Chapter 5: Patient-reported Health Instruments used for people with Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity and mortality and is characterised by airflow obstruction. It is usually progressive and the result of chronic inflammation resulting in airway and parenchymal damage usually as a result of smoking (NICE (2004). It represents a substantial economic and social burden throughout the UK and a significant contributor to mortality. The exact prevalence of COPD is difficult to determine and define and therefore frequently under diagnosed and under treated, which further compromises morbidity. The burden of COPD to patients and their families and carers is high, both in terms of health-related quality of life and health status affecting physical and emotional functioning (Belza et al., 2005). COPD can lead to feelings of anxiety because of breathlessness. People may reduce their activities to avoid becoming breathless and subsequently become dependant on people for carrying out activities of daily living.

Reducing the burden of COPD requires better evaluation and diagnosis, as well as improved management of chronic symptoms and understanding the effect on health-related quality of life (Halpin and Miravitlles 2006). Understanding the impact of the disease on patients and carers can facilitate targeted interventions thus improving their quality of life.

The following review provides current information available of the patient-reported health questionnaires used to measure health-related quality of life with patients with COPD.

Search terms and results: identification of articles

At the time of the review, the PHI database contained 12,000+ records (up to June 2005). The primary search strategy, using the terms 'chronic obstructive pulmonary disease' and 'respiratory' keyword searching generated 468.records, as shown in Table 4.1. All abstracts were reviewed. When assessed against the review inclusion criteria, 220 articles were retrieved and reviewed in full. Of these, 46 articles were included in the review.

Table 5.1

Source	***Results of search***	***No. of articles considered eligible***	***Number of articles included in review***
PHI database: original search (up to June 2005) **Total number= 12,562**	468	220	41
Supplementary search	-	-	5
TOTAL	-	-	**46**

Supplementary searches which included hand searching of titles from 2004 to 2006 of the following key journals:
-Chest
-Health and Quality of Life Outcomes
-Medical Care
-Quality of Life Research
-Respiratory Medicine
-Thorax

Further searches were conducted within the bibliography and using Pub Med per instrument up to September 2006.

Identification of patient-reported health instruments
Seven generic and 5 COPD-specific instruments were included in the review. The developmental and evaluative studies relating to the instruments reviewed are listed in Tables 5.2 to 5.14. Table 5.15 illustrates instruments where only one publication was identified. Table 5.16 details instruments which were excluded from the review.

RESULTS: GENERIC PATIENT-REPORTED HEALTH INSTRUMENTS

Seven generic instruments were identified which were evaluated with patients with COPD. For full details of the development, domains and scoring methods are detailed in Chapter 3.

The following instruments measurement properties are reported:

a) SF-36
b) SF-20
c) SF-12
d) EQ-5D
e) Nottingham Health Profile
f) COOP Charts
g) Sickness Impact Profile

a) SF-36:

Eleven studies were identified which provide evidence of measurement properties for the SF-36. Two studies were conducted in the UK (Harper et al., 1997, Wilson et al., 1997). Three studies evaluated the SF-36 as the principal instrument (Benzo et al., 2000; Ruffin et al., 2000; Sprenkle et al., 2004); and the remaining included the SF-36 in concurrent evaluations.

Six studies reported that the SF-36 was self-completed; the others were either interview administered by telephone or face to face. All patients included in the studies had Chronic Obstructive Pulmonary Disease but two studies provided specific diagnoses for example Viramontes and O'Brien (1994) included patients with asthma, chronic bronchitis and emphysema. Patients were generally over 60 years old in the studies and representative of the disease population.

The number of patients included in the studies was variable and most sample sizes were less than 200. Exceptions were Ruffin et al., (2000), Sprenkle et al., (2004) and Wyrwich et al., (1999) with the number of patients ranging from 329 to 8345. Although most had predicted associations between similar constructs for validity and high levels of reliability, none provided a priori hypotheses for the strength of correlation.

Reliability

Reproducibility for the SF-36 following a six month period of testing was generally poor (lower than the 0.70 threshold) with the exception of the PF (0.86) and the MH (0.74) (Harper et al., 1997). However, this is a long period in which to assess reproducibility.

Internal consistency reliability was generally high for all domains with all exceeding 0.80 with exception of the GHP domain (Desikan et al., (2002; Harper et al., 1997; Wyrwich et al., 1999).

Item total correlations

Thirty-three of 35 item correlations were greater than 0.40 in Harper et al., (1997) but no details were provided of which items.

Validity

Health service use

Patients who had been in hospital during the last six months had worse scores for the Pain and Physical functioning domains of the SF-36 than population norms. No differences were found for the MCS (Harper 1997). The PCS was independently associated with healthcare utilisation with odds ratios of 1.54 ((95% CI 1.26 to 1.87) for high primary care and 1.46 (95%CI, 1.21 to 1.78) specialty medicine utilisation. No association was found for MCS and healthcare utilisation (Sprenkle et al., 2004). In addition, The SF-36 PCS and MCS were independent predictors of mortality with increasing hazard ratios with worsening quartiles compared to the reference population (first quartile) (Sprenkle et al., 2004).

Health status

Viramontes and O'Brien (1994) evaluated the discriminative validity of the SF-36 with patients with chronic lung diseases including asthma, emphysema and chronic bronchitis and reported significantly different domain scores between disease severity subgroups based on the UK Medical Research Council symptoms classification. Lower SF-36 scores were associated with higher dyspnoea scores as expected and moderate to large correlation was reported for activity threshold and SF-36 physical functioning, general health perception and energy. There was no relationship between disease severity and SF-36 ER, SF, Pn and MH. Furthermore, the SF-36 domains discriminated patients with breathing problems in the last four weeks with statistically significantly lower scores than those patients without breathing difficulties (Wyrwich et al., 1999).

Large effect sizes (≥0.80) (where patients were classified into severe and less severe breathlessness cases) for SF-36 Physical functioning; Moderate (<0.80) effect sizes, SF-36 SF, VT and GH and Small effect sizes ≥0.20 to <0.5) for SF-36 Pain, MH and RL emot.) (Harper et al., 1997)

SF-36 PCS was moderately correlated as hypothesised with a symptom severity score (Chronic Lung Disease Index) (Dyspnoea with PF -0.53) with small correlation for the MCS (-0.19) and Dyspnoea. All other correlations were less than -0.60 for all SF-36 domains and Cough and Wheeze (Ruffin et al., 2000).

Generic patient-reported health instruments
Strong correlation was observed for some related domains between the SF-36 and NHP in patients with chronic airflow limitation being assessed for home oxygen therapy. For males SF-36 PF and NHP Energy -0.67; MH with NHP Energy -0.66; Energy/VT with NHP Energy -0.80; PF with NHP Emotional reactions -0.54; MH with NHP Emotion -0.73; MH with NHP social isolation -0.61; PF with NHP Physical mobility -0.66. Scales from the two instruments that assessed different traits were not correlated as expected. For females there was strong correlation between the SF- 36 BP with NHP Pain -0.74; Energy/VT with NHP Energy -0.62. All other correlations were small to moderate for similar domains and no correlation for different domains as would be expected (Crockett et al., (1996).

COPD-specific patient-reported health instruments
Strong correlation (greater than 0.60) was found between the SF-36 and CRQ related domains (PF and Dyspnoea; Vitality and Fatigue; RE, MH and Emotional function). There was moderate correlation with all SF-36 domains and the CRQ Mastery domain (Wyrwich et al., (1999).

Respiratory function
The following domains were strongly correlated with the Baseline Dyspnoea Index: PF 0.91; RP 0.72; VT 0.60 and GHP 0.68. PF was also strongly correlated with FEV (Mahler and Mackowiak 1995).

Responsiveness
Several studies provide evidence of responsiveness of the SF-36. There were significant differences in change scores for the SF-36 PF and SF between sub-groups differing in their views of change on a transition question (Harper et al., 1997). The responsiveness of the SF-36 was reported in Benzo (2000) with small effect size for Pain and RP; and moderate effect sizes for other domains. This was a small study (22 participants of a rehabilitation programme) and the authors attribute the lack of improvement and responsiveness of the RP domain to the variance in the group.

The SF-36 was responsive to change applying a one-SEM criterion with similar percents of change across most domains (Wyrwich et al., 1999). The SF-36 PCS showed similar responsiveness to the CRQ and the Activities and Impact domains of the SGRQ but the MCS was not as responsive as the related emotional domains of these COPD-specific instruments (Puhan et al., 2006).

Clinically important difference
An expert physician panel established small, moderate and large clinically important change levels for the SF-36 as follows: *Small change* 8.3 (RE) to 12.5 (RP, VT, SF); *Moderate change*: 16.7 (RE) to 25 (RP, VT, SF); *Large change*: 25 (RE) to 37.5 (RP, VT, SF) (Wyrwich et al., 2003).

Precision
Floor effects have been reported in two studies (Harper et al., 1997; Wyrwich 1999) for Role Limitations: physical, Role Limitations: emotional. Ceiling effects were found for RL emotional (Harper et al., 1997) and RP and SF in Wyrwich et al., (1999).

Acceptability and Feasibility
The SF-36 is generally acceptable to patients but some evidence exists of missing data (20%) (Harper et al., 1997; Wyrwich et al., 1999).

SF-20
One study provided evidence of the measurement properties of the SF-20 (Mahler and Mackowiak 1994).

Reliability
No evidence reported.

