

Evaluating Reliability and Validity
of the Chinese Version of the St. George's Respiratory Questionnaire
in Patients with Chronic Obstructive Pulmonary Disease in Taiwan

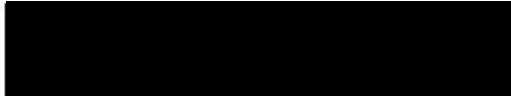
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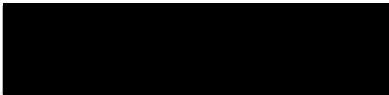
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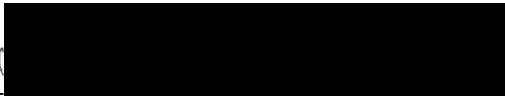
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Abstract

Title: Evaluating Reliability and Validity of the Chinese Version of the St. George's Respiratory Questionnaire in Patients with Chronic Obstructive Pulmonary Disease in Taiwan

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Treatment of diseases causing COPD is largely directed toward relief of symptoms and improvement in the quality of life. Given the increasing interest in multinational clinical studies measuring perceived health status, the St. George's Respiratory Questionnaire (SGRQ) was chosen for translation and evaluation in Taiwanese COPD patients. In this study, a cross-sectional correlational survey design was used. A convenience sample of 100 patients diagnosed with COPD, as defined by the American Thoracic Society, was recruited from a pulmonary clinic of a university hospital in Taipei, Taiwan. The sample was recruited from July 20 to September 20, 1998. The short form of the Sickness Impact Profile (SIP) was used as a criterion variable.

The SPSS (Statistical Program for the Social Sciences) for Windows was used for the analysis of data. FEV₁ showed negative correlations with the SGRQ total score and its

three sections ($r = -.37$ to $-.44$). The SGRQ scores were negatively correlated with the 6-minute walk distance ($r = -.33$ to $-.48$). Dyspnea ratings on the Borg scale were moderately positively correlated with the SGRQ scores. The correlations became stronger as patients spent a longer time performing walking test. The correlation between the SGRQ total score and the SIP68 total score was $.69$ ($p < .01$).

Construct validity of the Chinese translation of the SGRQ (CSGRQ) was demonstrated by building hierarchical multiple regression models with the CSGRQ total and section scores as well as the SIP68 and its subscales as the dependent variable and smoking history, hospitalized times, FEV₁ % of predicted, distance walked in 6 minutes, and dyspnea after 6-minute walking test as independent variables. These five predictors could explain 47% of the variance in the CSGRQ total score and 58% of the variance in the SIP68 total score.

Internal consistency of each section score of the SGRQ was assessed by Cronbach's α coefficient, which was $.76$ for the Symptoms section, $.79$ for the Activity section, $.86$ for the Impacts section, and $.92$ for the total SGRQ. The Cronbach's α coefficient of the SIP68 was $.82$ in this sample. These α values were greater than $.70$ and reached an acceptable level (Nunnally, 1978). The findings of these procedures suggest that the CSGRQ can be used to measure health-related quality of life in Chinese COPD patients. However, additional qualitative data and longitudinal design research should be undertaken to further develop our understanding of the CSGRQ performance within the Chinese culture.

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CHAPTER I

INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD)

COPD is defined as a disease state characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema. The airflow obstruction is generally progressive, may be accompanied by airway hyperreactivity, and may be partially reversible. The obstruction in many patients with COPD may include a significant reversible component and some patients with asthma may go on to develop irreversible airflow obstruction indistinguishable from COPD (American Thoracic Society, 1995).

COPD is a progressive debilitating disease with an insidious onset. COPD is usually diagnosed in the middle to later years of life after a long history of gradually worsening dyspnea, coughing, disability, low energy levels, and increased sputum production (Herbert & Gregor, 1997). Statistics indicate that COPD was the tenth leading cause of death in Taiwan in 1996 and is the only leading cause of death that is increasing in prevalence worldwide (Canadian Thoracic Society Workshop Group, 1992).

Health-Related Quality of Life (HRQL)

McSweeney and colleagues (1982) concluded from a study comparing 203 people with severe COPD to 73 healthy individuals that those with COPD showed much greater impairment of quality of life. Depression, anxiety, fatigue, social-role functioning, and home management activities were particular problematic areas (McSweeney, Grant, Heaton, Adams, & Timms, 1982). However, the relationships between impaired lung function and impaired functional status are often too weak to allow one to be predicted

reliably from the other (Jones, 1991). Delay in recognition of the true impact of COPD may also occur because the disease develops at a time of life when people generally begin to modify their leisure and recreational activity to less strenuous pursuits (Jones, 1995). Based on clinical observations, these are also true in Taiwan. The goals of COPD treatment are mainly palliative (reducing symptoms, increasing functions of daily life, and improving quality of life of the patient). Interest in assessing "health-related quality of life" has increased in the last decade. After their study in a long-term multicentre trial, Kaptein et al. (1993) concluded that there was a need for the development of a disease-specific quality-of-life instrument for patients with chronic lung disease (Kaptein, Brand, Dekker, Kerstjens, Postma, Sluiter, and the Dutch CNSLD study group, 1993).

Treatment of diseases causing COPD is largely directed toward relief of symptoms and improvement in the quality of life. There are two questionnaires which claim to measure the quality of life of patients with COPD that are currently available: the Chronic Respiratory Questionnaire (CRQ) (Guyatt, Berman, Townsend, Pugsley, & Chambers, 1987) and the St. George's Respiratory Questionnaire (SGRQ) (Jones, Quirk, & Baveystock, 1991). A more in-depth review of these measures is presented in Chapter 2.

Purpose of the Study

Instruments that measure patients' progress from professional nursing interventions are well developed in western society. To take advantage of the well-developed and widely used instruments, translation of instruments to another language becomes an issue in order to adapt instruments. Given the increasing interest in multinational clinical studies measuring perceived health status, the St. George's Respiratory Questionnaire (SGRQ)

was chosen for translation and evaluation in this study. The SGRQ is a disease-specific questionnaire measuring pulmonary diseased patients' quality of life, specifically for asthma and COPD patients. The weights attached to each item were obtained from 141 asthmatic patients recruited from six countries (England, Holland, Finland, Italy, Thailand, & the United States). The questionnaire has been applied in even more countries, including Japan, Spain, Switzerland, and Sweden (Hajiro, Nishimura, Tsukino, Ikeda, Koyama, & Izumi, 1998; Ferrer, Alonso, Prieto, Plaza, Marrades, Aguar, Khalaf, & Anto, 1996; Janssens, Rochat, Frey, Dousse, Pichard, & Tschopp, 1997; Engstrom, Persson, Larsson, & Sullivan, 1998). The purpose of this study is to translate the St. George's Respiratory Questionnaire (SGRQ) into Chinese and to assess the feasibility, reliability, and validity of the translated instrument in COPD patients in Taiwan.

Measures must be reliable and valid for a specific population. As a research learner from Taiwan, it is energy-saving and also a good learning process for the investigator to adapt well-developed instruments from Western societies into Chinese culture. It is generally assumed that the more the researchers and the participants have in common, the greater the potential for an accurate understanding of the health concern or problem of interest as experienced by the target population (Sawyer et al., 1995). Increasingly, there is support for diversifying research populations and for ensuring that the researcher is an insider to the culture of research participants (Lipson & Meleis, 1989; Merton, 1972).

Significance for Nursing

One of the important functions of nursing is to assist persons in coping with the effects of disease on their daily living (Mitchell, 1986). Subjective judgments, however,

capture both the personal evaluative nature of health and the more positive aspects of the quality of life. The predictive power of self-evaluations of health status go above and beyond the contribution to prediction made by indexes based on the presence of health problems, physical disability, and biological or lifestyle risk factors (Patrick & Erickson, 1993). Perhaps health profiles and utility measures should be included in any clinical trial in which the major focus is patient benefit (Guyatt, Feeny, & Patrick, 1993).

There is an increasing interest in empowering patients with COPD by providing relevant knowledge regarding self-care in Taiwan. As nursing has become more scientifically grounded and the costs of care higher, the focus has shifted from whether nursing care helps to make the patient better to whether the approach to care or the intervention is the most effective and efficient (Strickland, 1997). Adapting an instrument that has been widely used in other countries has the potential to compare and evaluate the effectiveness of nursing interventions that may improve quality of life in COPD patients in Taiwan. Much can be learned by comparisons of cultural approaches to disease specific problems.

CHAPTER II

REVIEW OF THE LITERATURE

This review provides the background underlying the dissertation study. According to the purpose of this study, the review of literature is organized into five sections: (1) COPD and its impact on patients, (2) conceptual issues and measures of quality of life in COPD patients, (3) the cultural values of Chinese society that affect patients' beliefs and behaviors, and the current practice of pulmonary medicine in Taiwan, specifically with respect to COPD, (4) issues in adapting an instrument to a different language and culture, and (5) conceptual organization of the study variables and research hypotheses generated from the review for this study.

COPD

This section describes the impacts of aging on the respiratory system, the pathophysiological changes of COPD on the respiratory system, the physiological and psychological effects of COPD on patients' functional status. In this section, the clinical characteristics of COPD are delineated.

The Impacts of Aging on the Respiratory System

With increasing age, the lung "rounds out." There is an increase in the anteroposterior diameter, perimeter, area, and height up to the age of 59 years (Thurlbeck, 1976). After this age, anteroposterior diameter increases more than height, producing a more obvious change in shape. The spaces in respiratory bronchioles, alveolar ducts, and alveolar sacs increase in size with age (Thurlbeck, 1976). The proportion of the lung that the alveolar walls form decreases steadily from about 11% at age 20 years to about 8% at

age 80 years (Thurlbeck, 1967). It may represent the loss of capillary bed that occurs in other organs with age.

When the peripheral airways of old nonsmoking subjects are compared with those of young nonsmoking subjects, there is less muscle in the bronchioles of older subjects (Nagai, West, Paul, & Thurlbeck, 1985). In contrast, increased muscle was found in subjects of comparable age with chronic airflow obstruction and moderate or severe emphysema, all of whom were smokers. There is an increase in average severity of emphysema in nonsmokers with increasing age (Thurlbeck, Ryder, & Sternby, 1974). The forced expiratory volume in one second (FEV₁) in nonsmokers without respiratory disease declines by 25 to 30 ml per year beginning at age 35 (American Thoracic Society, 1995).

The aging lung loses some of its elastic recoil and the intrapleural pressures, therefore, become less negative. Basal regions of the lung may be only intermittently ventilated, with resulting defective gas exchange. Adequate respiratory muscle strength is required to maintain ventilation and to facilitate airway clearance. Evidence shows that both peripheral and respiratory muscle strength decline with old age (Brooks & Faulkner, 1994). Age-related declines in respiratory muscle strength have been demonstrated in men and women over 50 years of age (Black & Hyatt, 1969). Berry and colleagues (1996) provided cross-sectional evidence of a linear decline in respiratory muscle strength with aging, except for maximal inspiratory pressure in older men (Berry, Vitalo, Larson, Patel, & Kim, 1996).

Limitations of maximal exercise capacity with age appear to result from a decrease in maximal heart rate and decrease in stroke volume with age. The latter decline may be

minimized by vigorous training, but the decline in heart rate with age cannot be minimized (Gole, 1994). Some elderly persons complain of limited exercise capacity because of dyspnea of unknown cause. The dyspnea may be related to decreased maximal respiratory pressures with age (Black, & Hyatt, 1969), to excessive ventilation relative to oxygen uptake, or both. Elderly individuals with cardiorespiratory disease may commonly experience breathlessness (Silvestri & Mahler, 1993).

In summary, aging is accompanied by characteristic changes in the morphology, functional behaviors, and biochemical composition of lungs that have slight but measurable effects on gas exchange, but little effect on breathing during ordinary daily life (Plopper & Thurlbeck, 1994).

The Significance of COPD Study

COPD is a major public health problem in the U. S. for at least four reasons: it is a major cause of death, it affects a large number of persons, there is an increasing incidence, and it has a major impact on activities of daily living (National Institutes of Health, 1979). COPD was the fourth leading cause of death and the second leading cause of morbidity in the United States in 1995. The death rate from COPD in the U. S. was 4.5% of total deaths in 1995 (Anderson, Kochanek, & Murphy, 1997). There were 9.5 per 100,000 people who died from COPD in Taiwan in 1996 compared to 39.2 per 100,000 people in the United States in 1995 (Anderson, Kochanek, & Murphy, 1997). The rate of death due to COPD in the U. S. is 4 times greater than in Taiwan.

The combination of emphysema, chronic bronchitis, and asthma (combined as COPD) was the tenth leading cause of death in Taiwan in 1996. The death toll from

COPD in 1996 was 2036 (9.5 per 100,000 people) in Taiwan. This was 1.69% of total deaths. There was 7.75% of the total population above the age of 65 in Taiwan in 1996. COPD is the ninth leading cause of death for elderly people. Among the COPD death toll, 1677 persons were elderly. There were 100.94 deaths per 100,000 people or 2.28% of total deaths among elders (National Department of Health in Taiwan, 1996). The death rate from COPD in the United States was 234.1 per 100,000 among people 65 years old and older in 1990 (Dorgan, 1995). The rate of death due to COPD is 2 times greater in the U. S. than in Taiwan among elderly people. The difference between the U. S. and Taiwan rates narrows among elderly people. It is expected that the elder population will continue to grow in Taiwan. The study of COPD patients is significant and needed.

Risk Factors for COPD

The relation between cigarette smoking and COPD is more complex than often appreciated. Despite the strong association between the two, cigarette smoking alone appears insufficient to produce the disease. Obstructive airways disease develops in only a minority (about 15%) of long-time cigarette smokers; this implies the existence of other unknown factors that predispose people to suffer airway injury (American Thoracic Society, 1995; Canadian Thoracic Society Workshop Group, 1992). Overall, cigarette smoking accounts for an estimated 80 to 90% of the risk of developing COPD (U.S. Surgeon General, 1984). This is to say, smoking by itself does not always lead to COPD, but 80% to 90% with COPD have been smokers. In addition to cigarette smoking, asthma, recurrent respiratory infections, and unidentified familial factors were identified as possible risk factors for chronic airway obstruction. Alpha1-antitrypsin (AAT) deficiency

is the only known genetic abnormality that leads to COPD. (AAT is also known as α 1-protease inhibitor, a term used in many references to work on this subject.) But this heritable condition accounts for less than 1% of COPD cases in the United States (Redline & Weiss, 1989). AAT is a serum protein produced by the liver and normally found in the lung; its main role is the inhibition of neutrophil elastase (NE). The AAT gene is highly pleomorphic. In normal individuals, AAT protects the fragile alveoli from the chronic burden of NE released by neutrophils that have gained access to the lower respiratory tract (Crystal et al., 1989). In patients with AAT deficiency, the secretion of AAT by the liver is reduced, and thus a marked reduction of the AAT levels in blood and throughout the body, including the lung (Brantly, Nukiwa, & Crystal, 1988; Crystal et al., 1989). This leaves the fragile alveolar walls vulnerable to proteolytic destruction of the alveolar walls by NE. Over many years, the unfettered NE slowly destroys alveoli, a process that is accelerated in cigarette smokers (Brantly, Nukiwa, & Crystal, 1988; Crystal et al., 1989). Severe AAT deficiency leads to premature emphysema, often with chronic bronchitis and occasionally with bronchiectasis. The onset of pulmonary disease is accelerated by smoking in subjects with AAT deficiency; dyspnea begins at a median age of 40 years in smokers, and a median age of 53 years in nonsmokers (American Thoracic Society, 1995). Apart from homozygous AAT deficiency, COPD may aggregate in families (Redline & Weiss, 1989). Researchers showed evidence that smoking cessation improves prognosis of chronic airflow diseases regardless of age (Postma & Sluiter, 1989).

Pathology and Structural Effects of COPD

COPD is characterized functionally as progressive and incompletely reversible

airflow obstruction (Canadian Thoracic Society Workshop Group, 1992). Lung elastic recoil in patients with COPD may be reduced (West, 1994). Two hypotheses exist regarding the pathophysiological mechanisms of COPD: some authors favor the concept that emphysematous destruction of the lung is responsible for adversely affecting expiratory flow by either interfering with the parenchymal support of the peripheral airways (Swinburn, Wakefield, & Jones, 1985), or by decreasing the elastic recoil force responsible for driving air out of the lung (Mahler, Weinberg, Wells, & Feinstein, 1984). Others have argued that the major cause of the reduction in forced expiratory flow is an inflammatory process in the small conducting airways that causes them to narrow and close prematurely (Mahler & Harver, 1982; Mak, Bugler, Rooberts, & Spiro, 1993).

Because emphysema and bronchiolitis occur together in moderate or severe COPD, it is no simple matter to determine the relative roles of these two lesions in causing airflow obstruction. The relation between airflow obstruction and bronchiolar pathology persists as airflow obstruction and emphysema become moderate in severity. Cosio and coworkers (1978) studied 36 smokers or ex-smokers who had lung resection for solitary nodules. A semiquantitative scoring system was applied to the airways less than 2 mm in diameter. The severity of the pathologic changes in the bronchioles was related to the ratio of FEV_1/FVC (forced vital capacity) (Cosio, Ghezzi, & Hogg, 1978). In subjects with severe airflow obstruction, there is no relation between FEV_1 and the membranous bronchiolar score or any of its components (Naigai, West, & Thurlbeck, 1985), possibly due to restriction of range in FEV_1 or bronchiolar score.

In summary, there is often only a weak correlation between lifetime smoking history and the severity of pathologic changes, suggesting that there is marked individual variation in the response of the lungs to long-standing cigarette smoking. The reasons for this variation in response are not known. However, the difficulty in demonstrating the relation of bronchiolitis to airflow obstruction does not exclude the likelihood that such changes are important contributors to the pathogenesis of emphysema and to the reversible component of airflow obstruction (Snider, Faling, & Rennard, 1994).

Clinical Characteristics of COPD

Clinical features of COPD commonly present in the fifth decade with productive cough or an acute chest illness (American Thoracic Society, 1995). Patients with COPD have usually been smoking at least 20 cigarettes per day for 20 or more years before symptoms develop. Sputum production is insidious, initially occurring only in the morning. Cough is a frequent symptom in COPD but is rarely troublesome. Acute chest illnesses characterized by increased cough, purulent sputum, wheezing, dyspnea, and occasionally fever may occur intermittently. The history of wheezing and dyspnea may lead to an erroneous diagnosis of asthma (American Thoracic Society, 1995). Dyspnea or an acute chest illness of sufficient severity to bring the patient with COPD to the physician usually occurs in the sixth or seventh decade (Stulbarg & Adams, 1994).

