Q No	Question (Low Score Answer)	Missing >15%	Floor > 40%	Age Correlation	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			Q13
9	I am happy with the length of time to see GP				Rasch	
10	I really enjoyed pulmonary rehabilitation	X				Q11
11	I found pulmonary rehabilitation useful	X	X			Q11
12	I understand my condition and this helps me to manage my fear			X		
13	The information I have been given is consistent		X			Q8
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					Q20
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				Expert	
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**	**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'

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Competing Interests - None Declared

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