Validity
Lung function
The SF-20 PF domain was strongly correlated with Baseline Dyspnoea Index (BDI) (0.70) which was greater than for other physiological measures. Overall, correlations with the SF-20 domains and other physiological measures (FEV, FVC) were less than 0.60 with no relationship for the Pain domain. The authors in this study hypothesised that the BDI would have greater impact on self-reported health status than other physiological lung function, a hypothesis which was supported in the results (Mahler and Mackowiak 1994).

No other measurement criteria evaluated

SF-12

One study provided evidence of the measurement properties of the SF-12 (Katz et al., 2005).

Health status
Scores on the SF-12 MCS were comparable to population norms and PCS scores were in the lower quartile of scores compared to norms (Katz et al., 2005). The authors hypothesised that poorer physical health (PCS) would be associated with difficulty with self-care and recreational activities. There was strong association with PCS scores and self care and recreational difficulty and consequent psychological distress in regression analyses (Katz et al., 2005).

No other measurement criteria evaluate

Table 5.2: Developmental and evaluation studies relating to the SF-36, SF-20 and SF-36 applied in patients with COPD

Study/ Country	**Population (N) Age Method of administration Setting**	**Measurement properties**					
SF-36		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Benzo et al., (2000) USA	COPD (22) participating in a rehabilitation programme Age: mean 64 Self-complete Out-patients			✓			
Crockett et al., (1996) Australia	Chronic Airflow limitation. Patients being assessed for home oxygen therapy (60) Age: mean Females 70; Males 67 Self-completed Out-patients		Construct ✓				
Desikan et al., (2002) USA	COPD (40) Age: range 41 to 71 Telephone interview	Internal consistency ✓	Construct ✓				
Harper et al., (1997) UK	COPD (156) Age: mean 67 Self-completed Out-patients	Internal consistency ✓	Construct ✓	✓	✓	✓	
Mahler and Mackowiak (1995) USA	COPD (50) Age: mean 72 Self-completed Out-patients		Construct ✓				
Puhan et al., (2006) Canada	COPD (177) participating in a rehabilitation programme Age: mean 69 Self completion Out-patients			✓			

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
SF-36		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Ruffin et al., (2000) Australia	Chronic Lung Disease (329) Age: mean 44 Interview administered		Construct ✓				
Sprenkle et al., (2004)| USA	Veterans with self-reported diagnosis of COPD (8345) Age: mean 60 Postal survey		Construct ✓				
Viramontes and O'Brien (1994) Canada	Patients with asthma, chronic bronchitis and emphysema (102) Age: mean 62 Self-completed but interview administered in patient's own homes		Construct ✓				
Wilson et al., (1997) UK	Patients with bronchiectasis (111) Age: mean 52 Self-completed Out-patients	Test re-test ✓	Construct ✓	✓			
Wyrwich et al., (1999) USA	COPD (487) Age: mean 58 Telephone interview		Construct ✓	✓	✓	✓	
SF-20							
Mahler and Mackowiak (1992) USA	Symptomatic COPD (110) Age: mean 67 Self completed Out-patients		Construct ✓				
SF-12							
Katz et al., (2005) USA	COPD (334) Age: mean 64 Telephone interview		Construct ✓				

b) EuroQol- EQ-5D

Three UK evaluations provide evidence of the measurement properties of the EQ-5D (Harper et al., 1996; Hazell et al., 2003; Paterson et al., 2000).

Reliability
Test re-test reliability for the EQ-5D, [6 months] 0.67 in Harper et al., (1996).

Validity
Age
The EQ-5D index and VAS scores decreased significantly with age with moderate correlations (-0.41; -0.34) as predicted by the authors (Hazell et al., 2003).

Health status
Hazell et al., (2003) reported the ability of the EQ-5D to discriminate patients with respiratory disease. A postal survey including the ED-5D and a respiratory questionnaire identifying patient with symptoms associated with obstructive airways disease. The survey was posted to all patents identified from a primary care practice in the UK (10,471) and those with self-reported respiratory symptoms were included in the analysis (6828, with 5944 questionnaire computable). The EQ-5D index and VAS scores were significantly lower for those with respiratory symptoms compared to those without. The EQ-5D also discriminated patients with COPD indicating poorer health than pop norms (Harper et al., 1996).

Responsiveness
Responsiveness was examined in a concurrent evaluation of the EQ-5D, MYMOP and MOS-6A (Patterson et al., 2000). Responsiveness for the EQ-5D was variable with the SRM comparable to the MYMOP (0.71) but the VAS not responsive (SRM 0.37).

Precision
EQ-5D no floor or ceiling effects were reported in Harper et al., (1996).

Acceptability
87% of responses for the EQ-5D were computable in a postal survey (6828) with the highest proportion of missing values for the self-care domain (5.7%); anxiety/depression (4.4%); usual activities (4.3%); pain (4.1%); mobility (3.9%). The VAS though had a greater proportion of missing responses (6.3%) (Hazell et al., 2003; Patterson et al., 2000). Completion rates were 92-96% in Harper et al., (1996).

Table 5.3: Developmental and evaluation studies relating to the EQ-5D applied in patients with COPD

Study/ County	Population (N) Age Method of administration Setting	Measurement properties					
EQ-5D		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Harper et al., (1997) UK	Patients with COPD (156) Age: mean 67 Self-completed Out-patients	Test re-test ✓	Construct ✓	✓	✓	✓	
Hazell et al., (2003) UK	Asthma related symptoms including COPD (5944) Age: mean 48 Postal survey Primary care practice		Construct ✓			✓	
Paterson et al., (2000) UK	Acute exacerbation of chronic bronchitis (81) Age: mean 61 Self-completed Out-patients		Construct ✓	✓		✓	

c) NHP

Reliability
No evidence found.

Validity
Generic patient-reported health instruments
Strong correlations were observed for some related domains between the SF-36 and NHP in patients with chronic airflow limitation being assessed for home oxygen therapy. For males SF-36 PF and NHP Energy -0.67; MH with NHP Energy -0.66; Energy/VT with NHP Energy -0.80; PF with NHP Emotional reactions -0.54; MH with NHP Emotion -0.73; MH with NHP social isolation -0.61; PF with NHP Physical mobility -0.66. There was no correlation with scales with similar traits as would be expected. For females there was strong correlation between the SF- 36 BP with NHP Pain -0.74; Energy/VT with NHP Energy -0.62. All other correlations were small to moderate for similar scales and no correlation for other domains (Crockett et al., (1996).

No other measurement criteria reported

Table 5.4: Developmental and evaluation studies relating to the NHP applied in patients with COPD

Study/ County	Population (N) Age Method of administration Setting	Measurement properties					
NHP		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Crockett et al., (1996) Australia	Chronic Airflow limitation. Patients being assessed for home oxygen therapy (60) Age: mean Females 70; Males 67 Self-completed Out-patients		Construct ✓				

d) COOP Charts

One study provided evidence of measurement properties (Eaton et al., 2005).

Reliability

ICC assessed after 2 months were as follows in a study by Eaton et al., (2005): PF 0.45; DA 0.48; Pain 0.61; SA 0.43; SS 0.38; Feelings 0.53; OH 0.51; Change in Health 0.17 (ns/s) QOL 0.36.

Validity

Respiratory specific patient-reported health instruments

Stronger associations were reported for the COOP Feeling domain with CRQ emotional function 0.70 and HAD anxiety 0.70. The COOP Physical with CRQ dyspnoea was moderately correlated (0.40), consistent with expectations of two related but different constructs (Eaton et al., 2004).

Generic patient-reported health instruments

There was moderate correlation with the COOP PF with SF-36 PF 0.4 which was not as high as was expected. Strong correlations were found for similar domains in the two instruments (BP and Pain; SA with SF) (Eaton et al., 2004).

Responsiveness

There was moderate longitudinal correlation between the COOP PF with SF-36 PF 0.5; COOP DA and SF-36 RP 0.5; BP and Pain 0.80; SA with SF 0.60; Feelings with RE 0.50; Overall health with GHP 0.50 (Eaton et al., 2004). Effect size statistics (Standardised means: SE) were moderate for SA and Change on health (-0.51; -0.59) but small for other domains (Eaton et al., 2004).

Precision

No evidence found

Acceptability
The COOP was easy to administer; no patient required assistance to complete and there were no missing values in Eaton et al., (2004).

Feasibility
No evidence found

Table 5.5: Developmental and evaluation studies relating to the COOP Charts applied in patients with COPD

Study/ County	**Population (N) Age Method of administration Setting**	**Measurement properties**					
COOP		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Eaton et al., (2004) New Zealand	COPD (50) patients participating in a RCT of ambulatory oxygen therapy Age: mean 68 Self completion Out-patients	Test re-test ✓	Construct ✓	✓			

e) Sickness Impact Profile

Two studies provide evidence of validity of the SIP (McSweeny et al., 1982; Okubadejo et al., 1996) one of which was conducted in the UK.

Reliability
No evidence found.

Validity
Respiratory function
There was no correlation with the SIP Physical with FEV 0.10; Psychosocial 0.02; Total 0.14. Similar results were reported for PaO2 and PaCo2 (Okubadejo et al., (1996). Small to moderate correlation with SIP Total and maximum workload during exercise and Oxygen transport was reported in McSweeny et al., (1982).