Because of intrinsic airway narrowing in chronic bronchitis and dynamic airway compression in emphysema, COPD is characterized by expiratory flow limitation. Severe COPD is characterized by limited exercise capacity as a result of changes in pulmonary mechanics, abnormal gas exchange, altered cardiac function, respiratory muscle

dysfunction, nutritional factors, and dyspnea. In particular, patients with COPD demonstrate widely variable exercise capabilities that do not always correlate with the severity of airflow obstruction (Epstein & Celli, 1993). At rest, COPD is characterized by marked ventilation-perfusion mismatch that results in increased dead-space ventilation (dead space is areas that are ventilated but hypoperfused) and increased pulmonary shunt (areas hypoventilated but normally perfused) (Brown & Wasserman, 1981). As the disease progresses, the symptom-free periods between acute exacerbations tend to become shorter. Hypoxemia may result in cyanosis and is often associated with chronic hypercapnia and polycythemia (Snider, Faling, & Rennard, 1994).

In summary, airflow obstruction in COPD is primarily irreversible and is caused by disease of the small airways, which is due in part to the effects of inflammation in those airways and in part to the loss of alveolar septal tethering of small airways that accompanies the destructive changes of emphysema. Bronchoconstriction due to inflammation accounts for a limited amount of reversible airway obstruction (American Thoracic Society, 1995).

Physiological Effects of COPD on Patients

Dyspnea

Dyspnea is a clinical term for the subjective report of breathlessness or shortness of breath experienced by patients. These terms are used interchangeably by most authors. There are no precise data on the prevalence of dyspnea, although it is a primary symptom of respiratory disease. The symptom of dyspnea encompasses a multiplicity of sensations experienced when breathing seems difficult, labored, or uncomfortable, or there is a

feeling of a need for or hunger for more air (Schwartzstein, Manning, Weiss, & Weinberger, 1990).

There are two main categories in evaluating dyspnea: indirect methods, which attempt to define severity in terms of the degree of functional limitation imposed by the presence of the symptom (e.g., the Chronic Respiratory Questionnaire, 6-minute walking test), and direct methods, which attempt to quantify the perceived intensity of the sensation itself (e.g., the Visual Analogue Scale, Borg Scale) (Stulburg & Adams, 1994). Both methods are used frequently in research studies.

Dyspnea is a frequent and distressing symptom experienced by patients with COPD. Dyspnea and fatigue were identified as major problem areas by 100 subjects who were asked how their lives were negatively affected by COPD (Guyatt, Townsend, Berman, & Pugsley, 1987). Dyspnea on effort usually does not occur until the sixth or seventh decade in nonsmokers with COPD (American Thoracic Society, 1995). The neurophysiologic mechanisms that give rise to the sensation of dyspnea are poorly understood. The problem of dyspnea in patients with lung disease could result from a more intense ventilatory stimulus, the consequent increase in efferent activity to respiratory muscles in the absence of an appropriate ventilatory response, or afferent information from a mechanically constrained respiratory system (Stulburg & Adams, 1994). Whatever its precise neurophysiologic basis, the idea that the sensation of breathlessness derives primarily from the sensing of central nervous system activity and not from specific peripheral receptors represents an important development in our understanding of dyspnea (Davies, McQuaid, & Iber, 1987).

In her study with 126 COPD patients, Anderson (1995) found that dyspnea (measured by Visual Analogue Scale) was significantly correlated ($p < .05$) with FEV₁ ($r = -.24$), distance walked in 6 minutes ($r = -.20$), depression ($r = .34$), anxiety ($r = .36$), self-esteem ($r = -.22$), and quality of life ($r = -.18$) (Anderson, 1995). Meanwhile, deconditioning as a cause of breathlessness can be found in elderly patients with and without cardiorespiratory disease (Silvestri & Mahler, 1993) because of premature lactic acidemia stimulating ventilation at apparently inappropriately low levels of exertion. Any disorder associated with decreased oxygen delivery to the tissues, either because of decreased effective hemoglobin or inability to increase cardiac output, may cause dyspnea by premature lactic acidemia (Stulburg & Adams, 1994).

Although pulmonary function tests are critical for the diagnosis of dyspnea (Pratter, Curley, Dubois, & Irwin, 1989), the degree of abnormality in tests of respiratory function correlate only moderately with severity of dyspnea (Killian & Campbell, 1983). Jassens et al. (1997) found that there was no relationship between resting dyspnea ratings and pulmonary function tests in 79 chronic lung diseased patients (63% were COPD) in Switzerland (Jassens et al., 1997). Even if the patient unequivocally has COPD, the degree of dyspnea may seem out of proportion to the degree of spirometric abnormality (Epstein & Celli, 1993). Nevertheless, it is important to note that the influence of disease severity on dyspnea severity is substantial even if indirect (Moody, McCormick, & Williams, 1990).

Impaired Respiratory Muscle Function

Patients with COPD often have impaired respiratory muscle function at rest

(Rochester & Braun, 1985). The presence of respiratory muscle dysfunction in response to increased workloads, altered length-tension muscle fiber relationships, and progressive weight loss in COPD patients have been documented in several studies. The lung volume at which contraction of ventilatory muscles occurs greatly affects the strength of contraction. At the functional residual capacity (FRC) level or below, inspiratory muscles are capable of exerting their maximal force, while as lung volume increases above the FRC level, inspiratory muscle fibers shorten and the force they can generate diminished (Bradburne & McCool, 1990). The ventilatory muscle length producing maximum tension, and thus maximum strength, is at or below FRC level. Inspiratory muscles may become fatigued and fail to contract adequately despite effective neural stimulation (Gold, 1994). Hyperinflation, as noted in COPD, shortens inspiratory muscle length, especially that of the diaphragm. As FRC increases, the diaphragm flattens and muscle fibers are no longer stretched to their optimal length at the beginning of inspiration. These disadvantaged muscles are incapable of exerting their normal force (Kacmarek, 1992). FRC, FEV₁, and FVC may also be decreased associated with a decreased lung elastic recoil, suggestive of decreased outward recoil of the chest wall (Gold, 1994).

The cause of excessive weight loss is mainly a 15% to 25% increase in resting energy expenditure, perhaps the result of a markedly elevated work of breathing in COPD patients (Donahoe, Rogers, & Wilson, 1989; Goldstein, Askanazi, & Weissman, 1987). The main consequence of this excessive weight loss is reduced muscle strength including weakness of both the inspiratory and expiratory muscles (Rochester & Esau, 1984). As the severity of COPD increases, there is a shift in the way that respiratory muscles are

recruited: the rib cage accessory and abdominal muscles, rather than the diaphragm, become the principal pressure generators (Martinez, Couser, & Celli, 1990). Gray-Donald et al. (1996) proposed that poor nutritional status, as measured by low body weight for height, is associated with an increased risk of respiratory mortality in patients with severe COPD (Gray-Donald, Gibbons, Shapiro, Macklem, & Martin, 1996). Respiratory muscle dysfunction, weakness, or fatigue—particularly of the inspiratory muscles—in turn can lead to sequelae such as dyspnea, hypoventilation with hypercapnia and reduced oxygenation of the body tissues, respiratory failure with metabolic acidosis, and death (Breslin, 1996).

Limited Exercise Capacity

Disturbance of physical activity in patients with early COPD is restricted largely to leisure and recreation (Jones, 1995). Patients with COPD demonstrate a limited ability to exercise, primarily because of a reduced ventilation capacity in the face of an increased ventilatory demand. Exercise capacity in patients with COPD with severe airway obstruction is more strongly related to inspiratory muscle strength and lung function than to dyspnea and quality of life (Wijkstra, ten Vergert, van der Mark, Postma, van Altena, Kraan, & Koeter, 1994). Most patients with COPD demonstrate positive responses to exercise conditioning. Dyspnea is reduced and work tolerance is extended with little or no change in pulmonary function noted (Carter, Coast, & Idell, 1992).

In their review article, the Canadian Thoracic Society Workshop Group (1992) stated that walking is the preferred form of exercise for most COPD patients. While spirometric measurements seem to be related to maximum ventilation in a bicycle ergometer performance (Carter, Peavler, Zinkgraf, & Fields, 1987), in general they

correlate weakly with less stressful tests such as the walking distance (Mahler, Weinberg, Wells, & Feinstein, 1984; Swinburn, Wakefield, & Jones, 1985). Weaver and Narsavage (1992) concluded that exercise capacity should be consistently used as a measure of current state and outcome in COPD patients (Weaver & Narsavage, 1992).

In summary, no single measurement of lung function can satisfactorily summarize the variable disturbances that may cause breathlessness in patients with COPD (Jones, 1995). The correlation between measures of airway obstruction and exercise impairment is inconsistent and frequently poor (Carter, Peavler, & Zinkgraf, 1987; Matthews, Bush, & Ewald, 1989; Swinburn, Wakefield, & Jones, 1985) which hampered the use of exercise capacity as a single evaluative tool monitoring COPD patients' progress.

Psychological Effects of COPD on Patients

In examining longitudinal changes in clinical measurements in 110 patients with COPD, Mahler and colleagues (1995) stated that it is possible that physical functioning is the initial health component to decline, whereas a longer time period may be required to demonstrate changes in other components. Alternatively, patients with COPD may adapt to deterioration in dyspnea and physiologic function by adjusting their lifestyle to maintain role and social functioning, mental health, and health perceptions (Mahler, Tomlinson, Olmstead, Tosteson, & O'Connor, 1995). Several investigators have described psychologic responses and effects that are characteristic of persons with COPD. Dyspnea on exertion is not the only effect of COPD. Cough and sputum production have physical, social, and emotional effects on patients. Anxiety and depression levels may be raised in patients with COPD (Jones, 1995). Patients with COPD may suffer from breathlessness,

exercise limitation, anxiety and depression, and problems related to social activities (Jones, 1991; Schrier, Dekker, Kaptein, 1990; Schayck, Rutten, Doorslaer, 1992).

Depression complicates many chronic diseases. It is estimated that 42% of patients with COPD have depressed mood (Gift & McCrone, 1993). Covino and colleagues (1982) found that those with COPD have a unique pattern of depression. They fell into a pattern of low self-esteem and denial of impulsiveness. Thus they lacked confidence in themselves and avoided spontaneity in life (Covino, Dirks, Kinsman, & Seidel, 1982). Weaver and Narsavage (1992) found that approximately half of the 104 COPD patients had a mean depressed mood score greater than normative values on the Multiple Affect Adjective Check List Revised. They also found that both depressed mood ($r=-.40$) and self-esteem ($r=.41$) were significantly correlated ($p < .01$) with functional status (Weaver & Narsavage, 1992). In her study of 126 COPD patients, Anderson (1995) concluded that in addition to its effects on dyspnea and functional status, depression had a significant ($p < .05$) negative impact on quality of life ($r=-.58$) in COPD. Her study also showed that depression was significantly correlated ($p < .05$) with anxiety ($r=.66$), self-esteem ($r=-.60$), optimism ($r=-.45$), and social support ($r=-.39$) (Anderson, 1995). Janssens et al. (1997) found that age, gender, and FEV₁ (% of predicted) were not related to depression scores in 79 chronic lung diseased patients (among them, 63% were COPD) in Switzerland (Janssens et al., 1997).

Anderson (1995) also found that anxiety was significantly correlated ($p < .05$) with quality of life ($r=-.37$), dyspnea ($r=.36$), distance walked in 6 minutes ($r=-.29$), depression ($r=.66$), self-esteem ($r=-.42$), and optimism ($r=-.21$) in 126 COPD patients (Anderson,

1995). DeVito (1990) used a qualitative approach to explore 96 American COPD patients' perceptions of dyspnea and found that five themes commonly faced by them were fear, helplessness, loss of vitality, preoccupation, and legitimacy. She further stated that acknowledging the potential for these perceptions and validating their presence with individual patients may be therapeutic in and of itself (DeVito, 1990).

In addition, Small and Graydon (1993) described continual uncertainty, defined as the inability to determine the meaning of illness-related situations, faced by 25 hospitalized COPD patients. The subjects were perceiving uncertainty in relation to their illness and hospitalization, and were endeavoring to manage it through the process of cognitive coping. Two themes that reflect coping resources emerged from the data, they were positive thinking, and social support and material resources (Small & Graydon, 1993). Graydon and Ross (1995) also found that mood directly, and social support indirectly, influenced the functioning of those who were not receiving oxygen in 91 COPD patients (Graydon & Ross, 1995). In a retrospective case analysis with 33 male veterans, Stehr and colleagues (1991) identified a psychosocial variable that distinguished COPD patients who relapsed from acute exacerbation from those who did not in the emergency department. Patients who relapsed at least once ($n=21$) were more likely to have lost a first-order relative within 3 years (57.1% vs. 8.3%, $p < .006$) (Stehr, Klein, & Murata, 1991).

To explore the relationship between body image and presence of the chronic illness of COPD, Nicholas and Leuner (1992) examined patients with moderate ($n=37$) or severe ($n=50$) COPD compared with 49 healthy subjects. They found that individuals with more severe COPD had a lower ($p < .0001$) self-perception of body image than individuals in

whom the disease was less severe (Nicholas & Leuner, 1992). They further noted that it is important to carefully assess the patient with COPD, knowing that functional limitations that occur as a result of COPD will require adaptation on the part of the patient. This period of adjustment could potentially be negative and may require interventions to facilitate positive alterations for the patients.

Renfroe (1988) studied the effect of progressive muscle relaxation on dyspnea and state anxiety in 20 American COPD patients, and found that reduction in anxiety and dyspnea (measured by Visual Analogue Scale) were positively correlated during each session ($r=.36$, $p=.002$) and at the end of 4 weeks ($r=.60$, p was not provided) (Renfroe, 1988). Gift and colleagues (1992) also found that taped relaxation message was efficacious in reducing dyspnea (measured by Visual Analogue Scale) and anxiety in 26 American COPD patients. They found that COPD subjects were able to achieve the preset criteria for relaxation using a taped message within one session. The findings of this study expand on those of Refroe (1988) who used a personal message rather than a taped message to teach relaxation to COPD patients (Gift, Moore, & Soeken, 1992). They suggested that teaching relaxation should be considered for COPD patients.

In evaluating the effect of a pulmonary rehabilitation program, Schere and Schmieder (1997) found that higher self-efficacy scores on the Self-Efficacy Scale were correlated with lower perception of dyspnea and greater distance walked in 12 minutes in 60 COPD patients (Schere & Schmieder, 1997). Kaptein et al. (1993) argued that reporting of respiratory symptoms, absence from work, and hospitalization in patients with COPD is a matter both of physiology and psychology (Kaptein, Brand, Dekker, Kerstjens, Postma, Sluiter, & the Dutch CNSLD study group, 1993). Other researchers also

suggested that a direct focus on psychological interventions to ameliorate depression and improve mastery is likely to improve quality of life with some resultant positive effect on functional status (Moody, McCormick, & Williams, 1990).

Functional Status of COPD Patients

The World Health Organization (WHO) defined health as a “state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity” (WHO, 1948). Although the WHO definition was not accompanied by operational methods for measuring “well-being” in these three areas, the comprehensiveness of the definition has set a standard by which many measurement efforts have been judged. Among them, physical function is particularly important for assessing the impact of chronic disease and for evaluating rapidly emerging technologies and their effects on the course and outcome of chronic disease such as chronic respiratory conditions (Patrick & Erickson, 1993).

In her review of summarizing the research of functional performance in people with COPD, Leidy (1995) stated that it is apparent that disease severity, measured by FEV₁ % predicted, does not play a clinically significant, direct role in functional performance. Studies to date suggest that dyspnea and exercise or walk tolerance have direct effects on functional performance in COPD. Leidy proposed that studies to date have overlooked comorbidity as a contributing factor to functional difficulties. Leidy also argued that psychosocial factors seem to influence functional performance, independent of the physiologic effects. It is important for health care providers to clearly understand the factors influencing functional performance in people with COPD (Leidy, 1995).

Response to therapy for COPD is usually evaluated in terms of improvement in

spirometric measurements or subjective improvement in symptoms (Epstein & Celli, 1993). Ability to carry out activities of daily living is also among the most frequently measured concepts of health and well-being in intervention studies. McSweeney et al. (1982) stated that those with COPD were found to have “low ego strength” and little ability to cope flexibly with life changes when compared to normal subjects (McSweeney et al., 1982). In general, patients with COPD made changes in dressing and grooming, were motivated to try alternative approaches for managing dyspnea, and necessarily modified their activity leading to social and geographical immobility. It was dyspnea and a loss of energy that increased the time necessary to perform activities (Barstow, 1974). Their lives were regimented by advanced planning of activities, resting places, medication regimens, and avoidance of precipitating situations (Carrieri & Janson-Bjerklie, 1986). Although activity restrictions and limitations in social role performance may be unrelated to each other or the presence of disease (Patrick & Erickson, 1993), either one of them can create variable impact on patient’s daily life and sense of well-being.

In their study, Graydon and Ross (1995) found that those who received oxygen at home, only symptoms directly, and FEV₁ indirectly, influenced the functioning of 52 COPD patients (Graydon & Ross, 1995). According to Moody, McCormick, and Williams (1990), dyspnea severity has a sizable effect on functional status ($r=-.40$, $p<.05$) and quality of life ($r=-.23$, $p<.05$) in 45 chronic bronchitis and emphysema study subjects. They proposed the disease as an antecedent variable resulting in increases in the mediating variables such as dyspnea and depression that in turn diminish functional status and quality of life (Moody, McCormick, & Williams, 1990). Weaver and Narsavage (1992) proposed

that both physiological and psychological factors are important in understanding functional status in COPD patients. In their study of 104 outpatient with COPD, they showed that the combination of exercise capacity and depressed mood accounted for 49% of the variance in functional status (Weaver & Narsavage, 1992).

Anderson (1995) found that quality of life ($r=.26$), age ($r=-.21$), FEV₁ ($r=-.32$), dyspnea ($r=-.20$), depression ($r=-.31$), anxiety ($r=-.29$), self-esteem ($r=.35$), optimism ($r=.25$), and social support ($r=.27$) have low but significant correlations ($p < .05$) with functional status (measured by the 6-minute walk distance) (Anderson, 1995). Weaver and coworkers (1997) suggested that efforts to improve functional status of individuals with COPD should focus on interventions that influence exercise capacity, dyspnea, anxiety, and depressed mood (Weaver, Richmond, & Narsavage, 1997). Borson et al. (1992) demonstrated that an effective antidepressant treatment enhanced the functional activities in 30 moderately to severely disabled COPD patients (Borson, McDonald, Gayle, Deffebach, Lakshminarayan, & VanTuinen, 1992). Graydon and Ross (1995) demonstrated that those who receiving oxygen therapy had significantly lower FEV₁ scores and experienced significantly poorer functioning (measured by SIP) than those who were not receiving oxygen therapy in 143 COPD patients (Graydon & Ross, 1995).

In summary, dyspnea as a major symptom of COPD has broad impact on patients' physical and psychological well-being which resulted in impaired functional capacity of the patient. Interventions that aimed at strengthening respiratory muscles and reducing the level of anxiety and depression have shown efficacious and improved functional capacity in COPD patients.