No other measurement criteria reported

Table 5.6: Developmental and evaluation studies relating to the SIP applied in patients with COPD

Study/ County	**Population (N) Age Method of administration Setting**	**Measurement properties**					
		Reliability	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Okubadejo et al., (1996) UK	COPD (41) Age: median 70 Self completion with supervision Out-patients		Construct ✓				
McSweeny et al., (1982) USA	COPD (203) Age: mean 65 Self completion Out-patients		Construct ✓				

COPD-SPECIFIC PATIENT- REPORTED HEALTH INSTRUMENTS:

Five COPD-specific instruments were identified which were evaluated with patients with COPD. Full details of the development, domains and scoring methods are detailed in Tables 5.7 and 5.8.

The following instruments measurement properties are reported:

a) Breathing Problems Questionnaire
b) Chronic Respiratory Disease Questionnaire
c) Functional Performance Inventory
d) St. George's Respiratory Questionnaire
e) Seattle Obstructive Lung Disease Questionnaire

a) Breathing Problems Questionnaire (BPQ)

The Breathing Problems Questionnaire (BPQ) items were derived from focus groups with fifteen patients and refined by 89 COPD patients (Hyland 1994). The instruments foundation was based on three constructs of quality of life: Problems, Negative evaluations and Positive evaluations. Following factor analysis two factors emerged with 27 items constituting the BPQ problems score and 6 items the BPQ negative evaluations score. Further modifications have been made with a shortened version of ten items and a single scale score (Hyland et al.,1998).

b) Chronic Respiratory Disease Questionnaire (CRQ)

The Chronic Respiratory Disease Questionnaire (CRQ) was developed following interviews with 100 patients with chronic airflow limitation to identify the impact on their quality of life and how important their symptoms were (Guyatt 1987). The most frequently reported and important items were selected and provided the conceptual framework for the instruments which were categorised into four domains: Dyspnoea, Fatigue, Emotional function and Mastery. The Dyspnoea domain is individualised and related to activities which patients report their degree of dyspnoea. A list is provided to aid selection where needed.

The CRQ has four domains with a total of 20 items and include Dyspnoea (5 items); Fatigue (4 items); Emotional functioning (7 items); Mastery (4 items). Scoring is by domains and uses a seven-point Likert scale with higher scores reflecting no impairment.

c) Functional Performance Inventory (FPI)

The FPI was developed in the USA involving both patients and clinical experts. Focus groups with patients informed an activity profile and content evaluated by clinical experts. Pre-testing of the instruments face validity was evaluated with a group of patients. The FPI is based on a conceptual framework of functional status as a multidimensional concept involving activities carried out to meet basic need, fulfill roles and maintain health and well-being (Leidy., 1999). The FPI has six domains (65items): Body Care (9); Household Maintenance (21); Physical Exercise (7); Recreation (11); Spiritual Activities (5) and Social Activities (12). Response options range from 1 where the activity can be performed easily to 4 where the activity is no longer performed for health reasons. Higher scores reflect high functioning. Domain

and Total scores are computable. Modifications have been made to scoring by Larson et al., (1998).

d) St. George's Respiratory Questionnaire (SGRQ)

The SGRQ was developed in the UK to measure the impact of asthma and chronic obstructive pulmonary disease (COPD) from a patient perspective. There are two parts of the instrument. Part 1 is concerned with symptoms focusing on the severity, frequency and effect of respiratory symptoms over the last year and responses are obtained with a 5 point Likert scale. Part 2 includes two domains: Activity limitations and social and psychological Impact and focuses on the patient's current state with True or False responses. Three components scores are calculated and a total score. All items have empirically derived weights and normative data are available. Scoring algorithms and calculators are available from the developers. Scores are expressed as the percentage of overall impairment with 100 equaling to worst possible health and zero the best.

Items were initially derived from studies with adult patients with asthma examining distress ratings relating to symptoms and the impacts of asthma (Quirk and Jones1990) and the influence of demographic and disease factors with the degree of distress (Quirk et al., 1991). Empirical weights were obtained from one hundred and forty patients with asthma (Quirk et al., 1991). Further analysis of previously derived weights was compared with patients with COPD with thirty-six patients (mean age 66) (Jones 1991) and no significant differences between the item weights from the asthma patients (Quirk et al., 1991) and COPD patients.

The final instrument has 50 items and 76 weighted responses divided into three components Symptoms, Activities and Impacts

e) Seattle Obstructive Lung Disease Questionnaire

The Seattle Obstructive Lung Disease Questionnaire (SOLQ) was developed using the CRQ model of functional status but with the intention of providing a self-reported questionnaire which can be computer scannable and therefore processing and scoring enabling feasibility. Dimensions were selected from patient interviews, literature, and clinical experience of the developers and the CRQ model of COPD specific health-related quality of life.

The instrument comprise of four domains: Physical functioning, Emotional functioning, Coping skills and Treatment satisfaction with 29 items. Scoring is on a simple linear scale with lowest scores indicating poorer functioning. Domain scores are computed. Permission for use is required from the author:

COPD-SPECIFIC INSTRUMENTS:

Table 5.7: COPD-specific patient-reported health instruments

Instrument	***Domains (no. items)***	***Response options***	***Score***	***Administration/ Completion (time)***
Breathing Problems Questionnaire (BPQ)	*Thirteen domains (33),* Two subscales: Problems and Emotional evaluations Walking (3) Bending or reaching (2) Washing and bathing (2) Household chores (3) Social interactions (3) Effects of weather and temperature (4) Effects of smells and fumes (2) Effects of colds (1) Sleeping (2) Medicine (2) Dysphoric states (5) Eating (2) Excretion urgency (2)	4 point Likert	Subscale scores Lower scores better quality of life	
Chronic Respiratory Disease Questionnaire (CRQ)	*Four domains (20 items)* Dyspnoea (5) Fatigue (4) Emotional functioning (7) Mastery (4)	7 point Likert	Domain Higher score indicate no impairment	Maximum 30 minutes
Functional Performance Inventory (FPI)	*Six domains (65 items*): Body Care (9); Household Maintenance (21); Physical Exercise (7); Recreation (11); Spiritual Activities (5) and Social Activities (12).	5 point Likert	Total and Domain Higher scores reflect high functioning	
Seattle Obstructive Lung Disease Questionnaire (SOLQ)	*Four domains (29 items)* Physical functioning Emotional functioning Coping skills Treatment satisfaction	Linear scale	Domain score Lower score indicate lowest function	5-10 minutes completion Computer scannable
St. George's Respiratory Questionnaire (SGRQ)	*Two parts; Domains (3)/17 items* Part 1: Symptom scores (8) Part 2: Activity and Impact (9)	Part 1: 5 point Likert Part 2: True or False	Weighted scoring Total and domain scores Percentage of overall impairment 0=best possible health and 100 worse	Self- report but recommended interview administered 8- 15 minutes to complete

Table 5.8: Summary of COPD-specific instruments: health status domains

	Instrument domains (after Fitzpatrick et al., 1998)								
Instrument	**Physical function**	**Symptoms**	**Global judgement**	**Psychol. well-being**	**Social well-being**	**Cognitive functioning**	**Role activities**	**Personal construct**	**Treatment satisfaction**
BPQ	x	x		x	x		x		x
CRQ	x	x		x				x	
FPI	x				x		x	x	
SGRQ	x	x		x	x		x		x
SOLQ	x			x				x	x

COPD- SPECIFIC PATIENT- REPORTED HEALTH INSTRUMENTS

a) Breathing Problems Questionnaire (BPQ)

Two UK studies provide evidence of measurement properties for the BPQ (Hyland et al., 1998; Yohannes et al., 1998). Both studies administered the questionnaire by interview in an out-patients setting.

Reliability
Test re-test reliability was adequate in Hyland et al., (1998): 0.73 Problems and 0.64 for Emotional evaluation.

Internal consistency alphas for all domains were greater than 0.75 pre and post rehabilitation (Hyland et al., 1998).

Validity
Internal validity
Empirical evidence was established in the developmental study with two factors emerging; the BPQ Problems score (27 items) and BPQ Negative evaluations score (6 items) (Hyland 1994). Further analysis of the structure of the instrument was conducted to examine the relationship between personality and measures of problems both negative and positive and thus total life satisfaction. It was predicted that negative evaluations and positive evaluations contribute independent variance to total life satisfaction. The revised Eysenck Personality Questionnaire (EPQ-R), Satisfaction with Life Questionnaire and the Satisfaction with Illness Scale were administered to test these hypotheses. The results were as predicted that negative evaluations were correlated with neuroticism and that positive evaluations correlated with extraversion (Hyland 1994).

Health status
The BPQ scores for patients with chronic airflow limitation were statistically significantly higher (indicating poorer quality of life) than controls with no lung disease (Yohannes et al., 1998).

Respiratory function
A lower value measured by the Shuttle Walk Test which is associated with morbidity was most strongly correlated with the Problems sub-scale (Hyland 1994). Small but significant correlation between changes observed by the Shuttle Walk Test and Treadmill Endurance Test and nine of the items within the instrument indicating an improvement in exercise associated with an improvement in QoL (Hyland et al., 1998).

No other measurement criteria reported

Shortened version
Following analysis of change in BPQ items before and after rehabilitation the magnitude of effect sizes determined the items selected for the shortened version: seven items for the Problems scale and 3 for the emotional evaluations. Scoring was proposed as a single scale (Hyland et al., 1998). Correlations between the full version

of the BPQ and the shortened version ranged from 0.74 for Emotional to 0.91 for Total score.

Table 5.9: Developmental and evaluation studies relating to the BPQ applied in patients with COPD

Study/ County	Population (N) Age Method of administration Setting	Measurement properties					
BPQ		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Hyland (1994) UK	Development study COPD patients Interview administered		Construct ✓				
Yohann es et al., (1998) UK	CAL (151) Age: mean 78 Out-patients Interview administered		Construct ✓				

b) Chronic Respiratory Disease Questionnaire (CRQ)

Eighteen studies provide evidence of measurement properties for the CRQ. Five were with a UK population (Brightling et al., 2001; Harper et al., 1997; Singh et al., 2001; Williams et al., 2001, 2003). Four studies used self-completion of the questionnaire. These studies compared both interview-administered and self-report methods with patients (Schunemann et al., 2003; 2005; Williams et al., 2001; 2003).

The participants included in the studies were representative of COPD patients and sample sizes ranged from 24 to 156. Only one study recruited an adequate number of patients (487) (Wyrwich et al., 1999).

Reliability
Internal consistency was high for all domains (greater than 0.70) in studies by Harper et al., (1996) and Wyrwich et al., (1999).

Reproducibility was greater than 0.90 for individual analysis for all domains in Brightling et al., (2001); Desikan et al., (2002) and greater than 0.70 in Aaron et al., (2002).

ICC's were comparable for self-reported and interview administered versions of the instruments in Williams et al., (2001). In a small sample of patients with COPD (15) results were similar with the exception of Fatigue: 0.20 (Martin 1994).

Validity
Health status
The CRQ domains discriminated patients who had breathing problems in the last four weeks with statistically significantly lower scores than those patients who had no breathing problems in a study by Wyrwich et al., (1999).

Respiratory-specific patient-reported health instruments
A small study of 41 patients reported moderate correlation with the CRQ domains and patient- global ratings of similar constructs. The Fatigue domain was the only strongly correlated domain with Patient global rating fatigue 0.62 (Guyatt 1987). Moderate correlation was found for the CRQ and respiratory function and global ratings of change for dyspnoea, fatigue and emotions which were lower than hypothesised in the study by Guyatt et al., (1999). Small correlations were found with, Shuttle walk test 0.33, treadmill 0.29 and no correlation with FEV (Singh et al., 2001).

Internal validity
The four hypothesized factors were supported in the study by Wyrwich et al., (1999).

Validity of different versions and methods of administration
Two RCTs provide measurement properties for different versions and methods of administration (Schunemann et al., 2003, 2005). The CRQ-Self Administered version (CRQ-SA) and Interview administered (CRQ-IA) were further within- randomization to individualized and standardized Dyspnoea ratings. Overall there was greater correlation for the standardised component of IA and SA methods.

Further evidence is reported for self-reported vs. interview administered CRQ completion with no statistical difference in mean scores for Mastery and Fatigue but there was a statistically significant difference for Dyspnoea and Emotion (Williams et al., 2001).

Generic patient-reported health instruments
There was greater correlation for the 'standardised' Dyspnoea domain for both IA and SA methods with the SF-36 PCS. Other domain correlations for both methods were moderate to strong for similar items and domains (Schunemann et al., (2005).

Stronger correlations (greater than 0.60) was found between the SF-36 and CRQ related domains (PF and Dyspnoea; Vitality and Fatigue; RE, MH and Emotional function). There was moderate correlation with all SF-36 domains and the CRQ Mastery domain (Wyrwich et al., (1999). No correlation with SF-36 and the CRQ Mastery domain and only small to moderate for other domains in small study by Martin (1994)

Responsiveness
It was hypothesised that patients participating in a rehabilitation programme would improve following intervention. Two weeks following discharge substantial improvement was observed in scores on all four domains. Higher responsiveness statistics were found for CRQ than for other instruments in groups of patients distinguished in terms of level of change on the Transition Dyspnoea index. As hypothesized, correlations between changes in FEV and CRQ were uniformly higher than RAND and Oxygen Cost Diagram 0.55 vs. 0.28 and 0.43 (Guyatt (1987). In contrast to cross sectional validity there was no trend for higher correlation for the standardised dyspnoea component for either SA or IA. The individualised component was more responsive than the standardised. The SA was more responsive than the IA (Schunemann et al., 2003; 2005).

There were no statistically significant differences in responsiveness or longitudinal validity for the CRQ with the SGRQ according to whether patients were reminded of their baseline scores in a study by Schunemann et al., (2002).

Longitudinal changes were correlated between the CRQ and SGRQ but the strength of correlation less than 0.60 (de Torres et al., 2002). Longitudinal changes between CRQ and FEV and TDI were greater for all domains (greater than 0.60 (Aaron et al., 2002).

The CRQ- self-completion and interview administered versions were equally as responsive to change with large statistical and clinically significant changes in mean scores and no difference was observed in the magnitude of change between the two methods (Williams et al., 2003). However, the SRM's were higher for the CRQ-SA compared to the CRQ-IA in a study by Puhan et al., (2005). The CRQ standardized Dyspnoea domain was more responsive than the Fatigue, Emotions and Mastery domains but also the SGRQ and SF-36. The Emotional and Fatigue domains were also more responsive to change following a rehabilitation programme than the SF-36 similar domains.

Weak longitudinal correlation was found between the CRQ all domains with QWB scale and SIP with no correlation with the SG (Guyatt et al., 1999).

Large effect sizes (≥0.80) were observed for CRQ Dyspnoea (where patients were classified into severe and less severe breathlessness cases); Mastery: Moderate (<0.80) and small effect sizes (≥0.20 to <0.5) for Fatigue (Harper et al., 1997). Effect sizes representing responsiveness were 0.40 for Fatigue to 0.90 for Mastery in Guyatt et al., (1999).

The CRQ was responsive to change applying a one-SEM criterion with similar percents of change across most domains (Wyrwich et al., 1999). The responsiveness statistics for domains (dyspnoea, fatigue, emotion and mastery) were 2.2; 4.1; 2.5; 4.2 with greater than 1.5 indicating responsiveness by the authors (Aaron et al., 2002).

Clinically important difference

An expert physician panel established small, moderate and large clinically important change levels for the CRQ as follows: *Small change*: 2 (Fatigue) to 5 (Emotional function; *Moderate change*: 4 (Fatigue) to 10 (Emotional function); *Large change*: 6 (Fatigue) to 15 (Emotional function) (Wyrwich et al., 2003).

Precision

No floor or ceiling effects have been reported (Harper et al., 1996; Wyrwich et al., 1999)

Acceptability

More items were completed for the individualised version than the standardised version of the Dyspnoea domain (96 vs. 70%) on the SA and 98 vs. 75% on the IA. There was no missing data for the other domains (Schunemann et al., (2005). At least 80% of data were computable in Singh et al., (2001) and Wyrwich et al., (1999).

Feasibility

No evidence reported

Table 5.10: Developmental and evaluation studies relating to the CRQ applied in patients with COPD

Study/ County	**Population (N) Age Method of administration Setting**	**Measurement properties**					
CRQ		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Aaron et al., (2002) Canada	COPD (70) visiting ED Age: mean 70 ED Interview administered	Test re-test ✓	✓	✓			
Brightling et al., (2001) UK	COPD (61) Age: mean 66 Out-patients Interview administered	Test re-test ✓					
Desikan et al., (2002) USA	COPD patients (40) Age: range 41 to 71 Telephone interview	Test re-test ✓	✓				
de Torres et al., (2002) USA	COPD patients FEV<40% (37) Age: mean 63 Interview administered Out-patients			✓			
Guyatt (1987) Canada	COPD (41) participating in a rehabilitation programme Age no details Interview administered Out-patients		Construct ✓	✓			
Guyatt et al., (1991) Canada	Chronic Airflow Limitation (24) participating in a trial of bronchodilators Age: mean 66 Interview administered Out-patients			✓			

Study/ County	Population (N) Age Method of administration Setting	Measurement properties					
CRQ		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Guyatt et al., (1999) Canada	Chronic airflow limitation (89) Age: no details Interview administered		Construct ✓	✓			
Harper et al., (1997) UK	Patients with COPD (156) Age: mean 67 Self-completed Out-patients	Internal consistency ✓ Test re-test ✓	Construct ✓	✓	✓	✓	
Martin (1994) USA	COPD (15) Age: mean 67 Interview administered Out-patients	Test re-test ✓	Construct ✓				
Puhan et al., (2006) Canada	COPD (177) participating in a rehabilitation programme Age: mean 69 Self completion Out-patients			✓			
Schunemann et al., (2002) Canada	COPD (85) participating in a RCT of blind vs. informed response administration of the CRQ and SGRQ Age: mean 66 Interview administered Out-patients			✓			
Schunemann et al., (2003) Canada	COPD (51) Age: mean 67 Interview vs. self administered Out-patients		✓	✓			

Study/ County	Population (N) Age Method of administration Setting	Measurement properties					
CRQ		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Singh et al., (2001) UK	Patients with COPD participating in a rehabilitation programme (97) Age: mean 67 Interview administered Out-patients		Construct ✓	✓		✓	
Williams et al., (2001) UK	COPD (52) Age: mean 66 Interview vs. self-completion Out-patients		Construct ✓			✓	
Williams et al., (2005) UK	COPD (35) Age: mean 67 Interview vs. self-completion Out-patients			✓			
Wyrwich et al., (1999) USA	COPD (487) Age: mean 58 Telephone interview	Internal consistency ✓	Construct ✓	✓	✓	✓	

c) Functional Performance Inventory (FPI)

Three studies form the USA provide evidence of measurement properties (Larson et al., 1998; Leidy et al., 1999a, b). Two studies used a postal survey and one self-completion during an out-patients visit. Small numbers of patients were recruited in these studies (23 to 154).