Conceptual Issues Related to Quality of Life in COPD

Physical symptoms and sensations profoundly affect people's feeling of health (Patrick & Erickson, 1993). The consequences of a disease for the individual's daily life have been conceptualized in the term "quality of life", which encompasses the physical, psychological, and social functioning of a patient (Spilker, 1991). The integrity of the term quality of life has been justifiably challenged on the ground that it cannot be validly measured because it means so many different things to so many different people (Cella & Tulsky, 1990). Campbell (1977) acknowledged that the report of an overall quality of life may mean different things to different people. However, he argued that it is nevertheless essential to get these subjective evaluations by individuals concerning their personal values and the extent to which their needs are being filled (Campbell, 1977). Although Flanagan (1982) used an empirical approach to defining the main determinants of quality of life, he acknowledged that it is likely that some revisions and additions would be needed to develop a measure sensitive to measuring deficiencies and changes for persons with disability (Flanagan, 1982).

In an evaluation study of a rehabilitation program for COPD patients, Wijkstra et al. (1994) demonstrated that the improvement in quality of life measured by Chronic Respiratory Questionnaire was not correlated with the improvement in exercise tolerance (Wijkstra, Altena, Kraan, Otten, Postma, & Koeter, 1994). In addition, spirometric measures in general have been poorly correlated with general health indices such as the Quality of Wellbeing Scale (Kaplan, Atkins, & Timms, 1984) and the Sickness Impact Profile (Jones, Baveystock, & Littlejohns, 1989; Schrier, Dekker, Kaptein, & Dijkman,

1990).

Patrick and Erickson (1993) defined health-related quality of life (HRQL) as the value assigned by individuals, groups, or society to the duration of survival as modified by impairments, functional states, perceptions, and social opportunities influenced by disease, injury, treatment, or policy. Widely valued aspects of life exist that are not generally considered as “health”, for example, income, freedom, and quality of the environment are not included in HRQL (Patrick & Erickson, 1993). In the context of medicine, HRQL is used to signify the gap between desires and achievements that is specifically due to disease (Jones, 1995). HRQL is important for measuring the impact of chronic disease (Patrick & Erickson, 1993). Health care used by COPD patients appears to be related even more to an impaired quality of life than to the severity of the lung disease itself (Traver, 1988). In a study of 227 subjects of a random sample of the general British population, Renwick and Connolly (1996) found no significant relationship between health-related quality of life (measured by the St. George’s Respiratory Questionnaire) and age. However, the mean Activity score of the SGRQ was significantly higher for subjects aged ≥ 65 years (geometric mean=1.04, SD=.71) than for those aged < 65 years (geometric mean=.81, SD=.76; $t = -2.34$, $p = .02$). They concluded that the impact of airway obstruction on quality of life does not decrease with advancing age (Renwick & Connolly, 1996).

In a chronic disease such as COPD, there are four basic objectives of medical therapy: reduced mortality; modification of the natural history of the disease; fewer acute episodes; and a reduction in the impact of the disease on daily life (Jones, 1995). Possibly individuals would have other priorities. Quality of life instruments are designed to quantify

the latter. It seems probable that changes in quality of life would have been better detected by use of a disease-specific health instrument. It is recommended that disease-specific health instruments be used in intervention studies and that quality of life be measured frequently during the early phase of the intervention, for instance, once a month (van Schayck, Dompeling, Rutten, Folgering, van den Boom, & van Weel, 1995).

A disease-specific health instrument has the advantage of covering specific aspects of the clinical disorder under study that are not relevant for a generic well-being scale (Patrick & Deyo, 1989). The impact of COPD on a patient's life and well-being cannot be predicted reliably from measurements of airways obstruction and respiratory symptoms, because the relationships between them are too complex (Jones, 1991). Quality of life measurements complement data from traditional measures of outcome, and may provide valuable summative estimates of overall treatment efficacy (Jones et al., 1994).

The Measurement of Quality of Life in COPD

Description of Measures

There are two questionnaires measuring the health-related quality of life (HRQL) specifically for chronic airflow obstructive patients: the Chronic Respiratory Questionnaire (CRQ) and the St. George's Respiratory Questionnaire (SGRQ). HRQL instruments may be useful in monitoring patients' progress or in determining the most appropriate choice of treatment. They are designed to summarize a broad spectrum of the effects of disease on patients' lives and perceived well-being (Jones, Quirk, & Baveystock, 1991). These two instruments have been widely used in experimental studies as well as in survey research recently. In thinking of selecting one instrument to be translated into Chinese culture, the

discussion will focus mainly on these two instruments. Each instrument will be discussed separately.

The CRQ

The CRQ was the first disease-specific measure developed for COPD (Guyatt, Berman, Townsend, Pugsley, & Chambers, 1987). It examines four aspects of patients' lives: dyspnea (the subjective feeling of breathlessness), fatigue, emotional function, and mastery (the feeling of control over the disease and its effects). The questionnaire is administered by an interviewer and contains a total of 20 questions; each question is answered on a 7-point Likert scale. Higher scores represent poorer quality of life.

The first five questions are individualized with the patient being asked to select 5 activities from a list of 26. These activities are identified by the patient as ones that cause shortness of breath and are also the most important to that individual's daily life. Then the patient is asked to use a 7-point scale to indicate how much shortness of breath he/she has experienced during the last 2 weeks while performing those 5 activities. This part is not standardized, in that each patient is asked to select areas of activity that are important to each patient. The use of individualization characterizes the individual nature of impaired quality of life. The remainder of the questionnaire asks 15 standard questions, which are identical for each respondent. It has three standardized components covering emotion, mastery, and fatigue. Response options are presented as 7-point scales. Initial administration of the questionnaire takes a maximum of 30 minutes, and is usually 15-25 minutes. Follow up administration takes a maximum of 20 minutes, and usually 10-15 minutes (Guyatt, Berman, Townsend, Pugsley, & Chambers, 1987).

When examining the phrases used in the questions of the CRQ, the investigator found that it was confusing and difficult to answer regarding those emotional adjectives used in describing patients' conditions. The Chinese neither think nor talk in these ways. When the investigator showed the CRQ to 6 Chinese people, no matter whether they were from Taiwan or Mainland China, they all agreed that the CRQ was relatively difficult to answer compared to the SGRQ. For example, in evaluating the Chinese translation of the CRQ, 4 of 6 Chinese respondents found 2 items unclear: "feel frustrated" (in Item 5) and "feel discouraged" (in Item 15); 3 of 6 found the item "feel confident and sure that you could deal with your illness" (Item 9) was difficult to answer; 3 of 6 found the item "how much energy do you have" (Item 10) was confusing. The Chinese people are less emotionally expressive than their Western counterparts. The words used in describing emotions in Chinese society, though similar to western cultures, are different in context. The Chinese people tend to use more general (vague) words to describe their emotional status.

The SGRQ

The St. George's Respiratory Questionnaire (SGRQ) is a standardized self-administered, airway-disease-specific questionnaire developed by Jones et al. (Jones, Quirk, & Baveystock, 1991; Jones et al., 1992). This questionnaire was designed to allow direct comparisons of the health gain to be obtained with different types of therapy in both asthma and COPD. It was designed so that it may be used in long-term studies and is standardized.

The final version of the St. George's Respiratory Questionnaire (SGRQ) contains

50 items (covering 76 levels) divided into three sections. Section I is 'Symptoms' (8 items), concerns with level of symptomatology, including frequency of cough, sputum production, wheeze, breathlessness, and the duration and frequency of attacks of breathlessness or wheeze. Section II is 'Activity' (16 items), concerns with activities that either cause or are limited by breathlessness; and Section III is 'Impacts' (26 items), covers such factors as employment, being in control of health, panic, stigmatization, the need for medication and its side effects, and expectations for health and disturbance of daily life, which covers a range of aspects concerned with social functioning and psychological disturbances resulting from airway diseases. Items specifically relating to anxiety and depression are not included in the SGRQ because a number of established measures exist for this area of health (Jones et al., 1991; Jones et al., 1992). It takes 15 to 30 minutes to complete the SGRQ.

Each of the three sections of the questionnaire is scored separately in the range 0 to 100%, with a 0 score indicating no impairment of life quality. A summary score utilizing responses to all items is the total SGRQ score. This score also ranges from 0 to 100%. Higher SGRQ scores mean worse quality of life. The SGRQ scores are calculated using weights attached to each item in the questionnaire. The weights provide an estimate of the distress associated with the symptom or state described in each item. They were obtained empirically from 141 patients with asthma from six countries: England, Finland, Holland, Italy, Thailand, and the United States. Factors including age (1.5% of the total variance), sex (1.4% of the total variance), current and worst spirometry (.7% and 1.1% of the total variance), size of variation in spirometry (.4% of the total variance), and

duration of disease (.7% of the total variance) accounted for a very small proportion of the observed interpatient differences in these weights (Quirk & Jones, 1990). There is evidence that patients appear to respond to the questionnaire in a similar way in different countries (Jones & the Nedocromil Sodium Quality of Life Study Group, 1994).

Intervention studies using the SGRQ to measure chronic lung diseased patients' quality of life includes: bronchodilator therapy (Congleton & Muers, 1995; Jones & Bosh, 1997), compliance with medical regimen by computer-assisted telephone interview (Anie, Jones, Hilton, & Anderson, 1996), home nebulized therapy (Bosley, Corden, Rees, & Cochrane, 1996), long-term oxygen therapy (Okubadejo, Paul, Jones, & Wedzicha, 1996), and cognitive and behavioral psychotherapy (Eiser, West, Evans, Jeffers, & Quirk, 1997).

The questions in the SGRQ are not difficult to answer or to recall. They are questions about symptoms and activities that happened 2 weeks ago or over the last year that have caused shortness of breath. Section II and section III with true or false options are easy to answer and seem sensitive to detective clinical changes. Besides, there seem to be no culturally inappropriate questions based on review by 6 Chinese raters, although some might be difficult to answer. Minor modifications might be required, for example, for an activity like shoveling snow because it does not snow in most areas in Taiwan.

The SGRQ and CRQ are both designed to evaluate aspects of the health status of patients with chronic lung disease. It is assumed that the primary potential uses of the translated questionnaire in Taiwan will be to measure the effect of nursing interventions on a group of patients as well as to measure an individual patient's progress. The SGRQ can be used as a screening tool to identify target patients who might benefit from intervention.

The standard format will allow direct comparisons between different studies and between different therapies (Jones, Quirk, & Baveystock, 1991). It may be useful to adapt a standardized instrument like the SGRQ.

Assessing Reliability and Validity of Instruments Used in COPD Patients

Reliability

Reliability is consistency (Goodwin, 1997). Reliability can be defined as the relative absence of errors of measurement in a measuring instrument (Kerlinger, 1992). Reporting reliability is less frequent in studies using physiologic variables than in psychological studies (Pugh & DeKeyser, 1995). Most measurement textbooks emphasize that reliability is a necessary but not a sufficient condition for validity. That is to say, a measure cannot correlate with something else if it does not first correlate with itself (Goodwin, 1997). Reliability refers to the degree to which test scores are free from measurement errors. Different approaches to reliability estimation attend to different sources of errors. In classical test theory, it is assumed that the traits measured are constant and that measurement errors are random (Pedhazur & Schmelkin, 1991). Psychometric reliability means that the test can be expected to consistently discriminate between individuals from one occasion to the next (Carver, 1974).

Theoretically, reliability is actually the proportion of observed variance that is systematic true variance. Reliability estimates are essentially squared correlation coefficients between observed and true scores. The correlation coefficient is population specific. The same instrument may appear more or less reliable, depending on the variability of the population of interest. Psychometric reliability is properly estimated in

terms of error variances, product-moment reliability coefficients, and standard errors of measurement (Carver, 1974). The relevant reliability estimate is the one obtained for the sample used in the study under consideration (Pedhazur & Schmelkin, 1991).

The conception of test-retest reliability is based on the assumption that, when individuals are measured repeatedly, their true scores remain unchanged (Pedhazur & Schmelkin, 1991). Using the test-retest method, subjects have been shown to be able to reliably repeat measures of subjective sensations on the Visual Analogue Scale (Luria, 1975; Revill, Robinson, Rosen, & Hogg, 1976). The test-retest reliability of the 12-minute distance walk was examined and supported in patients with COPD (Larson, Covey, Vitalo, Alex, Patel, & Kim, 1996). Anderson et al. (1989) presented new evidence for the interday reliability of functional assessment for a health status measure, the quality of well-being scale, from patients with COPD (Anderson, Kaplan, Berry, Bush, & Rumbaut, 1989). Stable measures are more likely to be obtained with chronic patients while those patients with changing sensations are unlikely to produce stable results (Gift, 1989).

Estimates of reliability will differ, to a greater or lesser extent, depending on the specific sources of error being addressed. It is imperative that reports of reliability include sufficient information about the procedure used in its estimation so that readers can ascertain the sources of error that have been addressed. Measuring people twice in a row with the same measure is particularly prone to biases due to carry-over effects (Pedhazur & Schmelkin, 1991). Generally speaking, carry-over effects tend to lead to overestimates of stability from one period to another, possibly resulting in inflated estimates of reliability. In the test-retest model, it is not possible to separate the reliability of a measure from its

stability. It is generally suggested that the interval between the two administrations be relatively short, for instance, 1 to 2 weeks. It is recommended that test-retest reliability not be used or that it be used with caution for attributes that are not expected to be stable (Pedhazur & Schmelkin, 1991).

Reliability of the CRQ. The dimensions of fatigue, emotion and mastery of the CRQ showed high internal consistency and high test-retest reliability in 40 Dutch patients with COPD. The internal consistency and test-retest reliability for each dimension were: Fatigue ($r=.78$ and $.90$), Emotion ($r=.81$ and $.93$), and Mastery ($r=.83$ and $.91$). The Dyspnea dimension of the CRQ showed low internal consistency ($r=.51$) and a moderate test-retest reliability ($r=.73$) in COPD patients (Wijkstra et al., 1994).

Reliability of the SGRQ. To estimate the reliability of the SGRQ, the questionnaire was presented to 40 asthmatic and 20 COPD patients on two occasions, 2 weeks apart. The repeatability of the component sections of the SGRQ was very similar in both groups of patients. The intraclass correlation for the total SGRQ score obtained on the two occasions was $.91$ from the asthmatic patients, $.92$ from COPD patients (Jones et al., 1992). The Cronbach's α reliability coefficients for the Spanish version of the SGRQ were $.94$ for the total score, $.72$ for Symptom, $.89$ for Activity, and $.89$ for Impacts subscales in 318 male Spanish COPD patients (Ferrer et al., 1996).

Validity

In general, validity examines whether the instrument is measuring what it is intended to measure; reliability is the accuracy of a measuring instrument. If one does not know the reliability and validity of one's data, little faith can be put in the results obtained

and the conclusions drawn from the results (Kerlinger, 1992).

When measuring certain physical properties and relatively simple attributes of persons, validity is no great problem (Kerlinger, 1992). In the biologic sciences, validity is a term rarely used; instead, terms such as accuracy, sensitivity, and specificity are seen. In biometric and medical literature, accuracy is defined as validity, which is how close an obtained measurement is to its true value (Abbey, 1990; Howanitz & Howanitz, 1987). A meaningful and essential question to raise about a measure is whether it is consistent with the definition of the construct it is meant to tap. A prerequisite for a critical evaluation of the definition of a construct is knowledge of theory and research findings relevant to the construct under consideration (Pedhazur & Schmelkin, 1991).

Criterion validity (an instrument is valid if its results correspond to those of the criterion standard) is applicable when a shorter version of an instrument (the test) is used to predict the results of the full-length index (the gold standard) (Pedhazur & Schmelkin, 1991). A correlation coefficient between a predictor and a criterion is referred to as a validity coefficient. It is unwise to rely solely on validity coefficients because they are population specific. To minimize ambiguity, it is essential to specify, at the very least, for what, for whom, and under what circumstances are inferences from a set of scores being made (Pedhazur & Schmelkin, 1991).

When no gold or criterion standard exists or if the purpose is not to substitute for gold standard or predict some other criteria, researchers introduce content and construct validity. Content validity examines the extent to which the domain of interest is comprehensively sampled by the items, or questions, in the instrument (Pedhazur &

Schmelkin, 1991). Quantitative testing of content validity is rarely attempted (Guyatt, Feeny, & Patrick, 1993). Since the typical approach to content validation does not consider the scores of respondents, some theorists have questioned whether it is really validity at all (Messick, 1989; Pedhazur & Schmelkin, 1991).

The most rigorous approach to establishing validity is called construct validity. A construct is a theoretically derived notion of the domain(s) one wants to measure (Pedhazur & Schmelkin, 1991). Construct validity is the degree to which an instrument measures the construct or characteristic under investigation (Bausell, 1986). The steps to obtain construct validity evidence involve: delineating the meaning of the construct, usually in terms of a theoretical framework; developing hypotheses from this same theoretical basis; and using empirical and logical procedures to test the hypotheses (Goodwin, 1997). Factor analysis and related techniques are often used to estimate construct validity. However, if the results of a factor analysis are interpreted without theoretical guidance, it can lead to misleading conclusions concerning the validity of measuring instruments (Carmines & Zeller, 1979). Convergent validity demonstrates that a measure is related to other measures of the same construct, or variables that it theoretically should be related to (Goodwin, 1997). To evaluate empirically the psychometric validity of a test, individual differences on the test may be compared to individual differences on another variable that is assumed to be highly related to the test (Carver, 1974). In essence, all attempts to obtain validity evidence are aimed at discerning what one can and cannot infer about the scores one obtains from use of the measure (Goodwin, 1997).

Validity of the CRQ. The construct validity of the Chronic Respiratory Questionnaire (CRQ) was assessed by correlating it with the Symptom Checklist (SCL-90) in 40 Dutch patients with COPD (Wijkstra et al., 1994). The Emotion component of the CRQ was significantly correlated ($p < .001$) with Anxiety ($r=.50$), Depression ($r=.49$), and Somatization ($r=.52$) of the SCL-90. The Fatigue component of the CRQ was significantly correlated ($p < .001$) with Depression ($r=.53$), and Somatization ($r=.55$) of the SCL-90. The Mastery component of the CRQ was significantly correlated ($p < .01$) with Anxiety ($r=-.50$), Depression ($r=-.48$), and Somatization ($r=-.40$) of the SCL-90. The Dyspnea component of the CRQ was not significantly correlated with the Somatization scale of the SCL-90.

Validity of the SGRQ. Although the SGRQ was developed specifically for asthma and COPD patients, it has been validated in 111 patients with bronchiectasis (Wilson, Jones, O'Leary, Cole, & Wilson, 1997). Repeatability was tested over 2 weeks in 23 patients ($r=.97$). The SGRQ Symptoms score correlated with Medical Research Council Wheeze score ($r=.63$), SGRQ Activity score correlated with shuttle walking test ($r=-.66$), and SGRQ Impacts score correlated with SF-36 Health Survey Questionnaire, physical fatigue ($r=.61$) (all $p < .0001$). There were significantly worse SGRQ total scores of patients who deteriorated compared to those who improved over the 6 months in respect to wheeze ($F= 5.60$, $p < .01$) and breathlessness ($F= 6.05$, $p \leq .01$) (Wilson, Jones, O'Leary, Cole, & Wilson, 1997).