Reliability
The FPI was reproducible in a study by Leidy et al., (1999a) with ICC values as follows: Total 0.87: BC 0.76; HM 0.89; PE 0.66; R 0.85; SpA 0.71; SoA 0.82.

Internal consistency of the FPI was high with alphas all above 0.70 for all domains (Larson et al., 1998; Leidy et al., 1999a) and 0.90 for Maintaining household (Larson et al., 1998; Leidy et al., 1999a) and FPI Total 0.96 (Leidy et al., 1999a).

Less than 3% for the total instrument inter-item correlations exceeded 0.50 and items with weak item-total correlations (less than 0.20) reflected low levels of physical activity from the Body Care domain and were consistent with ceiling effects noted in this scale (Larson et al., 1998).

Validity

Generic patient-reported health instruments
Strong correlation was observed for the FPI Total and SIP Physical (-0.60); PPI Body Care and SIP Physical and Total (-0.64, -0.62).The FPI Total correlated with SF-36 PF (0.69), FPI Body care, Maintaining household and Physical exercise were strongly correlated with the SF-36 PF. There was moderate correlation with other similar domains for the FPI and SF-36 and SIP (Larson et al., 1998).

FPI correlations were strong (0.60 and above) between the FPI and Functional Status Questionnaire for BC, HM, PE and Total. Weak correlation was reported for Spiritual activities. Moderate correlation was reported between the FPI and DASI (Leidy and Kapella 1999a).

Respiratory function
The range of correlations were weak to strong for FPI and respiratory function tests as follows: 0.12 for Spiritual activity to 0.63 for Total with: FEV, Bronchitis Emphysema Symptom Checklist (Leidy and Kapella1999a).The FPI Maintaining household was the only domain which was strongly associated with lung function tests in a small study of 23 patients with COPD (Leidy et al., 1999b). Strong correlation with self-reported functional performance was reported tin this study for all domains with exception of the Spiritual activity domain.

Responsiveness
No evidence reported.

Precision
There were no ceiling and floor effects for the Total FPI but floor effects were observed for the following domains of the FPI in a small study of seventy patients

with COPD: Spiritual activity (26%), Work/school (66%). Ceiling effects were 32% for Body Care and 18% for Spiritual activity (Larson et al., 1998).

Acceptability
Postal survey to 293 patients with COPD resulted in a 66% response rate (Leidy et al., 1999a).

23% missing data for the Work/School domain was reported in Larson et al., (1998). 3% to 6% of data were missing for all other domains except Body care and Spiritual activity with no missing data.

Feasibility
No evidence reported.

Table 5.11: Developmental and evaluation studies relating to the FPI applied in patients with COPD

Study/ County	**Population (N) Age Method of administration Setting**	**Measurement properties**					
FPI		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Leidy and Kapella (1999a) USA	COPD (154) Age: mean 64 Postal survey	Internal consistency ✓ Test re-test ✓	Construct ✓	✓	✓		
Leidy et al., (1999b) USA	COPD (23) Age: mean 64 Self completion Out-patients		Construct ✓				
Larson et al., (1998) USA	COPD (72) Age: mean 70 Telephone and postal survey		Construct ✓				

d) SGRQ

Ten studies provide evidence of the measurement properties for the SGRQ, five from the UK (Harper 1997; Jones et al., 1991; Okubadejo et al., 1996; Singh et al., 2001; Wilson et al., 1997). Five studies administered the questionnaire during an interview in out-patients, others were self-completed. The number of participants in all studies was less than 160.

Reliability
Four studies provided evidence of reliability (Jones et al., 1991; Desikan et al., 2002; Harper et al., 1997; Wilson et al., 1997).

High levels of test-retest reliability were reported for patients with COPD (Jones 1991) (Total 0.92). Test re-test reliability coefficients were greater than 0.70 but did not reach 0.90 in Harper et al., (1997 and Desikan et al., (2002) with the exception of

the Impact domain (0.46) (Harper et al., 1997). Higher levels of reproducibility were reported in Wilson et al., (1997) with all ICC's >0.90.

Internal consistency alphas were acceptable in Harper et al., (1997) and Wilson et al., (1997) (0.71 to 0.92).

Twenty-seven of 50 (54%) item total correlations for the SGRQ were greater than 0.40 Harper et al., (1997) but no details were provided of items inferring lack of homogeneity.

Validity
Eight studies provide evidence to support the validity of the SGRQ.

Health status
The SGRQ Symptoms domain discriminated between patients with respiratory symptoms and those without but was weakly correlated with physiological measures, dyspnoea grade, mood state and SIP scores (O.07 to 0.12) (Jones 1991). Moderate correlations were reported as hypothesised for the Activity and Impact domains and MRC dyspnoea grade, physical function test, psychological functioning and general health. Stronger correlations were reported for the Impact domain and anxiety and depression (Jones et al., 1991).

The SGRQ Activity, Impact and Total distinguished the presence of co morbidity in Harper et al., (1997) with large effect sizes (≥0.80) (where patients were classified into severe and less severe breathlessness cases) for SGRQ Total, Impact and Activity; small effect sizes ≥0.20 to <0.5) for SGRQ Symptoms (Harper et al., 1997).

The Symptoms score was significantly higher in patients with wheeze on most days compared with those who had occasional wheeze and higher in patients reporting more than three infections in the past year (Wilson et al., 1997).

Healthcare utilisation
Poorer quality of life as indicated by high SGRQ scores were related to a greater likelihood of hospitalisation, ER and primary care visits in (Alemayehu et al., 2002).

COPD-specific patient-reported health instruments
All correlations were strong between the SGRQ domains and the AQ30 and AQ20 (Alemayehu et al., 2002).

The SGRQ Total was moderately correlated with BPQ: -0.59; CRQ -0.39; and Global QOL -0.48. (Singh et al., 2001).

Generic patient-reported health instruments
Strong correlation was reported as predicted between the SGRQ Total and domains with the SF-36 PCS with smaller to moderate correlation for the MCS (Wilson et al., 1997). Similar results were reported for the SIP Physical and Psychological scores. Small to moderate correlations were reported between the SGRQ Total, HAD anxiety and HAD depression (0.20 for Symptoms to 0.58 Impact (Wilson et al., 1997).

Respiratory function
Three studies evaluated the relationship between HRQL with the SGRQ and respiratory function reporting small to moderate correlations which were less than expected (Okubadejo et al., 1996; Singh et al., 2001; Wilson et al., 1997). Respiratory function was measured using FEV, Shuttle walk test, Treadmill, and oxygen tension (PaO2 and PaCO2). No correlation was observed between FEV and Symptoms (0.03) in Okubadejo et al., (1996).

Responsiveness
There was little change in a small group of patients with COPD in a study by Jones et al., (1991) for physiological variables, dyspnoea grade and SIP scores (Jones et al., 1991). Changes in SGRQ scores were most positively correlated with dyspnoea grade (0.22). With small changes in health in a group of patients over six months (Wilson et al., 1997) hypothesised correlations were stronger for the SGRQ and Physical component score (SF-36) than changes in the Mental component. The SGRQ Total score and Impacts domain were more responsive than the SF-36 following a rehabilitation programme but less so than the CRQ in a concurrent evaluation (Puhan et al., 2006). However for the other domains of the SGRQ, the SRM's were similar to the SF-36. The correlations with the SGRQ and MRC dyspnoea scale were also stronger for Impact and Total (0.43; 0.38) than Symptoms and Activity (0.15; 0.27).

The SGRQ did not correlate as strongly as the CRQ with changes Fatigue with Shuttle walk test and Treadmill endurance in a concurrent evaluation (Singh et al., 2001). The SGRQ and the CRQ had moderate correlations of change in a concurrent evaluation by de Torres et al., (2002).

Using a transition question of patient perceived change, statistically significant differences between groups with different levels of change were reported for Symptoms, Activity and Total but not for the Impact domain (Harper et al., 1997). SRM's for [6 months and 12 months] were as follows: SGRQ Total Large (≥0.80), SGRQ Symptoms and Activity moderate (≥0.5 to <0.80) (Harper et al., 1997).

Precision
A normal distribution and no floor or ceiling effects were found with patients with COPD (Jones et al., 1991; Wilson et al., 1997). Floor effects for Activity (25.9%) were reported in Harper et al., (1997).

Acceptability and Feasibility
Higher completion rates were reported when the SGRQ was administered in out-patients but in a concurrent evaluation the SGRQ had the lowest completion rates compared to the EQ-5D and SF-36 (Harper et al., 1997). Further evidence of missing data were reported in Singh (2001) with 68% of data complete and only 50% of questionnaire computable in a postal survey by Alemayehu et al., (2002) although this study included the AQ20 and AQ30 and the authors only included in analysis responses to all questionnaires.

Table 5.12: Developmental and evaluation studies relating to the SGRQ applied in patients with COPD

Study/ County	**Population (N) Age Method of administration Setting**	**Measurement properties**					
SGRQ		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Jones et al., (1991) UK	Studies including patients with asthma and COPD COPD patients (20) Age: mean 66 Interview but patient completed Out-patients	Test re-test ✓	✓	✓			
	Patients with chronic airflow limitation (141) Age: mean 63		Construct ✓	✓	✓		
Alemayehu et al., (2002) USA	COPD (181) Age: mean 68 Postal survey		Construct ✓				
Desikan et al., (2002) USA	COPD patients (40) Age: range 41 to 71 Telephone interview	Test re-test ✓	✓				
de Torres et al., (2002) USA	COPD patients FEV<40% (37) Age: mean 63 Interview administered Out-patients			✓			
Harper et al., (1997) UK	Patients with COPD (156) Age: mean 67 Self-completed Out-patients	Internal consistency ✓ Test re-test ✓	✓	✓	✓	✓	

Study/ County	Population (N) Age Method of administration Setting	Measurement properties					
SGRQ		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Puhan et al., (2006) Canada	COPD (177) participating in a rehabilitation programme Age: mean 69 Self completion Out-patients			✓			
Schunemann et al., (2002) Canada	COPD (85) participating in a RCT of blind vs. informed response administration of the CRQ and SGRQ Age: mean 66 Interview administered Out-patients			✓			
Singh et al., (2001) UK	Patients with COPD participating in a rehabilitation programme (97) Age: mean 67 Interview administered Out-patients		Construct ✓	✓			

e) SOLQ

Three studies provided evidence of measurement properties, two of which were large studies by postal survey with over 1000 and 3000 patients with COPD. All patients were representative of the COPD population.

Reliability

High levels of internal consistency were reported for postal administration (0.79 for Emotional function to 0.93 for Physical) (Tu et al., 1997).

Test re-test reliability over a four month period was 0.64 for Treatment satisfaction to 0.87 Physical functioning (Tu et al., 1997).

Validity

Healthcare utilisation

In a large postal survey using the SOLQ, patients Physical function scores which were in the 0-25th percentile were six times more likely to have a COPD related hospitalisation within a year of baseline measurement. For other domains Odds Ratios for hospitalisation were 3.0 for Emotional function and 3.2 for Coping Skills (Fan et al., 2002).

COPD-specific patient-reported health instruments

Hypothesised correlations between the SOLQ and the CRQ were supported in Tu et al., (1997) but the expected strength of correlation not specified a priori. Correlations were small to moderate for all domains. Treatment satisfaction was strongly correlated with overall satisfaction measured by the Patient Satisfaction Questionnaire (0.54) as hypothesised.

Generic patient-reported health instruments

There was large hypothesised correlation between the SOLQ Physical functioning domain and the SF-36 PCS but only moderate correlation between the similar emotional domains for each instrument (Belza et al., 2005).

Respiratory function

Small correlations were reported between the SOLQ and lung function (FEV and 6 min Walk test (Tu et al., 1997, Belza et al., 2005).

Responsiveness

The SOLQ was able to detect change with high responsiveness statistics for each domain (0.78 to 0.87) (Tu et al., 1997). Correlation of change with the SF-36 and the SOLQ were moderate with none greater than 0.60 (Belza et al., 2005).

Clinically important difference

MCID was reported using patient-reported assessment of improved, unchanged or deteriorated and a change of 5 points was observed (Tu et al., 1997) and statistically significant change in scores post rehabilitation (Physical 3.79; Emotional function 9.20; Coping skills 7.26) (Belza et al., 2005).

Precision

No evidence reported

Acceptability
There was a 60% response rate to the SOLQ postal survey (Fan et al., 2002).

Feasibility
No evidence reported

Table 5.13: Developmental and evaluation studies relating to the SOLQ applied in patients with COPD

Study/ County	**Population (N) Age Method of administration Setting**	**Measurement properties**					
SOLQ		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Tu et al., (1997) USA Development study	COPD: 203; 97; 920 Age: mean 70 Postal survey	Internal consistency ✓ Test re-test ✓	Construct ✓				
Fan et al., (2002) USA	COPD (3282) Age: mean 65 Postal general health survey		Construct ✓			✓	
Belza et al., (2005) USA	COPD (58) participating in a rehabilitation programme Age: mean 66 Self completed Out-patients		Construct ✓	✓			

Other COPD-specific instruments identified from the review.

The following table provides an overview of other records of COPD-specific instruments identified of either newly developed instruments or single study reporting of measurement properties and/or evaluation.
Table 5.14

Instrument/ reference	*Population (N) Age Method of administration Setting*	*Reliability*	*Validity*	*Responsiveness*	*Precision*	*Acceptability*	*Feasibility*	*Comments* *No other records identified unless stated*
Single studies								
AQ30 and AQ20 Chen et al., (2006)	COPD (352)		✓					Validity of the AQ20 established with moderate correlation with the SF-12 No advantage over the AQ30 over the AQ20. Correlations reported with respiratory function, SGRQ and AQLQ Junipers. AQ30 and AQ20 evaluated in patients with Asthma (Quirk 1994) Foreign language evaluations and one UK translation to Bengali (Griffiths 2000)
Manchester Respiratory Activities of Daily Living Questionnaire Yohannes et al., (2000) UK	COPD (188)	✓	✓					Instruments developed from selected items from Nottingham Extended ADL Questionnaire and Breathing Problems Questionnaire. Domains focus on mobility and activity limitations
Pulmonary Functional Status Score Weaver et al., (1998) USA	COPD (365)	✓	✓					Three factors: Daily activities/social functioning; Psychological functioning and sexual functioning

Table 5.15: Instruments excluded from the review

Instruments excluded	***Reason for exclusion***
The Breathless, Cough and Symptoms Scale	Not multidimensional. Measures the severity of symptoms
Baseline Dyspnoea Index/ Transitional Dyspnoea Index	Dimension-specific. Assesses the severity of dyspnoea
COPD Severity Score	Not multidimensional
San Diego Shortness of Breath Questionnaire	Assesses self-reported shortness of breath while performing activities of daily living
Pulmonary Functional Status and Dyspnoea Questionnaire	Assesses intensity of dyspnoea and affect on activities
London Chest ADL Scale	Measures breathlessness when carrying out activities

SUMMARY - GENERIC INSTRUMENTS

A total of seventeen articles were included in this review of evaluation studies of generic instruments for COPD. Seven generic instruments were identified that had been evaluated with people with COPD (SF-36; SF-20; SF-12; EQ-5D; SIP; Dartmouth COOP and NHP). The most frequently reported instrument evaluated was the SF-36 with evidence of all measurement properties.

The number of participants included each was generally small with only five studies recruiting greater than 200 participants: Ruffin et al., (2000), Sprenkle et al., (2004) and Katz et al., (2005) for the SF-36; Hazell et al., (2003) for the EQ-5D and McSweeny et al., (1982) for the SIP. Six studies were conducted in the UK with one using the SIP, 3 using the EQ-5D and 2 studies the SF-36. Although in all studies the patients completed the questionnaires, many were administered during an interview. Two studies used a postal survey as the method of administration and one using a telephone interview. Patients were recruited from primary care practices or out-patient settings. No study was conducted whilst a patient was in hospital. Patients all had a general diagnosis of COPD, but some studies recruited patients with specific lung disease such as emphysema, bronchiectasis and airflow limitation including asthma.

Generic instruments included domains, items and scoring procedures are detailed in Chapter 3, Tables 1 and 2. All instruments are multi-dimensional with an average of six domains similar in construct.

Only two studies reported internal consistency reliability for the SF-36 with high alpha levels. Reproducibility was generally lower than the 0.70 threshold for group testing for the SF-36, EQ-5D and COOP charts. No other generic instruments have reliability evidence in the COPD population. Construct validity is supported for all generic instruments included in the review with extensive evaluation for the SF-36. The SF-36 PCS scores were predictive of healthcare utilisation and discriminated patients with different disease severities. The MCS was not predictive or discriminative. The EQ-5D too discriminated between different health states and respiratory disease severities. The internal structure was supported in one study for the SF-36. Strong correlations between the SF-36 and other generic instruments (NHP and COOP Charts) and the CRQ COPD-specific instrument were reported for scales of similar domains.

Evidence of responsiveness is reported for the SF-36, EQ-5D and COOP charts with the exception of the SF-36 MCS and the EQ-5D VAS which were not responsive to change. Recommended clinically important differences were reported from consensus group proceedings for the SF-36 only. Ceiling and floor effects were reported for the SF-36 but not for the EQ-5D. The other instruments were not evaluated for precision.

The COOP Charts was the most easy to administer instrument with no missing data. Missing data was reported for the SF-36 and EQ-5D particularly the VAS.

SUMMARY – COPD-SPECIFIC INSTRUMENTS

A total of twenty-nine studies were included in the review which reported results from evaluations of COPD-specific instruments. Five instruments were included in the review which had undergone different aspects of measurement performance (BPQ, CRQ, FPI, SOLQ and the SGRQ). A further three instruments were identified which had undergone one evaluation (Table 5.15) and 6 instruments were excluded (Table 5.16). The CRQ was the most frequently and comprehensively evaluated instrument (17) followed by the SGRQ (10).

Most studies recruited less than 200 participants with the exceptions of Wyrwich (1999) for the CRQ (477) and two studies with the SOLQ (Tu 1997) 920 and Fan (2002) 3282 patients. Generally the patients were older than 50 years of age and representative of the COPD population. Of the twenty-nine studies, 11 were conducted in the UK (BPQ, CRQ and SGRQ). The FPI and SOLQ were the only instruments to be completely self reported either by post or during and out-patient visit. The BPQ, CRQ and SGRQ were generally interview administered.

All instruments included scales to assess Physical functioning, psychological, social well-being, and role activities. Personal construct and treatment satisfaction were common domains in most. The number of items ranged from 17 (SGRQ) to 65 (FPI). Total and domain scores are computable for the FPI and SGRQ.

All instruments included in the review have evidence of reproducibility supporting application in studies involving groups of patients. All instruments have reported high levels of internal consistency.