In testing the SGRQ's construct validity, researchers used physiological measures to demonstrate their effect on HRQL, such as spirometry, especially the forced expiratory

volume in one second (FEV₁) (Ferrer et al., 1996; Jones & Bosh, 1997; Jones & the Nedocromil Sodium Quality of Life Study Group, 1994; Ketelaars, Schlosser, Mostert, Abu-Saad, Halfens, & Wouters, 1996; Okubadejo, Jones, & Wedzicha, 1996; Renwick & Connolly, 1996; Wilson et al., 1997), and the partial pressure of oxygen and carbon dioxide in arterial blood (Okubadejo et al., 1996) in their studies. Ketelaars et al (1996) demonstrated a significant negative correlation between FEV₁ and the “Activity” score of the SGRQ ($r=-.24$, $p<.01$) in 126 COPD patients (Ketelaars, Schlosser, Mostert, Abu-Saad, Halfens, & Wouters, 1996). Renwick and Connolly (1996) found significant correlations between FEV₁ and the SGRQ scores in 34 elderly COPD patients (absolute r values ranged from .40 to .51, $p<.001$). Okubadejo et al. (1996) found that the long-term oxygen therapy (LTOT) group ($n=19$) had higher SGRQ total scores than controls ($n=17$) ($p<.05$) at all visits, implying lower quality of life. Repeated measures analysis of variance showed no effect of LTOT on quality of life over 6 months ($F=.43$, $p=.79$) (Okubadejo et al., 1996).

Exercise performance measured by walking distance was also used frequently in intervention or validation studies using the SGRQ (Ketelaars et al., 1996; Eiser et al., 1997). In their study, Ketelaars et al. (1996) stated that the 12-minute walking test alone showed a significant negative correlation with the “Activity” and “Impact” components of the SGRQ ($r=-.39$ and $-.36$ respectively) in 126 COPD patients (Ketelaars et al., 1996).

Reference measures used in testing the SGRQ’s construct validity include the Medical Outcomes Study Short Form (SF-36) (Jones & Bosh, 1997; Wilson et al., 1997), the Sickness Impact Profile (SIP) (Jones et al., 1994; Okubadejo et al., 1996), the Asthma

Coping Questionnaire (ACQ)(Ketelaars et al., 1996), the Nottingham Extended Activities of Daily Living (Okubadejo et al., 1997), the Hospital Anxiety and Depression Scale (HAD) (Bosley et al., 1996; Eiser et al., 1997; Jones et al., 1994; Okubadejo et al., 1996; Wilson et al., 1997), and the Nottingham Health Profile (NHP) (Ferrer et al., 1996).

The scores of SGRQ and SF-36 were correlated well at baseline and significant correlations were also found between changes in SGRQ Total score and all SF-36 components, except Pain (Jones & Bosh, 1997). In a study designed to measure improvement in patients with asthma treated with nedocromil sodium, Jones and colleagues (1994) found highly significant correlations between patients' perception of health and scores for the HAD, SGRQ, and SIP. In the case of the SGRQ and SIP, the relationship to the patients' perception of health was stable across countries, they were Finland, Holland, Italy, Thailand, UK, and USA. But similar stability was not found in the case of the HAD. In addition, the SIP detected the improvement in health seen in all patients in the trial, but failed to identify the difference between nedocromil sodium and placebo treated patients (Jones et al., 1994). The components of "Avoidance" in the ACQ showed significant negative correlations with "Activity" and "Impact" of the SGRQ ($r=-.22$ and $-.20$ respectively, $p<.05$). The components of "Emotional reaction" in the ACQ showed a significant correlation with "Impact" of the SGRQ ($r=.36$, $p<.001$) in 126 COPD patients (Ketelaars et al., 1996). In adapting the SGRQ into Spanish, Ferrer et al. (1996) found that the SGRQ correlated more closely with dyspnea and FEV₁ % of predicted than the NHP, a generic measure of health status. Comparisons between the subscales of the SGRQ and the NHP dimensions showed a consistent pattern. Energy and

Physical Mobility, the two NHP dimensions frequently impaired in COPD patients, whose content is comparable with that of the SGRQ subscales, correlated considerably ($r=.70\sim.72$) more closely with “Activity” and “Impact”. The SGRQ “Symptom” section score was found to have the lowest correlation with NHP scores ($r=.27\sim.50$) (Ferrer et al., 1996).

To assess the validity evidence of the SGRQ, the SGRQ scores in the three sections were correlated with spirometry ($r=-.06$ to $.20$), 6-minute walking distance ($r=-.07$ to $.35$), the Medical Research Council dyspnea grade ($r=.13$ to $.50$), anxiety ($r=.12$ to $.38$), depression ($r=.08$ to $.39$), and general health measured using the SIP scores, Physical ($r=.12$ to $.48$), Psychosocial ($r=.07$ to $.42$), and total score ($r=.11$ to $.54$) to demonstrate its validity in 141 patients with chronic airflow limitation ($p < .01$ for all r values) (Jones et al., 1992).

Sensitivity of Outcome Measures for Intervention Studies

Nursing outcome studies seek to determine if nursing care makes a difference and may be conducted as part of a quality assurance program or within the context of a scientific study (Strickland, 1997). Different measures vary in their ability to measure precisely the concepts under study. The sensitivity of an instrument affects how small a variation in an attribute can be reliably detected and measured, it also determines how discriminating its measurements will be between individuals with differing amounts of an attribute (Polit & Hungler, 1995). Carver (1974) claimed that there are two dimensions of tests: psychometric and edumetric. Tests that focus on measuring between individual differences have been called psychometric. Edumetric dimension evaluates the extent to

which it reflects the within individual growth that traditionally has been of primary interest to educational testing (Carver, 1974). It is hoped that an appreciation of both dimensions will be held in future tests designed to solve measurement problems.

Stewart and Archbold (1992) addressed seven questions as guidelines to evaluate the sensitivity of an outcome variable and its measure. They are: 1) the conceptual link between the intervention and the outcome variable, 2) the extent to which the outcome variable is amenable to change, 3) the adequacy of the content validity of the outcome measure for detecting the effect of the proposed intervention, 4) the measure's construct validity for intervention studies, 5) whether the outcome variable measures have a potential distribution of scores that will allow detection of change, 6) what kind of reliability assessment is appropriate to consider for this outcome measure, and 7) how the level of correlational stability over time should be interpreted (Stewart & Archbold, 1992; Stewart & Archbold, 1993). In selecting an outcome measure for a study evaluating an intervention, the criterion of sensitivity to change is most important. There are also statistical procedures that permit a researcher to enhance the sensitivity of paper-and-pencil measures by assessing the degree to which each item is contributing to the instrument's power to make discriminations (Polit & Hungler, 1995). The sensitivity of an instrument is most likely to become an issue in certain kinds of situations. For instance, if important decisions are to be based on the measures resulting from an instrument, then the sensitivity of the instrument could have serious consequences. In nursing research, when experimental and control conditions are not maximally different, then highly sensitive instruments may be required to detect differences in the effects of the treatment (Polit &

Hungler, 1995). In general, when the measuring tool is imprecise and susceptible to errors, larger samples are needed to test hypotheses adequately (Lipsey, 1990).

Sensitivity of the CRQ and the SGRQ. The optimal method of assessing the effect of treatment on the day-to-day function of patients with chronic airflow limitation has not been established. Table 2.1 summarizes studies using the CRQ or the SGRQ to examine the effects of interventions in COPD patients. In another intervention study with 24 Dutch COPD patients, Wijkstra et al. (1995) demonstrated the long term benefits of rehabilitation at home by the CRQ. The researchers did not use the dimension of dyspnea in the CRQ as an outcome in their previous study (Wijkstra et al., 1994a) because it had a low reliability and validity. However, low reliability and low correlation with other measures may not have been good reasons to eliminate the Dyspnea scale as an outcome for detecting intervention effects (Nunnally, 1978; Stewart & Archbold, 1992; Stewart & Archbold, 1993). There were 36 patients in their study divided into three groups (group A and B were intervention groups which were visited weekly and monthly, group C was a control group). Although the researchers stated that there were no significant differences in lung function among the three groups, they did not specify if there was no difference in other variables. They noted that group B had significantly higher scores for all dimensions at all time points compared with the baseline values. The effect size was calculated from by comparing Groups A and C. The effect sizes were .26 and .07 on Fatigue, .54 and .52 on Emotion, and .39 and .43 on Mastery of the CRQ at 3 and 12 months. (Wijkstra et al., 1995).

In a randomized controlled trial of weightlifting exercise in 34 Canadian patients

with chronic airflow limitation, Simpson and colleagues (1992) showed significant effects of treatment in the dimensions of Dyspnea and Mastery ($p < .01$) and Fatigue ($p < .05$) but no change in Emotion of the CRQ. The researchers did not provide enough information for calculating their effect sizes (Simpson, Killian, McCartney, Stubbing, & Jones, 1992). However, in another intervention study of respiratory muscle training on 82 Canadian COPD patients, Guyatt and colleagues (1992) failed to strengthen respiratory muscles or improved exercise or functional capacity measured by the CRQ Dyspnea and Emotion and the 6-minute walking test. They believed the reason was that the expiratory flow rates were not controlled in their study (Guyatt, Keller, Singer, Halcrow, & Newhouse, 1992).

In examining the effects of long-term oxygen therapy (LTOT) in COPD patients' quality of life, Okubadejo et al. (1996) administered the SGRQ to 36 COPD patients, 19 subjects in the study group (LTOT) and 17 subjects in the control group, at four times in 6 months. The effect sizes were .84, .78, and .70 after 2 weeks, 3 months, and 6 months of oxygen therapy on the SGRQ total scores. Because of the self-selected nature of the study group and control group (by their disease severity), the study group (LTOT) had a significantly worse quality of life at baseline measure ($p=.008$), and the effect sizes might be inflated. Patients receiving LTOT had a slightly greater improvement in their quality of life compared to the control group, but this was not statistically significant during the study period. The researchers concluded that any quality of life gains with LTOT are small. Actually, effect sizes above are large. It is the small sample size that prevented them from being considered statistically significant. In this study, patients were not using ambulatory oxygen therapy. They stated that it is possible that the facility to use

ambulatory oxygen might improve quality of life in these patients. Furthermore, when each component of the SGRQ was considered, there were no statistically significant differences between the study group and the control group in terms of the mean change after 6 months in any component score (Okubadejo, Paul, Jones, & Wedzicha, 1996).

Congleton and Muers (1995) administered the Activity section of the SGRQ to 15 European patients with bronchial carcinoma with both breathlessness and airflow obstruction. They found that there was no significant change on the SGRQ score after 2 weeks of bronchodilator therapy. The effect size was .13. The “Activity” component consists of questions relating to activities of daily living that caused or are impaired by breathlessness. Mean “Activity” scores did not improve significantly, but did not deteriorate either. There was a highly significant improvement in the rating of breathlessness following treatment with bronchodilators. They did not offer any explanation of this specific result (Congleton & Muers, 1995).

Different methods of measurement of specific traits in a specific setting may be affected by halo, social desirability, and the like, thereby making the methods less different from each other than they appear to be (Pedhazur & Schmelkin, 1991). The credibility and usefulness of findings from research also depend on the validity of the measures used in data collection (Goodwin, 1997). Any inference relative to prediction, and/or to test scores, is based upon underlying constructs (Pedhazur & Schmelkin, 1991). Table 2-1 shows the intervention studies using CRQ or SGRQ as their outcome measures.

Table 2-1.
Intervention studies and their effect sizes using CRQ and SGRO as outcome measures

Researchers	Intervention (s)	Subjects	Effect sizes
Guyatt et al. (1991)	salbutamol and theophylline on dyspnea	24 COPD: Each patient received, in succession, four 2-week treatment periods as follows: salbutamol 200ug q.i.d. and oral theophylline in a dose previously titrated to produce a therapeutic blood level; active theophylline and a placebo inhaler indistinguishable from the active preparation; an active inhaler and placebo theophylline; and placebo inhalers and pills.	CRQ: 2.4 on Dyspnea for both salbutamol and theophylline groups.
Wijkstra et al. (1994c)	rehabilitation at home	COPD: 28 in rehabilitation group 15 in control group	CRQ: .85 on Dyspnea .57 on Fatigue .83 on Emotion .50 on Mastery
Wijkstra et al. (1995)	rehabilitation at home	COPD: 11 in rehabilitation group, visited their local physiotherapist twice a week for 12 weeks, thereafter, visited weekly. 13 received no rehabilitation at all.	CRQ: in 3 months .26 on Fatigue .54 on Emotion .39 on Mastery in 12 months .07 on Fatigue .52 on Emotion .43 on Mastery
Jones & Bosh, (1997)	different dosages of salmeterol	COPD: 95 in placebo group 94 in salmeterol 50ug group 94 in salmeterol 100ug group	SGRQ (16 weeks later): salmeterol 50ug: .20 on Symptom .05 on Activity .48 on Impact salmeterol 100ug .09 on Symptom .03 on Activity .11 on Impact
Okubadejo, Paul, Jones, and Wedzicha (1996)	long-term oxygen therapy	COPD: 19 in study group 17 in control group	SGRQ: total scores .84 (2 weeks) .78 (3 months) .70 (6 months)

The researcher has described types of validity, their definitions, and potential problems in practical settings. Construct validity is seen as the unifying and key meaning of validity (Goodwin, 1997). Examples were given with respect to COPD-related measures. In summary, reliability and validity deal with inferences and consequences of measurements and are complex multifaceted constructs (Goodwin, 1997). The reliability and validity of the CRQ and SGRQ are both acceptable in respiratory diseased patients. Based on the effect sizes from several research results, the CRQ may be more sensitive than the SGRQ in measuring the effects of intervention, especially on the Dyspnea subscale of the CRQ. However, because effect sizes for the CRQ and SGRQ are linked to different interventions, it may be that the CRQ was used with stronger interventions. While knowledge of existing measures is necessary, it is not sufficient in planning measurement strategies. Other methodological issues like cultural appropriateness, timing of administration, availability of personnel, responsibilities for quality control, and data management will arise in any proposed study (Cella & Tulsky, 1990). Attending to related issues is necessary for maximizing the rigor of any clinical study.

The Cultural Values in Chinese Society

Fate

In his *Fate and its Role in Modern Life*, Professor Yang Kuo-shu (1982) points out that since ancient times, China has been a country based on agriculture, and that the agrarian life-style requires large amounts of time and manpower and a stable social structure; this prompted the development of Chinese-style collectivism centered on the family clan. Within the clan, individuals strive to maintain solidarity and harmony among

its members, and they care about others' opinions about themselves.

Looked at from the standpoint of social psychology, ascribing the existence or absence and the quality of human relationships to an external factor--fate, with its connotations of predetermination--is nothing other than a process of attribution, in which responsibility for all meetings and partings between people is laid at fate's door. This attributional process not only has the effect of protecting oneself and others, but also enables people to better tolerate existing circumstances, and maintains the stability of the clan and of human relationships. This was essential in enabling the members of agricultural society to accept its rigid social structure without complaint.

In his *Social Science and Local Consciousness, as Evidenced by the Role of Fate in Medicine*, Professor Li Pei-Liang (1983) analyzes how belief in fate in regard to medicine affects how people seek treatment. His research shows that belief in the role of fate in medicine increases patients' propensity to switch doctors. Many people believe that doctors and patients must be linked by bonds of predestiny for treatment to be effective, apart from considering whether they and the doctor are linked by fate. Swift recovery shows that such links exist; a slow recovery shows that no link of fate exists, and the patient will seek another doctor. For those who believe in fate in medicine, changing doctors is a rational act which assists treatment and recovery.

Faced with each of the joys and tribulations of human existence, and the inexplicable pattern of life, by simply sighing, "It must be fate!" one can pick up the pieces of one's own emotions and be ready to face the next day. It seems that deep in their souls, Chinese people have forged inextricable links with fate. After all, by accepting fate one can

remain contented with whatever it brings.

Filial Piety

Chinese place special emphasis on the virtue of “filial piety.” Viewed superficially, “filial piety” is a familial ethic springing from a clan-oriented society; but more than this, it can be called a “universal ethic.” This is because an individual human life cannot be separated from the macro-level life of the universe (Hu, 1993a). Man’s respect and love for life is also the main expression of his reason for existence. It is only through filial respect for one’s parents that one most appropriately expresses respect and love for the source of life. Only through filial love and care of one’s parents, and loving kindness to one’s children is one better able to extend one’s experience of living from the past to the present and into the future, forming an unbroken stream of life, and expressing the creative continuity of the universe.

Views of Illness

The Chinese have a unique system of categorizing illnesses that is widely divergent from its Western counterpart. The philosophy behind Chinese medicine is that man lives between heaven and earth, and comprises a miniature universe in himself. The respiratory system regulates various intrinsic functions of the body, and maintains cybernetic balance. The theory used to describe the system of body functions and as a whole is referred to as the “latent phenomena.” The passage of the seasons and changes in the weather can have an influence on the human body. Those having the most pronounced effect are wind, cold, heat, moisture, dryness, and internal heat. Excessive or extraordinary changes in the weather harm the body, and are referred to as the “six external disease-causing factors.”

On the other hand, if mood changes within the individual, such as happiness, anger, worry, pensiveness, grief, fear, and surprise are too extreme, they will also harm the health. These emotions are called the “seven emotions.” In Chinese medicine, the six external disease-causing factors, interacting with the seven emotions, form the theoretical foundation of disease pathology (Hu, 1993b). These theoretical models, coupled with the “theory of latent phenomena,” are used to analyze the patient’s constitution and his/her illness, and diagnose the exact nature of his/her overall physical and psychological loss of balance. Based on this analysis, the doctor can prescribe a method to correct the imbalance. The object of Chinese medicine is the person, not just the illness. In Chinese medical thinking, illness is only one manifestation of an imbalance that exists in the entire person.

Because of the complex association between cigarette smoking and the development of COPD, not many Taiwanese COPD patients view smoking as a cause of their illness. Nevertheless, legislation of prohibiting smoking in public areas have been implemented in Taiwan since September, 1997. Raising the health insurance cost of smokers and sale price of cigarettes have been proposed and discussed by some parties and media in Taiwan.

Beliefs in Foods, Herbs, and Rest

“You are what you eat!” Chinese are also famous for the art of diet. Way back in the Chou dynasty, China had food officials responsible for the health of common people. In the Tang dynasty, the famous physician Sun Sze-miao said: “Whenever a physician seeks to heal, he should start by adjusting the diet, and only if dietary means fail should he prescribe drugs.” Tonic foods and tonic remedies have been around for thousands of

years. Tonifying is one of the eight methods of treatment in Chinese herbal medicine. The Chinese speak of “coordination between vital energy and blood”, and tonifying is a way of treating consumptive disease or deficiencies in the body’s vital energy and blood or bodily organs (Tong, 1990). Chinese medicine holds that the blood gives rise to the body’s vital energy, which falls into five categories--named after the Five Elements of metal, wood, water, fire, and earth--which have a growth-promoting or growth-prohibiting effect on one another. Balancing these types of energy is the key to physical health, and tonifying requires that you first know which type is deficient. Chinese medicine doctors examine the patient and inquire carefully to determine his physical state before suggesting what tonic decoctions or foods he should take.

Traditionally, Chinese people actually take tonics at every stage of their lives. Using foodstuffs to treat illness has two advantages: they are easy to come by and do not have drugs’ side effects. So why not give it a try? Older people need tonic foods once failing sight and thinning hair signal that their bodily organs are aging. This is the reason why herbs are widely used in Chinese folks’ daily lives. Traditional Chinese medicine is thought to be the best for correcting the imbalance of the chronic diseased person because of its gentle actions and slow progress with a hope that it might correct the imbalance completely. This is also why Chinese patients do not value gradual strenuous exercise in western rehabilitation programs, but do value low impact, slow motions, like Tai Chi Chuan in a rehabilitation program. People easily get hurt during strenuous exercise, especially when the person just recovered from an illness. In Tai Chi Chuan, throughout the positioning of a practitioner’s pose, movement could be either energetic or gentle,

with a low, rhythmic harmony characterizing the rate of movement. It is popular among Chinese elders who wish to better control bodily movements and to be more aware of the space through which they move during practice or in real life situations (Wolf, Coogler, & Xu, 1997). Chinese people believe in rest, food and herb regimen, slow exercise, and peaceful mind, whereas western society emphasizes medication, diet control, and exercise in treatment of chronic diseases.

Traditional Chinese Culture in Taiwan

The Chinese ethnical culture is still preserved in the Republic of China on Taiwan today. All cultural development in Taiwan over the past hundred years has vacillated between traditional and modern, Chinese and Western, trying to find what it is that belongs to “modern China.” Because of these traditional influences, Chinese elders do not value independence as much as their Western counterparts. In their thinking, to have someone or family members who can take care of them in their later life is deemed as a blessing. As a result, the Chinese place more value on interdependence. The traditional thinking about illness is practiced in their daily lives. Chinese believe that doing anything excessively can knock things out of balance. Chinese people still believe strongly in many things that they “know are so without knowing why they’re so.” Westerners might dismiss these behavior patterns as mere superstitions, but for the Chinese they relate to how a person apprehends and understands the cosmos. They are, in fact, trademark features of being Chinese.

For instance, COPD patients are reminded by family caregivers and/or friends about trivial things that might cause disturbances in their health. If the patients do not feel

well, then they should not try any strenuous activities or exercise. They had better drink warm water instead of cold water. The relationships between food and health are emphasized by patients as well as by family caregivers. Patients can decide which activity of daily life is tolerable and/or doable by them. Family members will do whatever is left that the patients can't or won't do regarding activities of daily living. Part of it is because of the status of the elder patient in the family. Elderly people are respected in the Chinese society simply because of their age. It is especially important for the elders to feel being respected. The Chinese also value the ability to do daily activities. Activities of daily living are thought to be important in evaluating a person's functional capabilities in Taiwan.

COPD in Taiwan

People in the Taiwan area enjoy ready access to comprehensive health care services island wide. A reliable medical infrastructure and health care network have been established and a universal national health insurance program has been implemented since 1995. For instance, patients make appointments with doctors by computer-assisted telephone. Patients with COPD go to clinics for regular follow-ups or for symptom relief. The most common causes for COPD patients to seek medical therapy are dyspnea and chest infections. Necessary examinations or tests are scheduled on an outpatient basis or a hospital admission is ordered according to patients' medical conditions. Patients with acute exacerbations are also admitted through the emergency room. The length of hospital stay varies, from 3 days to months. The role of a respiratory therapist in the chest ward is mostly to take care of the ventilator. Respiratory therapists make notes on patient progress and adjust the ventilator accordingly. The nurse's role is to take vital signs of the

patient, instruct the patient and/or family caregiver(s) how to use the medications correctly, and give medications.

The 6-minute walking test has been used for evaluating patients' functioning by respiratory therapists and pulmonary physicians in Taiwan. Some physicians study the effect of respiratory muscle fatigue on dyspnea in ventilator-dependent COPD patients. The relationship between self-care and social support, the compliance rate to the breath retraining techniques, quality of life, and the effect of taped progressive relaxation massage on ventilator-dependent patient have been examined in COPD patients by nurse researchers in Taiwan. Hsu and Yin (1988) studied life quality and associated factors of patients with COPD in Taiwan (1988) and found that the psychosocial resources (measured by Psycho-Social Assets Scale), health information (Health Information Scale), and health locus of control (Health Locus of Control) could explain 28.1% of variance in COPD patients' quality of life (measured by the SIP) (Hsu & Yin, 1988).

In summary, traditional Chinese culture still has some impacts on patients' health-related behaviors in Taiwan. While Chinese traditions are important in Taiwan, especially for elders, Taiwan is one of the most westernized of Asia countries. Thus, the domains of health-related quality of life are similar between Western society and Taiwan. The Chinese value interdependence and emphasize rest, the relationship between food and health, the use of Chinese medicine, and peaceful mind. Patients with COPD in Taiwan have ready access to comprehensive health care services. There is no comprehensive program of pulmonary rehabilitation in Taiwan.

Issues in Adapting an Instrument to a Different Language and Culture

This section explores issues related to adapting an instrument to a different language and culture. The influences of cultural values and cultural bias, and the importance of achieving cultural appropriateness in adapting an instrument are discussed. The procedures for obtaining an equivalent translation are delineated in this section.

Language has often been defined as a system of arbitrary symbols used for human communication (Hatch, 1992). When conducting research with subjects whose native language is different from the language of which the instrument was originally constructed, researchers need to go beyond the proper translation of their original questions or topics into the other language (Marin & VanOss Marin, 1991).

The Influences of Cultural Bias and Cultural Values on Instrument Adaptation

The development of culturally competent knowledge is an urgent research agenda (Sawyer, Regev, Proctor, Nelson, Messias, Barnes, & Meleis, 1995). Instruments commonly used in nursing research have been constructed mostly in English. Lots of measures reflect the culturally based world view of those individuals doing research. Questions have been raised periodically about cultural bias in the tools and tests used to measure psychosocial and cognitive variables. Cultural bias can exist in the content of an instrument, the process of test taking, or the format of an instrument.

Another source of cultural bias in instruments is the language in which the text was originally constructed, especially if colloquial expressions, slang, or cultural-specific labels or taxonomies were used (Flaskerud, 1988). The format of text may be culturally influenced by cultural preference and familiarity, and difficulties among some cultural

groups with the use of native stems, multiple-choice questions, and mark-sense answer sheets have been reported (Morishima & Mizokawa, 1979). Cultural bias in any of these areas may affect the validity of the instrument (Flaskerud, 1988). Cultural values associated with revealing personal information or taking a firm position on a controversial issue may create anxiety that can influence responses (Kinzie, Manson, Vinh, Nguyen, Anh, & Pho, 1982).

The Importance of Achieving Cultural Appropriateness

The designers of all tools or tests consciously or unconsciously use many cultural requisites in the development of their tools (Flaskerud, 1988). For instance, problems in using Likert scales cross-culturally could be due to education, faulty translation, irrelevant content, lack of semantic equivalence, the differing character of social interactions in various groups, or the nature of the response required. It is also possible that the degree of variation Likert scales attempt to measure is meaningless to some cultural groups (Flaskerud, 1988). Changing examples or contexts in which questions are framed is not enough to produce a culturally appropriate instrument (Marin & VanOss Marin, 1991). To ensure the cultural appropriateness of the instrument to be used in the research project, it is important to know whether the research stimuli are being presented in equivalent ways to all of the individuals included in a study (Marin & VanOss Marin, 1991).

A danger in cross-cultural research is to assume erroneously the universality of a concept or construct (Marin & VanOss Marin, 1991). It is not enough to obtain a good translation of an instrument. Different factor structures also have been found for various well-known psychological instruments when translated and adapted for use in Latin

America (Marin & VanOss Marin, 1991).

Cultural Appropriateness of the CRQ and the SGRQ

The CRQ examines four aspects of patients' lives: dyspnea (the subjective feeling of breathlessness), fatigue, emotional function, and mastery (the feeling of control over the disease and its effects). It is administered by an interviewer and contains a total of 20 questions; each question is answered on a 7-point Likert scale (Guyatt et al., 1987). The 7-point CRQ Likert scale was evaluated by 6 Chinese respondents. Five of the 6 respondents had difficulty in discerning two adjacent phrases on the 7-point scale. For instance, the respondents could not differentiate between "most of the time" and "a good bit of the time." Another difficulty experienced by the Chinese respondents was that the items in the fatigue, emotion, and mastery subscales refer to adjectives that are seldom used in most Chinese people's daily life or thinking. For example, Chinese people would use "feel well" to describe confident (Item 9), have control (Item 12), and high in energy (Item 10); they would use "not feel so good" to express feelings of fatigue (Item 7), low in energy (Item 14), discouraged (Item 15), frustrated or impatient (Item 5), worn out or sluggish (Item 16), and restless (Item 19). Although there are many different words to describe different feelings in the literature, the Chinese neither think nor talk in this fashion in daily life. It would be difficult for Chinese people to complete the questionnaire. After completing a few items, the respondents would become confused because many of the items would be similar in content and it would be difficult for them to differentiate the items, using a Likert scale. Therefore, the answers from these questions would be not reliable and valid once respondents get confused and impatient with these questions.

The St. George's Respiratory Questionnaire (SGRQ) contains 50 items (covering 76 levels) divided into three sections. Section I is 'Symptoms', concerns with level of symptomatology, including frequency of cough, sputum production, wheeze, breathlessness, and the duration and frequency of attacks of breathlessness or wheeze. Section II is 'Activity', concerns with activities that either cause or are limited by breathlessness; and Section III is 'Impacts', covers such factors as employment, being in control of health, panic, stigmatization, the need for medication and its side effects, and expectations for health and disturbance of daily life, which covers a range of aspects concerned with social functioning and psychological disturbances resulting from airways disease (Jones et al., 1991; Jones et al., 1992). The conditions described in the SGRQ items are more specific, are similar to the conversations that would be held between patients and health care providers in Chinese culture; and the choices (either different conditions or true/false) are easier to answer than the 7-point Likert scale in the CRQ.

Procedures for Obtaining an Equivalent Translation

The steps in obtaining a target language version of an instrument should include:

- 1) translate from source to target language by native speakers of target language;
- 2) back-translate from target to source language by native speakers of source language;
- 3) repeat the process through discussion to see if there is any discrepancy between the original version and the back-translation version; and
- 4) select the final target language version, then apply to subjects of the intended health population (e.g., COPD patients) for whom the instrument was originally constructed. Psychometric properties are examined and compared with data from the original version. Usually factor analysis is carried out to

examine if the clusters of structure have changed after translation. For instance, the preliminary validation of the French text of the Critical Care Family Needs Inventory (CCFNI) was carried out by back translation method of the French form into English by three translators. Then the final French version was selected. The French version of the CCFNI was given to the immediate family members visiting a patient in the surgical intensive care unit of the University Hospital in Sherbrooke, Canada. The reliability of the French version yielded .91 as Cronbach's α coefficient. The Spearman-Brown split-half coefficient was .89, and the Guttman split-half coefficient was .88. Principal components analysis and factorial matrices were used to examine the clustering structure of the French version of this instrument (Coutu-Wakulczyk, & Chartier, 1990).

Issues in Back-Translation

Back-translation is the most common and highly recommended procedure to assure adequacy of any translated instrument or text (Brislin, 1986; Jones, 1987; McDermott & Palchanes, 1994). In back-translation, the translator whose native language should be the same as the source language, translates target language into the source language. Inaccuracies occur in back-translation when the translators share a sense of meaning for some nonequivalent words or when translators understand a poorly written translation and produce an acceptable back-translation version without correcting translation errors (Brislin, 1970; Jones, 1987). The number of translation errors is influenced by the similarity of the source to target language. Additionally, translators may be able to produce a target language version that contains a grammatical style unique to the source language which, though easily back-translated, is generally worthless for

monolinguals in the field (Brislin, 1970). The researcher must consider the potential lack of comparability across ethnic or cultural groups before translating a paper-and-pencil instrument (Marin & VanOss Marin, 1991).

In summary, various studies have shown that the internal structure of an instrument changes when it is adapted and translated into different languages. Instruments can lose certain important psychometric characteristics when translated and adapted. To make sure that the translated version of an instrument is fully equivalent to the original version, researchers should analyze the internal structure of the instrument as well as its internal consistency. Procedures such as factor analysis can provide a good indication of the factor structures inherent in the translated version. In addition, researchers need to identify other psychometric characteristics of the instruments to be used. An indication of the distributions of the scores in the population and psychometric norms of the test should be obtained. The issues studied must be meaningful to each of the research participants in the various cultures or groups and questions must be phrased in a way that will allow the researchers to measure equivalent constructs in all groups (Marin & VanOss Marin, 1991).

The development of culturally competent knowledge is an urgent research agenda (Sawyer et al., 1995). Adapting an instrument to a different language and culture is one of the scientific approach to establish culturally competent knowledge. Attending to culturally-sensitive translation issues, as well as analytical procedures and psychometric characteristics is needed for adapting an instrument to a different language and culture.

Conceptual Organization of Study Variables

From the literature reviewed to this point, it is clear that a variety of approaches have been used to assess and measure quality of life in COPD. The most common approach has been that some lung function measurements are used as objective evidence of disease severity (e.g., FEV₁), exercise performance is applied to assess patient's functional capacity (walking tests and stationary bicycle), a direct measure of patient's symptom (e.g., dyspnea) severity is used to assess how the level of symptom has changed during study intervention (e.g., the Visual Analogue Scale and Borg Scale), and other reference measures that claimed to measure the same phenomenon (e.g., the SIP, Medical Outcomes Study Short Form-36, etc.) are compared to show evidence of validity of the study measure. The SGRQ is chosen for this study. The relationships between the SGRQ and the study variables are discussed in this section.

Hsu and Yin (1988) administered the Chinese Version of SIP to 98 outpatients with COPD and 98 healthy subjects in Taiwan. The category of Sleep and Rest had fewest (5) items left after removing two items, had the lowest Cronbach's α (.32). The remaining 11 categories of the SIP had Cronbach's coefficient α ranging from .64 to .80 in 98 COPD patients. There were significant differences ($p < .05$) in all categories of the SIP between COPD and healthy subjects, especially in the categories of Ambulation, Mobility and Home Management, smaller differences were found in Recreation and Pastimes, Communication, and Eating. Unlike findings in McSweeney (1982) in which Recreation and Pastimes had the biggest difference between COPD and healthy subjects. Hsu and Yin also found that age and disease severity contributed to lower quality of life in 98

Taiwanese COPD patients (Hsu & Yin, 1988). The results of this study showed that the domains of quality of life is similar between Taiwanese and Americans, but weights could be different. In their report, Hsu and Yin stated that Taiwanese lack entertainment in their daily life, so the impact of respiratory disease was small in this respect.

HRQL and CSGRQ. The questions in the SGRQ relate to respiratory symptoms, their frequency and severity; activities that cause or are limited by breathlessness; and social functioning and psychological disturbances resulting from respiratory disease. These questions are similar to regular conversations between COPD patients and health care providers in Taiwan. The content of the questions in the SGRQ is relevant to the impact of disease on patients' life quality in Taiwan.

SGRQ and FEV₁. Okubadejo, Jones, and Wedzicha (1996) found that the FEV₁ was significantly correlated ($p < .05$) with the SGRQ Activity component ($r = -.34$) in 41 British COPD patients (Okubadejo, Jones, & Wedzicha, 1996). The SGRQ Activity was found to be significantly ($p < .01$) correlated with FEV₁ ($r = -.24$) in 126 Dutch COPD patient (Ketelaar et al., 1996). Wilson et al. (1997) found that FEV₁ was significantly correlated ($p < .01$) with Symptom ($r = -.25$) and Activity ($r = -.36$) in 111 European Patients with bronchiectasis (Wilson, Jones, O'Leary, Cole, & Wilson, 1997).

Researchers have also demonstrated the relationship between FEV₁ and the SGRQ scores by age. In a study of 227 British subjects with and without chronic obstruction and bronchial hyperresponsiveness, Renwick and Connolly (1996) found that the FEV₁ was significantly correlated ($p < .001$) with log SGRQ total score ($r = -.42$), log Activity score ($r = -.35$), log Impact score ($r = -.41$), and log Symptom score ($r = -.31$) in patients under age

65 years. In patients age 65 or older, the correlations were somewhat higher; the FEV₁ was significantly correlated ($p < .001$) with log SGRQ total score ($r = -.51$), log Activity score ($r = -.40$), log Impact score ($r = -.51$), and log Symptom score ($r = -.42$). The higher correlations may have been due to the larger range and variability of scores that are often found in elderly compared to younger persons.

Ferrer et al. (1996) found significant relationships ($p < .01$) between the Spanish version of the SGRQ and FEV₁ (% of predicted) in 318 Spanish COPD patients: FEV₁ correlated with Symptom ($r = -.29$), Activity ($r = -.53$), Impact ($r = -.37$), and Total score ($r = -.45$) (Ferrer et al., 1996). However, in another study of 79 patients with a variety of chronic lung diseased patients in Switzerland (63% of the subjects have COPD), Janssens et al. (1997) found that there were no significant relationships between FEV₁ (% of predicted) with the SGRQ scores (Janssens et al., 1997).

SGRQ and 6-Minute Walking Test. In understanding the determinants of health-related quality of life (HRQL) in patients with COPD, Ketelaar et al. (1996) found that the 12-minute walking test was significantly correlated ($p < .001$) with the SGRQ Activity score ($r = -.39$) and Impact score ($r = -.36$) in 126 Dutch COPD patients. They concluded that the 12-minute walking test is one of the determinants of HRQL in patients with severe COPD. Their data emphasize that exercise performance is relevant to daily functioning and HRQL in this group of patients. However, exercise capacity failed to account for all the variability in HRQL. Emotional reaction and FEV₁ were other variables that had independent influence on HRQL in patients with severe COPD in this study (Ketelaar et al., 1996).

Janssens et al. (1997) found that the average daily distance walked was significantly correlated ($p < .05$) with Activity ($r = -.59$), Impact ($r = -.51$) and Total score ($r = -.55$) of the SGRQ in 32 Switzerland chronic lung diseased patients (Janssens et al., 1997).

SGRQ and Borg Scale. Ferrer et al. (1996) found significant relationships ($p < .01$) between the Spanish version of the SGRQ and perceived dyspnea (measured by the Borg Scale) in 318 Spanish COPD patients: Symptom ($r = .43$), Activity ($r = .56$), Impact ($r = .56$), and Total score ($r = .59$) (Ferrer et al., 1996). In a study intended to identify measurements relevant to health-related quality of life in 32 European COPD patients, Janssens and colleagues (1997) found that Borg (resting dyspnea) significantly correlated ($p < .01$) with SGRQ Impact ($r = .65$) and Total score ($r = .58$), and significantly correlated ($p < .05$) with SGRQ Activity ($r = .43$). The Symptom section of the SGRQ relates mainly to daily cough and sputum production and wheezing; it was not significantly correlated with Borg (resting dyspnea) in this study (Janssens et al., 1997).