All instruments were assessed for validity through comparison with other instruments with similar constructs and predictions a priori about hypothetical relationships generally supported between similar domains with generic instruments particularly for the CRQ and SGRQ. There was often a poor relationship between COPD-specific measures and respiratory function. Evidence of responsiveness was reported for all instruments except the BPQ. In concurrent evaluations, the instruments included in the review performed better than generic comparator instruments.

Although for all instruments, complete data enabled analysis, many studies administered the questionnaires during an interview. The individualised version of the CRQ Dyspnoea domain had better completion rates than the standardised version.

There is good evidence of the measurement and practical properties for the CRQ and SGRQ with both including UK evaluations. There is limited evidence for the BPQ, FPI and SOLQ; further evaluations are required.

Some instruments have been identified in this review which report only one evaluation. There is insufficient evidence therefore to make firm recommendations about these at present.

Instrument	**Measurement properties**	**Availability**: Royalty; Scoring methods and interpretation guide	**Acceptability/Feasibility**: Patient acceptability Staff acceptability
COPD-specific			
BPQ	Developed in the UK (2 UK evaluations pre 2000) Limited evidence of reliability and validity	No details	Suitable for self-completion but 33 items 10 to 20 minutes completion No details of patient acceptability or feasibility
CRQ	Developed in Canada. 16 evaluations, 5 UK Several studies evaluating most measurement criteria Several studies evaluating most measurement criteria Good evidence of reliability, validity and responsiveness supporting application	License Agreement required	30 minutes completion time Interview administered Acceptable to patients although the individualised Dyspnoea domain difficult for some
FPI	.Developed in UK Three UK evaluations pre-2000 Some evidence of reliability and validity although two studies with small number of patients	No details	Self reported 68 items related to functional impairment. Some evidence of missing data
SGRQ	Developed in the UK Eight evaluations with people with COPD. Has been used with patients with Asthma Several studies evaluating most measurement criteria Good evidence of reliability and validity	Contribution to the St. George's Research Fund is requested from commercial organisations using the instrument. Permission should be obtained from the authors Scoring algorithms and calculators are available from the developers	Self- report but recommended interview administered 8- 15 minutes to complete Some evidence of missing data

Generic			
Instrument	**Measurement properties**	**Availability**: Royalty; Scoring methods and interpretation guide	**Acceptability/Feasibility**: Patient acceptability Staff acceptability
SF-36	Two UK evaluations Several studies evaluating most measurement criteria. Good evidence of reliability, validity and responsiveness supporting application	Permission and licensing should be obtained from the authors Scoring algorithms and manual are available from the developers	Self- report 10 to 15 minutes to complete Some difficulties experiences with completion
SF-20	One USA evaluation	Permission and licensing should be obtained from the authors Scoring algorithms and manual are available from the developers	Self-report 5 minutes completion Acceptable to patients
SF-12	One USA evaluation	Permission and licensing should be obtained from the authors Scoring algorithms and manual are available from the developers	Self-report 5 minutes completion Acceptable to patients
SIP	Limited evaluations and evidence of validity 2 evaluations, one UK		
Dartmouth COOP	Limited evidence One evaluation from Australia evaluating reliability, validity and responsiveness		
EuroQol	Three evaluations in the UK Some evidence of measurement properties	Permission and licensing should be obtained from the authors Scoring algorithms and manual are available from the developers	Self-report 5 minutes completion VAS higher proportion of missing responses
NHP	Limited evaluations and evidence of measurement properties. It has only been used as a reference measure.		

DISCUSSION AND RECOMMENDATIONS

Many evaluations have been identified in this review of both generic and COPD-specific instruments with patients with different disease severities. The evaluations were conducted mainly in an out-patient setting and although all instruments were completed by the patients, some were administered during interviews. There are limited UK evaluations. Most have been applied in the USA or Canada.

The methodological quality of the studies was variable. Adequate reporting of data enabled abstraction for this review but the small sample sizes of some studies may inflate results. In addition, although most studies predicted associations for example between similar domains, none specified the strength of association a priori.

The SF-36 is the most widely evaluated generic instrument. Amongst the COPD-specific instruments and the Chronic Respiratory Questionnaire and St. George's Respiratory Questionnaire have extensive evidence of measurement properties but further UK evaluations would strengthen evidence of their applicability for UK populations. There is limited evidence for the BPQ, FPI and SOQL. Further evaluations are required.

The generic instruments chiefly the SF-36, included in the review adopt a multi-dimensional perspective to the measurement of patient-reported health.

All reviewed COPD-specific instruments address multi-dimensional aspects of health-related quality of life. All include the assessment of symptoms; physical functioning and most also include psycho-social well-being. Other frequently assessed dimensions include the impact of COPD on role activities, personal constructs and treatment satisfaction.

Formal measurement properties are more commonly a feature of evaluative studies of instruments. The practical properties of instruments are less widely explored or defined in evaluations. No direct evidence was found for feasibility for staff in terms of time to administer, training required and processing of results. Some evidence is reported relating to the percentage of missing responses relating to patient acceptability. The instruments included in the review have been administered by different methods and many have adopted a postal survey or self completion in an out-patient setting.

The lack of studies directly comparing the performance of different generic instruments is disappointing. The SF-36 and NHP performed equally well in one concurrent evaluation (Crockett 1996).

Concurrent evaluations of COPD-specific instruments were dominated by comparative evaluations of modifications of the CRQ and SGRQ. Both instruments have evidence of high levels of internal consistency and reproducibility. Similar strength of correlation is reported for both instruments and generic measures supporting construct validity and both discriminated patients with different health status. The CRQ was slightly more responsive compared to the SGRQ with higher longitudinal correlations with respiratory function. The CRQ standardised dyspnoea domain version was more responsive than the individualised version. Although a

greater number of evaluations were identified for the CRQ, with some in the UK, the SGRQ has been developed in the UK and performance is comparable. In addition, the SGRQ has been evaluated with patients with asthma.

However, several studies report the concurrent evaluation of generic and COPD-specific instruments. Good evidence supports the reliability and validity of both generic (SF-36) and COPD-specific (CRQ, SGRQ) measures, supporting their combined use in people with COPD. However, and as expected, consistently higher levels of responsiveness were reported for the COPD-specific instruments.

Recommendations

Synthesising the available primary evidence reported in this review and extrapolating evidence from concurrent evaluations supports the use of both generic and COPD-specific patient-reported health instruments for people with COPD. The SF-36 is recommended as a generic instrument for the broad evaluation of health-related quality of life. Further evaluations are required, particularly concurrent evaluations of different generic instruments to inform further recommendations and for the UK population.

COPD-specific instruments, particularly the CRQ and SGRQ, are recommended and different administration methods have been evaluated. Further evaluations are needed to support the use of these instruments specifically in the UK.

REFERENCES

Aaron SD, Vandemheen KL, Clinch JJ, Ahuja J, Brison RJ, Dickinson G *et al*. Measurement of short-term changes in dyspnea and disease-specific quality of life following an acute COPD exacerbation. *Chest: the Cardiopulmonary Journal* 2002; **121:**688-96.

Alemayehu B, Aubert RE, Feifer RA, Paul LD. Comparative analysis of two quality of life instruments for patients with chronic obstructive pulmonary disease. *Value in Health* 2002; **5:**436-41.

Belza B, Steele BG, Cain K, Coppersmith J, Howard J, Lakshminarayan S.Seattle Obstructive Lung Disease Questionnaire: sensitivity to outcomes in pulmonary rehabilitation in severe pulmonary illness. *J Cardiopulm Rehabil. 2*005 Mar-Apr; **25**(2):107-14.

Benzo R, Flume PA, Turner D, Tempest M. Effect of pulmonary rehabilitation on quality of life in patients with COPD: the use of SF-36 summary scores as outcomes measures. *Journal of Cardiopulmonary Rehabilitation* 2000; **20:**231-4.

Brightling CE, Monterio W, Green RH, Parker D, Morgan MDL, Wardlaw AJ *et al*. Induced sputum and other outcome measures in chronic obstructive pulmonary disease: safety and repeatability. *Respiratory Medicine* 2001; **95:**999-1002.

Chen H, Eisner MD, Katz PP, Yelin EH, Blanc PD Measuring disease-specific quality of life in obstructive airway disease: validation of a modified version of the airways questionnaire 20.
Chest. 2006 Jun; **129**(6):1644-52.

Crockett AJ, Cranston JM, Moss JR, Alpers JH. The MOS SF-36 Health Survey questionnaire in severe chronic airflow limitation: comparison with the Nottingham Health Profile. *Quality of Life Research* 1996; **5:**330-8.

De Torres JP, Pinto-Plata V, Ingenito E, Bagley P, Gray A, Berger R *et al*. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. *Chest: the Cardiopulmonary Journal* 2002; **121:**1092-8.

Desikan R, Mason HL, Rupp MT, Skehan M. Health-related quality of life and healthcare resource utilization by COPD patients: a comparison of three instruments. *Quality of Life Research* 2002; **11:739-**51.

Eaton T, Lewis C, Young P, Kennedy Y, Garrett JE, Kolbe J. Long-term oxygen therapy improves health-related quality of life. *Respiratory Medicine* 2004; **98:**285-93.

Fan V, Curtis J et al. Using quality of life to predict hospitalization and mortality in patients with obstructive lung diseases. Chest 2002 **122**:429-436.