SGRQ and SIP. In a study designed to measure improvement in quality of life of patients with asthma, the SGRQ and SIP were used in a year long double-blind, placebo-controlled, group comparative study with Nedocromil sodium in a multi center trial from 6 countries. Score from the SIP generally decreased to a greater extent in Nedocromil sodium treated patients. After 24 weeks, the effect size on the SIP scores was .06 and .02 after 48 weeks. The article did not provide enough information to calculate the effect size on the SGRQ scores. All of the quality of life scores differed between countries ($p < .01$). When country was introduced as a factor into the analysis, the interaction between country

and general health assessment was not significant with the SGRQ or SIP scores ($p > .05$). This suggests that cultural or linguistic factors may not have influenced the patients' responses to quality of life measures (Jones et al., 1994).

In the same study, the SGRQ and SIP were administered among many other reference measures. The correlations between representative reference variables and the SIP and the SGRQ total scores were very similar. The Symptom section exhibited low but significant correlations ($p < .01$) with the SIP Physical ($r = .12$), the SIP Psychosocial ($r = .07$), and the SIP Total ($r = .11$). The Activity section significantly correlated ($p < .0001$) with the SIP Physical ($r = .38$), the SIP Psychosocial ($r = .28$), and the SIP Total ($r = .38$). The Impact section significantly correlated ($p < .0001$) with the SIP Physical ($r = .48$), the SIP Psychosocial ($r = .42$), and the SIP Total ($r = .54$). The investigators concluded that there was a large measure of agreement between the SIP and the SGRQ total score in terms of their relationship to a range of measures of disease activity in patients with airflow limitation, the major difference being the greater sensitivity of the SGRQ to differences in disease severity between patients (Jones, Quirk, & Baveystock, 1991)

Okubadejo et al. (1996) assessed the effect of long term oxygen therapy (LTOT) on quality of life in 19 British patients with hypoxemia and COPD compared with 17 less severe COPD patients by using the SGRQ and SIP, they found that the LTOT group had higher SGRQ and SIP scores than controls ($p < .05$) at all visits, implying lower quality of life among LTOT receivers. Patients receiving LTOT had a slightly greater improvement in their quality of life compared to the control group, but this was not statistically significant during the study period (Okubadejo et al., 1996). Repeated measures ANOVA

showed no statistically significant effect of LTOT on SGRQ and SIP over the 6 months ($p=.79$ and $.74$, respectively) (Okubadejo et al., 1996).

The SIP136 was translated into Chinese and used in COPD patients (Hsu & Yin, 1988). Two items from Sleep and Rest and 2 items from Recreation were removed after pilot study (132 items left, as SIP132). The Chinese Version of SIP132 was administered to 98 outpatients with COPD and 98 healthy subjects. It took about 15 to 20 minutes to complete the SIP132. The category of Sleep and Rest had fewest (5) items left after removing 2 items and, had the lowest Cronbach's α (.32). The remaining 11 categories of the SIP132 had Cronbach's coefficient α ranged from .64 to .80 in 98 COPD patients in Taiwan. There were significant differences ($p < .05$) in all categories of the SIP132 between COPD and healthy subjects (Hsu & Yin, 1988).

Hypotheses

Based on the review of the literature about the SGRQ in other cultures, the following hypotheses were generated regarding how the CSGRQ would perform in Taiwanese culture. These hypotheses were tested to examine the construct validity of the CSGRQ in Taiwan. In this study, the researcher compared the mean, standard deviation, range, reliability, and validity results to past research on SGRQ in other cultures. The researcher also examined the feasibility of the CSGRQ in Taiwanese culture.

1. CSGRQ scores will be negatively related to lung measurement (FEV_1 % predicted).
2. CSGRQ scores will be negatively related to distance walked in 6 minutes.
3. CSGRQ scores will be positively related to ratings on the Borg scales at rest.

4. CSGRQ scores will be positively related to the SIP68.

Some relationships among these variables have been identified in clinical research. However, the results were contradictory because of different operational definitions of variables of interest and different research designs. Therefore, those relationships were not included in the hypotheses for this study.

CHAPTER III

METHOD

Design

The research design was a nonexperimental, single group only design in which survey methods and correlational analysis were applied to address the research hypotheses. Because the research questions seek to evaluate the psychometric properties of the Chinese version of the SGRQ, a cross-sectional correlational survey design was selected. Sample selection is described below.

Setting and Sample

A convenience sample diagnosed with COPD, as defined by the American Thoracic Society, was drawn from a university hospital at its pulmonary clinic in Taipei, Taiwan. The Tri-Service General Hospital is one of the five university hospitals in Taipei, data collection occurred in this hospital.

Sample Recruitment

Prospective subjects were identified in two ways. The large majority of potential subjects were identified by a chart review to determine whether they meet criteria for inclusion in the study (see below). Patients who met the criteria were visited by the researcher introducing the study and inviting them to participate. Demographic and disease data were recorded on the sheet of basic information from the charts (see Appendix). Eligibility was clarified by asking the patient to perform a forced expiration on a portable spirometer after he/she gave written or oral consent to participate. When the researcher was satisfied that all inclusion criteria were met and the patient had agreed to

participate, an interview was conducted for data collection.

Inclusion and Exclusion Criteria

Inclusion Criteria. Patients were eligible for the study if they met the following criteria:

1. was at least 40 years of age;
2. understood Mandarin (the official Chinese language);
3. had a medical diagnosis of symptomatic COPD, chronic bronchitis, or emphysema with a best of FEV₁ % predicted $\leq 75\%$ or FEV₁/FVC $\leq 75\%$ on a spirometer
4. was willing and able to complete the study measures.

Exclusion Criteria. Patients were excluded from the study if they had any of the following:

1. legally blind or deaf;
2. pre-diagnosed cancer;
3. uncontrolled diabetes;
4. uncontrolled hypertension;
5. psychiatric illness;
6. Class 2 or greater New York Heart Association criteria for heart failure, because illness level would confound the impact of dyspnea on quality of life on the SGRQ;
7. not able to walk;
8. peripheral vascular disease with intermittent claudication;
9. current alcohol or other substance abuse problem;
10. ventilator-dependent;
11. unstable angina pectoris, because patients in unstable conditions can't perform 6-

minute walking tests; and

12. family members who were present at the time of data collection did not orally assent to the patients' participation in the study.

Nonprobability, convenience sampling for patients who met the selection criteria and signed the informed consent forms were used. The absolute values of the correlation coefficients in previous research ranged from .24 to .51 between the SGRQ and FEV₁, .36 to .59 between the SGRQ and 6-minute walking test, .43 to .65 between the SGRQ and the Borg scale, and .07 to .54 between the SGRQ and the SIP136. The needed sample size for this study was estimated to be 100 subjects. With 100 subjects and an α level of .01 to adjust for multiple correlations, the power was .80 to detect Pearson's correlations of .31 as statistically significant. The correlations of the SGRQ and the remaining study variables ranged from .24 to .65 in previous research. With 100 subjects and an α level of .01, the power was $\geq .58$ in this study.

Instrumentation

The St. George's Respiratory Questionnaire (SGRQ)

After discussions with the research committee, the investigator received their approval to proceed with the instrument adaptation of the SGRQ.

Adaptation into Chinese Version of the SGRQ (CSGRQ)

The author followed the suggestions from the developer, Dr. Paul W. Jones, using translation and back-translation method by bilinguals. A discussion of some issues regarding translation of the SGRQ into the Chinese version of the SGRQ (CSGRQ) follows.

Translating issues of the SGRO: word meanings. In the process of translations, the translators had difficulty adding words in the Chinese version to clarify the meaning while not changing the original meaning. Because of these considerations, the Chinese version sounds awkward. For instance, in the back translation, "often" and "frequently" were used according to the Chinese version to make the questions flow better in the Symptom section. The translators had a long discussion to clarify the differences between "wheezing" and "asthma" in Chinese. By dictionary, "wheezing" means breathing with difficulty, making a hissing or whistling sound; whereas "asthma" is a chest disease which makes breathing difficult. Wheezing is one of the clinical symptoms of asthmatic patients. In Chinese, there isn't much difference between "wheezing" and "asthma" in daily life conversations. In this sentence, "wheezing" was translated as "the asthmatic symptom" in the Chinese version.

Translating issues of the SGRO: measurement debate. The back-translation of the five options followed by each questions are clear and consistent with the meaning of the original questions. It is not clear what to do if patients have two or more conditions. For a given question, it is difficult for COPD patients with asthmatic component to choose one option when they have mixed conditions.

The vocabulary for time intervals involved in this instrument ranges between "these days" and "one year." Because most COPD patients are elders, the 1 year interval to recall is difficult for them to do accurately. In addition, there is no way to check if the response is accurate.

Another issue involved in translation of this instrument regards structure of the

questions. Equivalent meaning is more important than sentence structure. For example, in section 3 of part 2, the first option: "My cough hurts" is not a typical statement in Chinese. The format of instruments may be culturally influenced by cultural preference and familiarity; indeed, difficulties among some cultural groups with the use of mark-sense answer sheets have been reported (Morishima & Mizokawa, 1979). Claims for adequacy of translation are based on finding similarity in reliability, validity, and factor structure for the forms in both languages (Werner & Campbell, 1970).

A first translation was produced by three bilinguals (all of them received doctoral degrees from the United States), whose native language is Chinese and who were asked to keep conceptual rather than linguistic equivalence. This translation was reviewed by the researcher, and a linguistics professor at Portland State University whose wife is a Taiwanese and who lived in Taiwan for 4 years. We rated the equivalence between this first forward translation and the original version, identified inadequate or ambiguous items, and generated alternative expressions. Modifications were subsequently made and a second forward translation was produced. This version was back-translated into English by a bilingual, whose native language is English, to be compared with the original. This back-translation was reviewed by the researcher, one of the research co-chairs, and the same linguistics professor. We rated the equivalence between this first back-translation and the original version, identified inadequate or ambiguous items and reexamined the Chinese version. Modifications were subsequently made and a second back-translation was produced. Linguistic ambiguity can be resolved by repeated modification and back-translation cycles for apparent discrepancies.

Missing items with multiple-choice responses are treated as “No”, and for missing items with a “Yes/No” response pattern, the weight is subtracted from the total possible weight. In validating the SGRQ into Spanish, Ferrer et al. (1996) found that there were no differences in internal consistency between self- and interview-administered SGRQ (p for differences between correlations were .13 to .62) (Ferrer et al., 1996).

Lung Function Measurement:

The Forced Expiratory Volume in One Second % Predicted (FEV_1 % Predicted)

Assessment of pulmonary function testing plays a central role in diagnosing and grading in severity of patients on the basis of results from these tests. Commonly used measures for COPD are the FEV_1 (the forced expiratory volume in one second), FEV_1/FVC (forced vital capacity), and the slope of the FEV_1 over time (Buist & Vollmer, 1994). The American College of Chest Physicians has suggested that the FEV_1 , the FVC, and the $FEF_{25-75\%}$ (forced expiratory flow between 25% and 75% of FVC) are the simplest and most commonly available tests reflecting severity of airway obstruction (Snider, Woolf, Kory, & Ross, 1974). The ratio of the FEV_1 to FVC is often used to assess patients for airflow obstruction and is more sensitive than the FEV_1 to early disease (ATS, 1991). It is normally 75 to 85%, depending on the patient’s age in patients without COPD (Bailey et al., 1998). Burrows and coworkers (1986) found that the FEV_1/FVC decreased linearly with age, independent of FVC, and was similar in men and women (Burrows, Lebowitz, Camilli, & Knudson, 1986). For this reason, the FEV_1/FVC was not used in validity analyses in the current study.

Because of its ease of measurement and its very good reproducibility, FEV_1 is the

most widely used and quoted lung function test in clinical practice as well as in patient based research and in epidemiological studies of healthy subjects (Kerstjens, Rijcken, Schouten, & Postma, 1997). The FEV₁ percent predicted is readily available, inexpensive, and a reliable clinical indicator of disease severity in COPD. It is preferred over the absolute FEV₁ because it takes into account individual differences in gender, age, and height (Leidy & Traver, 1995). For the proper interpretation of any measured FEV₁, the sources of variation in one's equipment should first be appreciated. There is considerable variation due to technical and patient related sources (Kerstjens, Rijcken, Schouten, & Postma, 1997).

Many studies have found a low correlation between all kinds of quality of life scales and the lung function level (McSweeney, Heaton, Grant, 1980; Schrier, Dekker, Kaptein, 1990; van Schayck, Rutten, Doorslaer, 1992). The FEV₁ has been found to be a significant predictor of performance, but generally accounts for only 4 to 14% of the observed variance (Anderson, 1995; Jones, Baveystock, & Littlejohns, 1989; McSweeney et al., 1982; Weaver & Narsavage, 1992). This is consistent with the clinical observation that patients with equivalent pulmonary function can have disparate levels of functioning. In a longitudinal study of 110 COPD patients, Mahler et al (1995) found that FEV₁ was significantly related to changes in dyspnea at the different time periods (Mahler et al., 1995). Anderson (1995) found that disease severity (FEV₁% predicted) was significantly correlated ($p < .05$) with dyspnea ($r = .24$), distance walked in 6 minutes ($r = -.32$), depression ($r = .24$), self-esteem ($r = -.38$), optimism ($r = -.35$), and social support ($r = -.26$) in her study with 126 COPD patients (Anderson, 1995). The FEV₁% predicted is probably

as sensitive and specific as more complex measurements in assessing patients' progress (Canadian Thoracic Society Workshop Group, 1992).

In the current study, physiologic testing was performed on subjects on the same day that dyspnea was graded on the modified Borg scale. Spirometric measurements were performed with a Vitalograph compact II (portable spirometer, Vitalograph Limited, Grote Road, Ennis, Co. Clare Iceland). The Vitalograph wedge bellows dry spirometer was used to record the FEV₁ and FVC of participants. Measurements of Vitalograph were performed with the participants seated. Nose-clips were not used. The best of at least three consecutive measurements were recorded. The Vitalograph readings were corrected to body temperature, ambient pressure, and full saturation with water vapour by the Vitalograph agent before data collection. The Vitalograph has been tested in a study on 3490 Chinese residents of Hong Kong aged between 5 and 97 years by Hill and his colleagues (Hill, Snell, & Nunn, 1982).

For the current study, each subject performed the test at least three times before the walking test, and a maximal value was selected. Predicted normal values for FEV₁ are taken from Hill and his colleagues (Hill, Snell, & Nunn, 1982). It is calculated by $(-.016 \times \text{Age in years}) + [1.323 \times (\text{height in centimeter}/100)^2]$ for male (Standard Deviation= .19); $(-.012 \times \text{Age in year}) + [1.442 \times (\text{height in centimeter} /100)^2]$ for female (Standard Deviation= .17) (Vitalograph co, personal communication, 1998).

Exercise Performance: the 6-Minute Walking Test

Exercise testing may be valuable in patients with respiratory disease. It is clear that quantitative assessment of exercise performance is clinically useful for diagnostic

purposes, assessment of impairment, disability evaluations, and monitoring responses to therapy (Gold, 1994). Epstein and Celli (1993) proposed that cardiopulmonary exercise testing is a safe and effective method for objectively studying exercise performance and may be carried out using simple walk tests (Epstein & Celli, 1993). Walking distance and subjective disability are well correlated and probably quite closely linked (Jones, 1991). Exercise testing provides several potential advantages over nonexercise clinical methods for measuring breathlessness. First, exercise testing can stimulate or somewhat reproduce daily physical activities of a patient. Second, various physiologic variables can be measured during the exercise task. Third, exercise testing is frequently used to evaluate the problem of dyspnea in a patient (Mahler, 1992).

McGavin and colleagues (1976) introduced the 12-minute walking test as a measure of exercise capacity for patients with chronic lung disease (McGavin, Gupta, & McHardy, 1976). In addition, a subjective variable such as dyspnea, measured by the Chronic Respiratory Questionnaire, is more strongly related to walking tests ($r = -.41$, $p < .01$) than to bicycle ergometer tests (Wijkstra, ten Vergert, van der Mark, Postma, van Altena, Kraan, & Koeter, 1994).

The original 12-minute walking test has now been replaced in many centers with the 6-minute walking test after Butland et al. (1982) showed it to be equally useful. Butland and coworkers have shown that equivalent results may be obtained with 6, and possibly, 2 minute walking times. The correlation coefficients between 2-minute and 6-minute walk tests were .89, between 2-minute and 12-minute walk tests were .86 in 30 COPD patients. The linear regression equations were: 12 minute distance = 5.70 (2-minute

distance) - 73.3 meters; 6-minute distance= 2.76 (2-minute distance) + 3.12 meters (Butland, Pang, Gross, Woodcock, & Geddes, 1982). They concluded that shorter times are easier for both patient and investigator and are as reproducible but discriminate slightly less well and have less of a training role. The 6-minute walking test may represent a sensible compromise.

The 6-minute walk test is a less expensive and more readily available test for assessing exercise capacity (Milligan, Havey, & Dossa, 1997). It is a self-paced submaximal level of physical exertion and reflects the ability to perform walking under conditions similar to those experienced in daily life. It measures the distance a person can walk in 6 minutes. Its use with pulmonary patients has been well established (Guyatt et al., 1985; Larson et al., 1996). It is commonly used as an outcome measure of functional status in the rehabilitation or assessment of patients COPD and as a guide to assessment for lung transplantation (Anderson, 1995; Schere & Schmieder, 1997; Kadikar, Maurer, and Kesten, 1997). A similar test has been used for patients with left ventricular dysfunction (Milligan et al., 1997).

Guyatt and coworkers (1984) investigated the impact of encouragement on 2- and 6- minute walking tests performance in 43 patients with chronic lung and chronic heart disease and found that: 1) simple encouragement improved performance ($p < .02$ for the 6-minute walk), and 2) the magnitude of the effect was similar to that reported for patients in studies purporting to show beneficial effects of therapeutic maneuvers. Guyatt et al. (1984) suggested that important issues in administration of the walking test include the duration of the test, whether encouragement should be uniformly withheld or uniformly

given, and the number of practice sessions which are necessary before an intervention can be tested (Guyatt et al., 1984).

To establish the construct validity of the 12-minute distance walk as a measure of functional status in patients with COPD, Larson et al. (1996) used the Sickness Impact Profile (SIP), Physical Dimension; FEV₁ % of predicted; maximal inspiratory pressure; and exercise-related breathlessness in their study. The 12-minute walk correlated with the SIP, Physical Dimension ($r=-.45$); FEV₁% predicted ($r=.40$); maximal inspiratory pressure ($r=.52$); and exercise-related breathlessness ($r=-.49$). In assessing the psychometric properties of the 12-minute distance walk in COPD patients, Larson et al. (1996) found that learning continued through the third test, and the 12-minute distance walk was reliable after initial learning had occurred. They concluded that the 12-minute distance walk is a valid and reliable measure of functional status in patients with moderate to severe COPD (Larson et al., 1996).

The 6-minute walking test correlated strongly with a 12-minute walk in chronic respiratory patients (Butland et al., 1982). Guyatt et al. (1985) reported significant correlations ($p=.001$) between the 6-minute walking test and four self-report measures (oxygen cost diagram ($r=.50$), baseline dyspnea index ($r=.59$), specific activity scale ($r=.47$), and cycle ergometer ($r=.06$)) of functional status in 43 subjects with chronic heart and lung disease. They also found that the 6-minute walking test results proved extremely reproducible (its coefficient of variation was .05 in 43 patients with chronic heart and lung disease) (Guyatt et al., 1985).

The 6-minute walking distance was significantly correlated ($p < .001$) with total

lung capacity ($r=.62$) and peak esophageal pressure ($r=.58$) measured during a maximal semi-static inspiratory maneuver in 40 Dutch COPD patients (Wijkstra et al., 1994b). The total lung capacity and peak esophageal pressure explained 54% of the variance in the 6-minute walking test. Wijkstra et al. (1994b) concluded that subjective measurements are better related to a walking test than to a bicycle ergometer test (Wijkstra et al., 1994b). The 6-minute walking test had a moderately strong negative correlation ($R^2=.41$) with the SIP in 141 patients with chronic airflow obstruction (Jones, Baveystock, & Littlejohns, 1989). The relationship between 6-minute walking test and daily functioning has proven to be somewhat stronger among predictors ($r=.32$ to $.72$) (Anderson, 1995; Guyatt et al., 1987; Weaver & Narsavage, 1992; Jones et al., 1989).

For the current study, exercise performance was evaluated by a 6-minute walking test which was carried out in a hospital corridor 20.7 meters long. The 6-minute walk was defined as the maximal distance covered in 6 minutes while walking back and forth along a corridor in a hospital. Each patient was given the same instructions before the walk. Patients were asked to walk as far as possible in 6 minutes. They could determine their own pace, even stopped if necessary, and they were instructed that as the end they should feel as though they could not have walked any further. Chinese values regarding sick people advise and encourage rest. Butland and coworkers have shown that equivalent results may be obtained with 6, and possibly 2, minutes walking times (Butland et al., 1982). Therefore, the distance walked in 2 minutes was also collected during the 6-minute walk test to examine the relationship between different walking times and other study variables. The researcher stopped subjects at 2 minutes for breathlessness measure on the

Borg scale. This procedure took about 10 seconds. A simple encouragement sentence was given during the test. No practice section was executed because participants refused to do so.

The Pre-, During- and Post-Walk Rating of Breathlessness:

The Borg Scale

Most scientists and practitioners in the health sciences agree that it is important to understand subjective symptoms and how they relate to objective findings. Two scales, the Borg scale and the visual analogue scale, are the most commonly used instruments for rating breathlessness during an exercise test. In 1970, Borg described a 6-to 20-point scale for rating perceived exertion (RPE) during a standard exercise test (Borg, 1970). Borg (1982) developed a 0-to 10-category scale with ratio properties for exertion. Borg added descriptive categories referring to “perceived exertion” to give the ratios an anchor and allow subjects to respond in a more “absolute” way to the stimuli, and thus to allow for direct interindividual comparisons (Borg, 1982). The new 11-point scale has descriptors ranging from 0=“nothing at all” to 10=“maximum.”

The Borg Scale was modified to measure patients’ rating of perceived breathlessness (RPB). The RPB scale is vertically oriented, with a total of nine verbal anchors located to give it ratio properties. Scores range from 0 to 10. The nonlinear spacing of severity descriptors are anchored to specific numbers in the modified Borg Scale. This scale has ratio properties for sensation intensities (Mahler, 1992). In the current study, the vertical-oriented Borg Scale was used (see Appendix E). Symptoms, particularly perceived breathlessness, are regarded as important factors underlying

functional difficulties in people with COPD and are a key target of intervention efforts (Leidy & Traver, 1995). Such ratings are important complements to behavioral and physiological measurements of physiological performance and work capacity. The Borg scale is used extensively and has been shown to be a valid measure of perceived breathlessness, particularly with exercise (Borg, 1982; Mahler et al., 1987). The Borg category scale of perceived breathlessness has been widely used to quantify the subjective sensation of dyspnea (Borg, 1982; Muza, Silverman, & Gilmore, 1990).

Evidence for the validity of the RPB includes a strong correlation with peak pressure expressed as a percentage of the maximum inspiratory pressure ($r=.91$, $p < .001$) in 10 healthy nonsmoking subjects during a test of increasing airway resistance (Jones, Killian, Summers, & Jones, 1985) and a consistent relationship with FEV₁ ($r=.88$, p was not reported) in 45 asthmatic patients during a histamine inhalation test (Burdon, Juniper, Killian, Hargreave, & Campbell, 1982). Jones et al. (1985) recognized that using the modified Borg scale, the simple categories and discrimination between categories were easy to identify, and the subjects were able to freely extend their sensory estimates over the total stimulus range possible (Jones et al., 1985). Burdon et al (1982) proposed that from the psychophysical viewpoint, chronic airflow obstruction would be expected to result in a reduction in sensation because of prolonged and continuous stimulation (Burdon et al., 1982).

In evaluating the reproducibility of a Borg rating of dyspnea in 9 patients with COPD (with a mean FEV₁% predicted of 46%), Belman et al. (1991) found that the Borg ratings decreased with successive tests while other physiological measures stayed

unchanged, and concluded that desensitization to dyspnea may play a role in the improvement of patients after exercise. Researchers suggested that the continued improvement in the Borg score with test repetition indicates that considerable caution is necessary when using this scale to assess responses to treatment (Belman & Gaesser, 1988). In the absence of a control group or placebo treatment, a decrement in dyspnea measured by a Borg scale should not be ascribed to a therapeutic intervention alone (Belman, Brooks, Ross, & Mohsenifar, 1991).

In comparing the Visual Analog Scale (VAS) and modified Borg for the measurement of dyspnea during exercise, Wilson and Jones (1989) found that the Borg scale appeared to have greater stability than VAS measurements and to correlate with minute ventilation a little better in 10 young volunteers (Wilson & Jones, 1989). They also found that breathlessness estimation was highly reproducible by both scales after 1 week and after 40 weeks of the study (both $p > .05$) in 7 healthy volunteers (Wilson & Jones, 1991). Researchers concluded that a 30-cm vertical VAS is reproducible and correlates closely ($r = .99$) with simultaneous scores obtained by the 6- to 20 point Borg score when scaling the sense of effort to breath during exercise in 6 subjects with stable COPD (Muza, Silverman, & Gilmore, 1990). Silverman et al (1988) found that the perceptual estimate of the sense of effort involved in breathing during exercise in 6 advanced COPD patients (with mean FEV₁ % of predicted of 37%) correlates closely ($r \geq .92$ for all trials) with respiratory and metabolic measurements (i.e., minute ventilation and oxygen consumption) reflecting the intensity of the physiologic stress. They concluded that the intensity of the sense of effort present during breathing can be reliably assessed by the Borg scale in

patients with stable advanced COPD (Silverman, Barry, Hellerstein, Janos, & Kelsen, 1988). Mahler concluded that the ratings of breathlessness are generally reliable over time and are sensitive to evaluate an intervention in patients with stable respiratory disease (Mahler, 1992). Guyatt and colleagues (1991) suggested that dyspnea following the walk test should be measured along with the 6-minute walk (Guyatt et al., 1991).

Dyspnea can be defined for the patient, that is, “respiratory discomfort or breathlessness” especially if comparisons are planned with other patients or groups (Mahler, 1992). The bottom end of the scale is anchored as the most severe degree of breathlessness experienced by the patients in the past. The top end of the scale is anchored as the sense of breathlessness experienced at rest. The different verbal expressions are placed at appropriate points to represent the ratio properties of the psychophysical relationship between the sensory magnitude of respiratory effort and muscular tension (Stubbing, Ramsdale, Killian, & Cambell, 1983). For the current study, the patients were specifically instructed to scale their degree of discomfort evoked by breathing before the 6- minute walking test, at 2-minute mark of the test, and at the completion of the 6- minute walking test. The subject pointed to the number on three separate Borg scales at different time points for data collection mentioned above, which was immediately recorded by the researcher.

The Health-Related Functional Impairment:

The Sickness Impact Profile (SIP)

The sickness impact profile was first published in 1976. The SIP is a measure of “health-related changes in behavior associated with the carrying out of one’s daily

activities.” (Bergner, Bobbit, Carter, & Gilson, 1981). This measure of functional status includes 136 items that describe behaviors reflecting health-related functional impairment. It is organized into 12 categories: Ambulation, Mobility, Body Care and Movement, Social Interaction, Communication, Alertness Behavior, Emotional Behavior, Sleep and Rest, Eating, Work, Home Management, and Recreation and Pastimes. All categories are combined to provide a composite score for the total SIP; the first three categories are combined to form the SIP Physical Dimension; the next four categories are combined to form the SIP Psychological Dimension; the last five categories are used only in the SIP totalscore. Patients are instructed to rate their current level of functioning by identifying those behaviors of functional impairment that describe them and are caused by their state of health. The SIP is known to provide valid and reliable information on the functional status of respondents. The SIP is scored according to standard procedures, with items summed for each category and reported as a percentage of functional impairment. The possible range of score is 0 to 100%, with higher scores reflecting a lower quality of life. This instrument was developed especially for use in evaluating course and intervention outcomes for chronic diseases and recognized explicit physical and psychological aspects of disability associated with medical conditions. Since its revision in 1981 (Bergner et al., 1981), it has become one of the best known generic health status measures.

Bergner and colleagues (1981) evaluated the convergent and discriminant validity of the Sickness Impact Profile (SIP) by using the multitrait-multimethod technique in COPD patients. Its clinical validity was assessed by determining the relationship between clinical measures of disease and the SIP scores (Bergner, Bobbitt, Carter, & Gilson,

1981). Leidy and Traver (1995) found that 12-minute walking distance ($r=.22$ to $.51$, $p < .01$ to $.05$) and postwalk dyspnea (measured by Borg scale) ($r=.24$ to $.31$, $p < .01$ to $.05$) were significantly correlated with the SIP total, SIP Physical Dimension, and SIP Psychosocial Dimension in 81 COPD patients (Leidy & Traver, 1995). Borson et al. (1992) studied the effect of nortriptyline (an antidepressant and anxiolytic drug) on illness-related activity and behavior measured by the Sickness Impact Profile with 30 American COPD patients; they found there were significant and substantial improvements in SIP scores in the nortriptyline group ($p \leq .02$ to $.007$). The effect size was $.25$ on overall functional disability, $.19$ on physical disability, and $.10$ on psychosocial disability. They found nortriptyline to be superior to placebo in reducing depression. There were no severe drug-related toxicities seen in this study (Borson et al., 1992). Herbert and Gregor (1997) found a moderately strong relationship ($r=-.37$, $p \leq .05$) between the objective (measured by the SIP) and subjective measures of quality of life in 39 severe COPD patients (Herbert & Gregor, 1997).

The overall picture from these studies is that the SIP may differentiate between moderate and severe disease, but it appears to have low sensitivity for mild to moderate disease (Jones, 1991).

The SIP68: the Short Form of SIP

Compared to related instruments, the SIP is very long. Researchers recently developed a short version of the SIP (SIP68) (Bruin, Diederiks, Witt, & Stevens, Philipsen, 1994). The SIP68 was used in the current study. The SIP68 was developed from the original SIP; it contains 68 items, all of which are statements regarding behavior.

The items are divided into six subscales: they are somatic autonomy (SA) (17 items), mobility control (MC) (12 items), psychological autonomy and communication (PAC) (11 items), social behavior (SB) (12 items), emotional stability (ES) (6 items), and mobility range (MR) (10 items). The SA subscale deals with basic somatic functions, such as getting dressed, standing, walking, eating, and the help that is needed with these functions. Items in the MC subscale describe behavior related to the level of control that an individual has over his or her body. Items in this subscale are related to walking, or have to do with hand and are control. The PAC subscale describes behavior associated with the level at which an individual is able to operate without help in areas of mental functioning, including the ability to communicate verbally. The possible consequences of a health deviation in a person's functioning in relation to other people is described in the subscale of SB. Sexual activity, visiting friends, and activities in groups of people are included here. The ES subscale assesses the effect of the respondent's health status on his or her emotional status. Items concerned with irritability and/or acting disagreeably with oneself or others. The final subscale, mobility range, is concerned with the range of actions to which a person has limited and/or disposition, given his or her health status, such as shopping, housecleaning, and taking care of personal business affairs.

The selection of the items in the SIP68 was made on the basis of a multi diagnostic database containing 835 completed SIPs. The subscale "work" and items that were hardly ever checked were removed from the list. Further selection was based on findings from principal components analyses of the remaining items. The internal consistency of the SIP68 has Cronbach's coefficient α s ranging from .49 to .87 for the six selected subscales

in 51 rheumatoid arthritis patients (de Bruin, Buys, de Witte, & Diederiks, 1994). The SIP68 was able to predict total SIP136 scores almost perfectly ($R^2 = .96$) (Bruin et al., 1994). In evaluating the reliability and reproducibility of the SIP68 in 51 rheumatic outpatients, Bruin et al. (1994) found the test-retest reliability of the SIP68 ranged from .90 to .97 (expressed in intraclass correlation coefficient) administered 48 hours apart, its internal consistency ranged from .90 to .92 (expressed in Cronbach's coefficient α) (de Bruin et al., 1994). After a survey with 315 spinal cord injury patients, Post et al. (1996) concluded that the SIP68 is recommended as a useful generic outcome measure for research in rehabilitation medicine (Post, de Bruin, de Witt, & Schrijvers, 1996).

The selected items in the SIP68 were reviewed by 5 Chinese graduate students in health care professions who study in the U.S. and some minor deficiencies in the Chinese version were modified for its use in this study. The scoring of the Chinese SIP68 was calculated without weighting (de Bruin et al., 1994; Post et al., 1996).

Global Health Rating

The Global Health Rating has been used to test for differences in interpretation or completion of the SGRQ in adapting this quality of life instrument to a different language and culture (Jones & the nedocromil sodium quality of life study group, 1994; Engstrom, Persson, Larsson, & Sullivan, 1998; Ferrer, Alonso, Prieto, Plaza, Monso, Marrades, Aguar, Khalaf, & Anto, 1996). Its simplicity minimized ambiguities arising in translation (Jones, 1994). In the current study, subjects completed a four point scale for Global Health Rating, the categories of which were: no problem; slightly impaired; moderately impaired; and severely impaired.

Procedures in Data Collection

After obtained written consent from the patients, the FEV₁ was obtained by a Vitalograph spirometer. During the clinical visit, in addition to the Chinese version of the SGRQ, patients completed the Chinese version of SIP68 as well. The SGRQ and SIP68 were randomly ordered, half of the participants responded first to the SGRQ, and the other half responded to the SIP68 before the SGRQ.

During the 6-minute walk, the ratings on the modified Borg Scale were also collected. The perception of shortness of breath data was collected prior to the 6-minute walk, at the 2-minute mark of the walk, and at the completion of the 6-minute walk. All were recorded for data analysis. (See Appendix B for Study Instrument and Protocols).

The order of tests in the current study was:

1. performed three forced vital capacity maneuvers on a Vitalograph spirometer, with the best FEV₁ and FVC used for data analysis
2. CSGRQ (half of patients took SIP68 before CSGRQ)
3. Chinese SIP68
4. Borg ratings of breathlessness at rest
5. 6-minute walking test
6. Borg ratings of breathlessness in breathing at the 2-minute mark.
7. Borg ratings of breathlessness at the completion of the 6- minute walk.
8. Demographic and disease information that was not recorded in charts, patients' global health rating, and what patients think the problem of their disease is were also collected.

Sample

The sample was obtained from the outpatient respiratory clinic in the Tri-Service

General Hospital, Taipei, Taiwan. One hundred and nine patients who met the inclusion criteria were identified between July 20 and September 15, 1998. Five potential subjects refused to participate; they were either not interested in providing information for this study or they didn't like to be investigated. Four participants were excluded because they couldn't perform the pulmonary function tests under the researcher's instruction.

Eighty one percent of the participants were male. Eighty two percent of the participants were aged 65 and/or more, their mean age was 71.5 years old ($SD= 7.9$). The average years of education was 8.2 ($SD= 5.7$). Seventy six percent were married and lived with their spouse. Demographic data are summarized in Table3-1.

Table 3-1.

Subjects' report of demographic data and smoking history (N=100)

	Percentage	M	SD
Gender			
Male	81		
Female	19		
Age		71.5 (years old)	7.9
50~64	18		
65~74	43		
75~84	35		
85~88	4		
Levels of Education		8.2 (years of education)	5.7
No school	19		
Elementary	30		
Middle school	11		
High school	11		
College	27		
Graduate school	2		
Marriage Status			
Married	76		
Widowed	20		
Single	2		
Separated	1		
Divorced	1		

M= mean, SD= Standard Deviation

Protection of Rights of Human Subjects

The proposal of this study was sent to the Institutional Review Board (IRB), both at the Oregon Health Sciences University and the medical center in Taipei, Taiwan for human subjects review. Several strategies were applied to protect the rights of human subjects. Possible subjects were informed that participation is voluntary and that they had the right to refuse to participate or withdraw at any time. Because most patients were accompanied by at least one family member or friend, assent was obtained from their accompanying family member. Family members or friend who disagree with patient's participation in the study would blame the patient for giving consent. In their thinking, rest is the most important thing for diseased patients. Responding to the questionnaires and doing some tests do not benefit the patients and probably may make patients feel tired. To protect the patients from these awkward situations, assent was obtained from their companion(s). In this study, those who refused to participate were refused by the patients; family members accompanying patients were very cooperative and willing to help the patients to do their best in completing research instruments and tests.

Confidentiality of the subjects is assured at all times. Each subject was assigned an identification number. Responses to questionnaire items and tests were identified by the assigned subject number only. Data were coded and entered by subject number into a personal computer in the investigator's home. The original records of the results were kept in a file drawer accessible only to the investigator. A record of subject names and identification number were kept in a file separate from the data. All data are stored in a locked file cabinet in Taiwan and are only accessible to the researcher.

CHAPTER IV

RESULTS

This chapter will first present statistics of COPD-related characteristics of the sample, followed by descriptive statistics of main variables in this study. Internal consistency reliability estimates and item analysis were computed for scales on the Chinese version of the St George's Respiratory Questionnaire (CSGRQ) using responses from 100 participants in Taiwan. Initial evidence for construct validity is provided by using a variety of methods. Finally, some anecdotal data regarding what is missing from the questionnaire and researcher's observation during data collection are provided.

Descriptive Statistics

The SPSS (Statistical Program for the Social Sciences) for Windows was used for the analysis of data obtained in this study. Descriptive statistics were computed for the data on quality of life (the CSGRQ), the impaired health function (the SIP68), lung function (the FEV₁ % of predicted value and the ratio of FEV₁ and FVC), exercise capacity (the 6-minute walking distance), and dyspnea (breathlessness) (on the Borg scales) before, during, and after the completion of the walk test.