Guyatt GH, Berman LB, Townsend M, Pugsley SO, Chambers LW. A measure of quality of life for clinical trials in chronic lung disease. *Thorax* 1987; **42:**773-8.

Guyatt GH, Townsend M, Keller J, Singer J, Nogradi S. Measuring functional status in chronic lung disease: conclusions from a randomized control trial. *Respiratory Medicine* 1991; **85:**17-21.

Guyatt GH, King DR, Feeny DH, Stubbing D, Goldstein RS. Generic and specific measurement of health-related quality of life in a clinical trial of respiratory rehabilitation. *Journal of Clinical Epidemiology* 1999; **52:**187-92.

Hazell M, Frank T, Frank P. Health related quality of life in individuals with asthma related symptoms. Respir Med. 2003; 97(11):1211-8.

Halpin DM, Miravitlles M. Chronic obstructive pulmonary disease: the disease and its burden to society. *Proc Am Thorac Soc.* 2006 Sep; **3**(7):619-23

Harper R, Brazier JE, Waterhouse JC, Walters SJ, Jones NMB, Howard P. Comparison of outcome measures for patients with chronic obstructive pulmonary disease (COPD) in an outpatient setting. *Thorax* 1997; **52:**879-87.

Hyland ME, Bott J, Singh SJ, Kenyon CAP. Domains, constructs and the development of the breathing problems questionnaire. *Quality of Life Research* 1994; **3:**245-56.

Hyland M.E.[1]; Singh S.J.[2]; Sodergren S.C.[1]; Morgan M.P. Development of a Shortened Version of the Breathing Problems Questionnaire Suitable for Use in a Pulmonary Rehabilitation Clinic: A Purpose-Specific, Disease-Specific Questionnaire *Quality of Life Research*, Volume **7**, Number 3, 1998 , pp. 227-233(7)

Jones PW, Quirk FH, Baveystock CM. The St George's Respiratory Questionnaire. *Respiratory Medicine* 1991; **85:**25-31.

Katz PP, Eisner MD, Yelin EH, Trupin L, Earnest G, Balmes J, Blanc PD. Functioning and psychological status among individuals with COPD. *Quality of Life Research* 2005; **14**; 1835-1843.

Larson JL, Kapella MC, Wirtz S, Covey MK, Berry J. Reliability and validity of the functional performance inventory in patients with moderate to severe chronic obstructive pulmonary disease. *Journal of Nursing Measurement* 1998; **6:**55-73.

Leidy NK, Knebel AR. Clinical validation of the Functional Performance Inventory in patients with chronic obstructive pulmonary disease. *Respiratory Care* 1999a; **44:**932-9.

Leidy NK. Psychometric properties of the functional performance inventory in patients with chronic obstructive pulmonary disease. *Nurs Res* 1999b;48(1):20-8.

Mahler DA, .Mackowiak JI. Evaluation of the short-form 36-item questionnaire to measure health-related quality of life in patients with COPD. *Chest: the Cardiopulmonary Journal* 1995; **107:**1585-9.

Martin LL. Validity and reliability of a quality of life instrument: the Chronic Respiratory Disease Questionnaire. *Clinical Nursing Research* 1994; **3:**146-56.

McSweeny AJ, Grant I, Heaton RK, Adams KM, Timms RM. Life quality of patients with chronic obstructive lung disease. Arch Intern Med. 1982; **142:**473-478.

NICE (2004) Chronic obstructive pulmonary disease - Management of chronic obstructive pulmonary disease in adults in primary and secondary care. Clinical Guideline

Okubadejo AA, Jones PW, Wedzicha JA. Quality of life in patients with chronic obstructive pulmonary disease and severe hypoxaemia. Thorax 1996; **51:**44-7.

Paterson C, Langan CE, McKaig GA, Anderson PM, MacLaine GDH, Rose LB *et al*. Assessing patient outcomes in acute exacerbations of chronic bronchitis: the Measure Your Medical Outcome Profile/MYMOP, Medical Outcomes Study 6-item general health survey/MOS-6A, and EuroQol/EQ-5D. *Quality of Life Research* 2000; **9:**521-7.

Puhan MA, Scharplatz M, Troosters T, Steurer J. Respiratory rehabilitation after acute exacerbation of COPD may reduce risk for readmission and mortality - A systematic review. *Respiratory-Research* 2005; **6:**:12p.

Quirk FH, Jones PW. Patients' perception of distress due to symptoms and effects of asthma on daily living and an investigation of possible influential factors. *Clin Sci* 1990;79:17-21.

Quirk FH, Baveystock CM, Wilson RC, Jones PW. Influence of demographic and disease related factors on the degree of distress associated with symptoms and restrictions on daily living due to asthma in six countries. *Eur Respir J 1*991;4:167-71.

Ruffin RE, Wilson DH, Chittleborough CR, Southcott AM, Smith BJ, Christopher DJ. Multiple respiratory symptoms predict quality of life in chronic lung disease: a population-based study of Australian adults. *Quality of Life Research* 2000; **9:**1031-9.

Schunemann HJ, Guyatt GH, Griffith LE, Stubbing D, Goldstein RS. A randomized controlled trial to evaluate the effect of informing patients about their pre-treatment responses to two respiratory questionnaires. *Chest: the Cardiopulmonary Journal* 2002; **122:**1701-8.

Schunemann HJ, Griffith LE, Jaeschke R, Goldstein RS, Stubbing D, Guyatt GH. Evaluation of the minimal important difference for the feeling thermometer and the St. George's Respiratory Questionnaire in patients with chronic airflow obstruction. *Journal of Clinical Epidemiology* 2003; **56:**1170-6.

Schunemann HJ, Griffith LE, Stubbing D, Goldstein RS, Guyatt GH. A clinical trial to evaluate the measurement properties of two direct preference instruments

administered with and without hypothetical marker states. *Medical Decision-Making* 2003; **23:**140-9.

Schunemann HJ, Griffith LE, Jaeschke R, Goldstein RS, Stubbing D, Austin P *et al*. A comparison of the original chronic respiratory questionnaire with a standardized version. *Chest: the Cardiopulmonary Journal* 2003; **124:**1421-9.

Schunemann HJ, Puhan M, Goldstein R, Jaeschke R, Guyatt GH. Measurement properties and interpretability of the Chronic Respiratory disease Questionnaire (CRQ). *COPD-Journal-of-Chronic-Obstructive-Pulmonary-Disease* 2005; **2:**81-9.

Singh SJ, Sodergren SC, Hyland ME, Williams JEA, Morgan MDL. A comparison of three disease-specific and two generic health-status measures to evaluate the outcome of pulmonary rehabilitation in COPD. *Respiratory Medicine* 2001; **95:**71-7.

Sprenkle MD, Niewoehner DE, Nelson DB, Nichol KL. The veteran's short form 36 questionnaire is predictive of mortality and health-care utilization in a population of veterans with a self-reported diagnosis of asthma or COPD. *Chest*- 2004; **126:**81-9.

Tu SP, McDonell MB, Spertus JA, Steele BG, Fihn SD. A new self-administered questionnaire to monitor health-related quality of life in patients with COPD. *Chest: the Cardiopulmonary Journal* 1997; **112:**614-22.

Viramontes JL,.O'Brien BJ. Relationship between symptoms and health-related quality of life in chronic lung disease. *Journal of General Internal Medicine* 1994; **9:**46-8.

Weaver TE, Narsavage GL, Guilfoyle MJ. The development and psychometric evaluation of the pulmonary functional status scale: an instrument to assess functional status in pulmonary disease. *Journal of Cardiopulmonary Rehabilitation* 1998; **18:**105-11.

Williams JEA, Singh SJ, Sewell L, Guyatt GH, Morgan MDL. Development of a self-reported Chronic Respiratory Questionnaire/CRQ-SR. *Thorax* 2001;**56**:954-9.

Williams J E A, S J Singh, L Sewell, and M D L Morgan**.** Health status measurement: sensitivity of the self-reported Chronic Respiratory Questionnaire (CRQ-SR) in pulmonary rehabilitation**.** *Thorax*, June 1, 2003; 58(6): 515 - 518.

Wilson CB, Jones PW, O'Leary CJ, Cole PJ, Wilson R. Validation of the St. George's Respiratory Questionnaire in bronchiectasis. *American Journal of Respiratory and Critical Care Medicine* 1997;**156**:536-41.

Wyrwich KW, Nienaber NA, Tierney WM, Wolinsky FD. Linking clinical relevance and statistical significance in evaluating intra-individual changes in health-related quality of life. *Medical Care* 1999;**37**:469-78.

Wyrwich KW, Fihn SD, Tierney WM, Kroenke K, Babu AN, Wolinsky FD. Clinically important changes in health-related quality of life for patients with chronic obstructive pulmonary disease: an expert consensus panel report. *Journal of General Internal Medicine* 2003;**18**:196-202.

Yohannes AM, Roomi J, Waters K, Connolly MJ. A comparison of the Barthel Index and Nottingham Extended Activities of Daily Living scale in the assessment of disability in chronic airflow limitation in old age. *Age and Ageing* 1998;**27**:369-74.

Yohannes AM, Roomi J, Waters K, Connolly MJ. Quality of life in elderly patients with COPD: measurement and predictive factors. *Respiratory Medicine* 1998;**92**:1231-6

Yohannes AM, Roomi J, Winn S, Connolly MJ. The Manchester Respiratory Activities of Daily Living Questionnaire: development, reliability, validity, and responsiveness to pulmonary rehabilitation. *Journal of the American Geriatrics Society* 2000;**48**:1496-500.