Descriptive Statistics for Main Study Variables

The CSGRQ data were available from 100 patients. Analysis was completed on 100 participants' data on all but three variables. Among the 100 participants who took the tests for this study, 15 of them couldn't complete the 6-minute walking test, but they did complete a 2-minute walking test. The dyspnea rating on a Borg scale after completion of 6-minute walking test also had 15 missing data points. Finally, because the 17 items on the somatic autonomy (SA) subscale of the SIP68 referred to extremely disabled conditions (e.g., I got around in a wheelchair), no subjects checked these items. Thus the items had a

zero variance and were not included in the data analysis.

The sample was divided into three groups according to the American Thoracic Society's (ATS, 1995) statements on proposal of staging COPD, the criteria of the ATS statement on interpretation of lung function are: Stage I is $FEV_1 \geq 50\%$ predicted, Stage II is FEV_1 35 to 49% predicted, and Stage III is $FEV_1 < 35\%$ predicted. In the United States, Stage I COPD comprises the great majority of patients. Stage II COPD includes a minority of patients. Stage III COPD also includes a minority of patients (ATS, 1995). Sixty four percent of patients in this study had Stage I COPD, 25% had Stage II COPD, and 11% had Stage III COPD. In this study, the missing data (percentage) for the 6-minute walk test for each stage was 7 (11%) from Stage I, 2 (8%) from Stage II, and 6 (55%) from Stage III. There were disproportional missing data from Stage III. For those who did not complete 6-minute walk test, some patients refused to walk more after the 2-minute walk break, and some were unable to walk further.

COPD-related characteristics of participants are listed in Table 4.1. The number of hospitalized days was calculated by counting the nights patients stayed in a hospital over last year. The number of hospitalized times was calculated by adding hospitalized times and emergency room visits over last year which was/were due to their chest problems. The inconsistency between hospitalized times and hospitalized days were because some emergency room visits did not lead to staying overnight, so patients might have one hospitalized time but have a zero hospitalized day according to the definition of this term. Table 4.2 shows the smoking status of the participants. Table 4.3 shows descriptive statistics for main study variables.

Table 4.1.
Descriptive statistics for COPD-related characteristics of the sample (N=100)

	Percentage	M	SD
FEV ₁ % of Predicted		60.7	20.9
50 -118%	64		
35 - 49.9%	25		
20 - 34.9%	11		
FEV ₁ /FVC		52.0	14.0
60 -75.2%	38		
40 -59.9%	37		
23 -39.9%	25		
O ₂ user			
No	95		
Yes	5		
Global Health Rating			
Nothing	19		
Mild	29		
Moderate	30		
Severe	22		
Hospitalized Days/ Last Year		7.4	14.1
0	63		
1 - 10	14		
11 - 20	10		
21 - 30	7		
31 - 76	6		
Hospitalized Times and ER Visits/ Last Year		.9	1.2
0	48		
1	29		
2	15		
3 or more	8		

M= mean, SD= Standard Deviation

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

FEV₁: forced expiratory volume in one second; FVC: forced vital capacity

Table 4.2.
Smoking status of the sample (N=100)

	Percentage	M	SD
Smoking Status			
Never smoked	17		
Past smoker	56		
Current smoker	27		
Number of Cigarettes Consumed Packs/ Day		1.0	.8
0	17		
1	57		
2	20		
3	4		
4-5	2		
Years of Having/Had Smoked		35.2	20.8
0	17		
1 - 10	3		
11 - 20	9		
21 - 30	8		
31 - 40	14		
41 - 50	29		
51 - 60	17		
61 - 70	3		

M= mean, SD= Standard Deviation

Table 4.3.

Descriptive statistics for main study variables (N=100)

	Mean	SD	Range	% missing data
CSGRQ: Symptoms	40.0	21.2	0 - 100.0	0
Activity	30.3	20.3	0 - 80.3	0
Impacts	23.6	17.5	0 - 69.3	0
Total	28.4	16.9	0 - 66.6	0
SIP68: Total	4.5	3.7	0 - 16	0
MC	2.2	1.6	0 - 5	0
PAC	.02	.1	0 - 1	0
SB	1.5	1.4	0 - 6	0
ES	.05	.3	0 - 2	0
MR	.8	1.3	0 - 8	0
FEV ₁ % pred	60.7	20.9	20.0 - 118	0
FEV ₁ / FVC	52.0	14.1	23.0 - 75.2	0
2MWD (meters)	113.7	27.5	45.5 - 186.3	0
6MWD (meters)	348.8	79.4	124.2 - 538.2	15
Borg at rest	.3	.6	0 - 2	0
Borg2	1.4	1.3	0 - 7	0
Borg6	2.3	1.6	0 - 8	15

CSGRQ: Chinese version of the St George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, PAC: psychological autonomy and communication,

SB: social behavior, ES: emotional stability, and MR: mobility range.

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

FEV₁: forced expiratory volume in one second; FVC: forced vital capacity,

2MWD: distance walked in 2 minutes in meters,

6MWD: distance walked in 6 minutes in meters (N=85),

Borg at rest: dyspnea rating at rest on a Borg scale,

Borg2: dyspnea rating after 2-minute walk on a Borg scale,

Borg6: dyspnea rating after 6-minute walk on a Borg scale (N=85).

Reliability Assessments

Item-total Correlation Assessment for the CSGRQ

Item-total correlations between each individual item of each section of the CSGRQ (i.e., Symptoms, Activity, and Impacts of the SGRQ) and the remaining items in each section were calculated. The corrected item-total correlations (corrected for overlap) ranged from .35 to .57 for Symptoms of the CSGRQ, -.03 to .67 for Activity of the CSGRQ, -.11 to .64 for Impacts of the CSGRQ. The highest mean corrected item-total correlation was .47 for the Symptoms section, with somewhat lower mean corrected item-total correlations for the Activity section (mean $r = .39$) and for the Impacts section (mean $r = .39$).

Internal Consistency Reliability of Scales

Internal consistency of each section score of the CSGRQ was assessed by the Cronbach's α coefficient. The Cronbach's α coefficient was .76 for the Symptoms section, .79 for the Activity section, .86 for the Impacts section, and .92 for the total CSGRQ. The Cronbach's α coefficient of the SIP68 was .82 in this sample. These α values were greater than .70 and reached an acceptable level (Nunnally, 1978).

Table 4.4 shows results from tests of scaling properties of the CSGRQ sections in Chinese COPD patients. Table 4.5 shows the results of this study compared with results from countries using different language versions of the SGRQ. The mean scores in each section of the CSGRQ were significantly lower ($p < .01$) than those found in the Spanish (Ferrer et al., 1996) and in the Swedish (Engstrom, Persson, Larsson, & Sullivan, 1998) versions. It also shows more floor effect in the Chinese SGRQ. Except for the item-convergent validity of the Symptoms section, the ranges of item-convergent and item-discriminant validity were somewhat larger in the Chinese SGRQ than in other language versions.

Table 4.4.

Results from tests of scaling properties of the CSGRO subscales in COPD patients(N=100)

	Chinese Version of the St George's Respiratory Questionnaire			
	Symptoms	Activity	Impacts	Total
Items n	8	16	26	50
Number of possible scale levels in the range	29	16	31	76
Incomplete scale scores %	0	0	0	0
Theoretical range	0-100	0-100	0-100	0-100
Observed range	0-100	0-80	0-69	0-67
At ceiling %	1	0	0	0
At floor %	3	11	4	1
Item-convergent validity#	.47 (.35-.57)	.39 (-.03-.67)	.39 (-.11-.64)	-
Item-discriminant validity*	.34 (.17-.63)	.30 (-.12-.67)	.30 (-.11-.71)	-
Cronbach's α coefficient	.76	.79	.86	.92

#Mean (range) corrected item-total correlation (corrected for overlap).

*Mean (range) correlation between items and other scales.

Table 4.5.

Results from tests of scaling properties of the CSGRQ subscales compared with results from countries with different languages

	Different Versions of the St George's Respiratory Questionnaire		
	Chinese (N=100)	Spanish (N=318)	Swedish (N=68)
Descriptive statistics of observed range			
Symptoms	0-100	0-100	6-100
Activity	0-80	0-100	6- 93
Impacts	0-69	0- 95	0- 86
Total	0-67	2- 96	5- 91
Mean scores: (SD in parentheses)			
Symptoms	40.0 (21.2)	46.4 (21.6)**	54.5 (24.9)**
Activity	30.3 (20.3)	53.9 (26.2)**	60.7 (20.9)**
Impacts	23.6 (17.5)	36.5 (22.6)**	34.5 (19.8)**
Total	28.4 (16.9)	43.4 (21.4)**	46.0 (18.3)**
Ceiling and Floor effects :			
At ceiling %	1	9	1.2
Symptoms	0	4	0
Activity	0	2	0
Impacts	0	0	0
Total			
At floor %			
Symptoms	3	3	0
Activity	11	4	0
Impacts	4	0	8.6
Total	1	0	0
Item analysis and reliability statistics (range in parentheses)			
Item-convergent validity#	.47 (.35 -.57)	NA (.30- .63)	.55 (.40-.67)
Symptoms	.39 (-.03 -.67)	NA (.41-.66)	.55 (.34-.68)
Activity	.39 (-.11 -.64)	NA (.12-.65)	.44 (.17-.75)
Impacts			
Item-discriminant validity#			
Symptoms	.34 (.17-.63)	NA (.23-.41)	.40 (.22-.68)
Activity	.30 (-.12-.67)	NA (.23-.63)	.42 (.02-.64)
Impacts	.31 (-.11-.71)	NA (.14-.66)	.34 (-.06-.70)
Cronbach's α coefficients			
Symptoms	.76	.72	.81
Activity	.79	.89	.88
Impacts	.86	.89	.88
Total	.92	.94	.91

#Mean (range) correlation between items and other scales, NA= Not Available.

** p-value < .01 significant differences compared to Chinese SGRQ mean scores.

Validity Assessments

Construct validity was obtained using several different strategies (Messick, 1980). Construct validity of the questionnaire was assessed following four approaches. First, the correlations between clinical measures and the CSGRQ were analyzed (see Table 4.6).

Second, the pattern of relationships between the overall CSGRQ score and pulmonary function (FEV_1 % of predicted) and symptoms (the Borg scales) were compared to that of a generic HRQL measure, the SIP68 (see Table 4.6). The CSGRQ total, Activity, and Impacts scores had high correlations with dyspnea after 6-minute walking test on the Borg Scale ($r = .57 - .62$). The Symptoms subscale correlated moderately with dyspnea after 6-minute walking test ($r = .41$). The CSGRQ exhibited moderate negative correlations with the 6-minute walk distance and FEV_1 % of predicted ($r = -.32$ to $-.48$). Correlations of most of the SIP68 subscales (mobility control, social behavior, and mobility range) and SIP68 Total scores with two of these clinical indicators were lower than those found for the CSGRQ scores ($r = .41 - .53$ for dyspnea after 6-minute walking test; $r = -.29$ to $-.41$ for FEV_1 % of predicted). Correlations between these SIP 68 subscales and distance walked in 6 minutes were somewhat stronger than those with the CSGRQ ($r = -.39$ to $-.68$ for SIP68 compared to $r = -.33$ to $-.48$ for CSGRQ).

Table 4.7 shows correlations between subscales of CSGRQ and SIP68 scores. Correlations for Activity, Impacts, and Total scores of the CSGRQ with the two dimensions of the SIP68 addressing similar concepts (mobility control and social behavior) were higher ($r = .54 - .66$, $p < .01$) than correlations with noncomparable SIP68 dimensions (emotional stability, and mobility range) (range $r = .26 - .49$, $p < .01$). The psychological autonomy and communication subscale of the SIP68 had nonsignificant correlations with dyspnea after 6-minute walk and distance walked in 6 minutes.

Table 4.6.

Correlation coefficients between lung function, 2-minute walk distance, 6-minute walk distance, dyspnea at rest, after 2-minute walk, 6-minute walk, and HRQL scores

	FEV ₁ % predicted (N=100)	FEV ₁ /FVC (N=100)	Distance walked in		Dyspnea after		
			2 minutes (N=100)	6 minutes (N=85)	at rest (N=100)	2-minute (N=100)	6-minute walk (N=85)
			CSGRQ:				
Symptoms	-.42**	-.43**	-.35**	-.33**	.39**	.41**	.41**
Activity	-.42**	-.40**	-.55**	-.48**	.42**	.52**	.57**
Impacts	-.32**	-.37**	-.44**	-.39**	.45**	.54**	.58**
Total	-.41**	-.44**	-.51**	-.46**	.48**	.57**	.62**
SIP68							
MC	-.41**	-.30**	-.68**	-.68**	.39**	.45**	.52**
PAC	-.12	-.11	-.08	-.09	.04	.02	-.03
SB	-.29**	-.24*	-.39**	-.39**	.33**	.45**	.41**
ES	-.23*	-.15	-.11	-.11	.26*	.44**	.19
MR	-.32**	-.22*	-.53**	-.53**	.57**	.55**	.53**
Total	-.43**	-.32**	-.65**	-.67**	.52**	.60**	.60**

* p-value < .05; ** p-value < .01.

CSGRQ: Chinese version of the St George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, PAC: psychological autonomy and communication,

SB: social behavior, ES: emotional stability, and MR: mobility range.

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

Table 4.7.

Correlations between subscales of SGRQ and SIP68 scores (N=100)

	Symptoms	Activity	Impacts	CSGRQ total	MC	PAC	SB	ES	MR
CSGRQ:									
Activity	.47**								
Impacts	.63**	.76**							
Total	.73**	.88**	.96**						
SIP68:									
MC	.35**	.66**	.54**	.61**					
PAC	.09	-.02	-.01	.01	.12				
SB	.33*	.62**	.63**	.64**	.59**	.15			
ES	.32**	.26*	.29**	.32**	.16	-.02	.25*		
MR	.22*	.49**	.38**	.43**	.49**	-.03	.47**	.13	
Total	.39**	.72**	.64**	.69**	.86**	.14	.84**	.29**	.77**

*p-value < .05; ** p-value < .01.

CSGRQ: Chinese version of the St George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, PAC: psychological autonomy and communication,

SB: social behavior, ES: emotional stability, and MR: mobility range.

Third, convergent and discriminant validity of health constructs assessed by the CSGRQ were examined. Its item-discriminant validity was assessed by correlation coefficients between each item and the other two scales in the CSGRQ. As expected, the mean item-discriminant correlations were lower than their respective convergent correlations; the mean discriminant correlations were .34 for the Symptoms section, .30 for the Activity section, and .30 for the Impacts section (see Table 4.4).

Finally, to provide information about the underlying nature of each section, the proportion of variance of each CSGRQ section explained by other independent variables was computed. Table 4.8 shows the correlations between predictor and dependent variables in regression models. Hierarchical multiple regression analysis was carried out with each CSGRQ section score as the dependent variables (see Figure 4.1 and Figure 4.2). Smoking history, hospitalized times for chest problems, FEV₁ % of predicted, distance walked in 6 minutes, and dyspnea after 6-minute walking test were used to predict the CSGRQ total and section scores as well as the SIP68 and its subscales.

Smoking history, a risk factor for COPD and the first predictor entered, is an existing objective variable that is easy to obtain. This was a dichotomous variable with a yes or no answer. Hospitalized times over the last year caused by patients' chest problems, the second predictor entered, could be reviewed from patient's medical chart as well as patient's self report. This included patient's emergency room visits over the last year. FEV₁ % of predicted, the third predictor entered, is a physiological measure often used as a diagnostic or follow-up measure for COPD patients. Most research about COPD used FEV₁% predicted as one of the COPD-related characteristics, FEV₁% predicted was used for comparison with other research. Distance walked in 6 minutes, the fourth predictor

entered, is an objective measure to evaluate patients' exercise capacity. These four independent variables which are relatively objective in nature (smoking history, hospitalized times for chest problems, FEV₁ % of predicted, distance walked) were included as predictors in regression analyses. Dyspnea on exertion is a major symptom for which patients seek medical help. However, the rating of dyspnea at rest has often been used in the literature. The average FEV₁ % of predicted in the present study was higher than previous research. This may indicate that the subjects' disease in this study was less severe. Therefore, the rating of dyspnea at rest was not used in the regression analysis. Instead, a subjective variable, dyspnea after walking test, was the fifth and last variable to enter the regression analysis to explain the variance in the CSGRQ and the SIP68 scores.

Because there were 15 participants who could not complete the 6-minute walking test, two models were computed which differ on two predictors: Model 1 with distance walked in 2 minutes, dyspnea rating after 2-minute walk on a Borg scale, and Model 2 with distance walked in 6 minutes, dyspnea rating after 6-minute walk on a Borg scale. The percentage of variance explained for Model 1 and Model 2 were basically the same in the CSGRQ scores and the SIP68 scores.

With five independent variables, 47% of the variance in the CSGRQ total score was accounted for compared to 58% in the SIP68 total score in Model 2. The pattern of prediction differed, however, for the CSGRQ and SIP68 total scores. Three predictors, smoking history, hospitalized times for chest problems, and FEV₁ % of predicted accounted for 19.6% to 28.9% of the variance in the CSGRQ scores as compared to 16.5% to 29.4% in the SIP68 scores in Model 2. For Model 2, the fourth predictor, 6-minute walk distance, explained more variance in the SIP68 scores (5.4% to 28.2%) than

in the CSGRQ scores (1.2% to 9.2%). The fifth predictor, dyspnea after 6-minute walk, explained more variance in the CSGRQ scores (1.4% to 15.3%) than in the SIP68 scores (2.5% to 6.4%). Figure 4.1 shows these regression models with the CSGRQ, the SIP68, and their subscales in Model 1. Figure 4.2 shows these regression models with the CSGRQ, the SIP68, and their subscales in Model 2. Table 4.9 shows the variance change and the standardized β coefficients at final step for each dependent variable using Model 1. Table 4.10 shows the R^2 change and the standardized β coefficients at final step for each dependent variable using Model 2. Table 4.11 compares the differences of R^2 explained by these two models.

Because the sample size was only 100, factor analysis procedures were not used to assess construct validity of the CSGRQ. Construct validity of the CSGRQ was supported as similar correlations between the CSGRQ scores and other clinical variables emerged as described by the instrument developers. Most of the expected relations for convergent and discriminant validity were confirmed.

Table 4.8.

Correlations between predictors and dependent variables in regression models

Predictors	Dependent Variables							
	SGRQ:				SIP68:			
	Symptoms	Activity	Impacts	Total	MC	SB	MR	Total
Smoking history	.26**	.24**	.30**	.35**	.26**	.25*	.11	.26*
Hospitalized times	.41*	.26*	.30**	.34**	.27**	.25*	.26**	.34**
FEV ₁	-.42**	-.42**	-.32**	-.41**	-.41**	-.29*	-.32*	-.43**
2MWD	-.35**	-.55**	-.44**	-.51**	-.68**	-.39**	-.53**	-.67**
6MWD	-.33**	-.48**	-.39**	-.46**	-.68**	-.39**	-.53**	-.67**
Borg2	.41**	.52**	.54**	.57**	.45**	.45**	.55**	.60**
Borg6	.41**	.57**	.58**	.62**	.52**	.41**	.53**	.60**

*p-value < .05; ** p-value < .01.

CSGRQ: Chinese version of the St George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, SB: social behavior, and MR: mobility range.

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

2MWD: distance walked in 2 minutes,

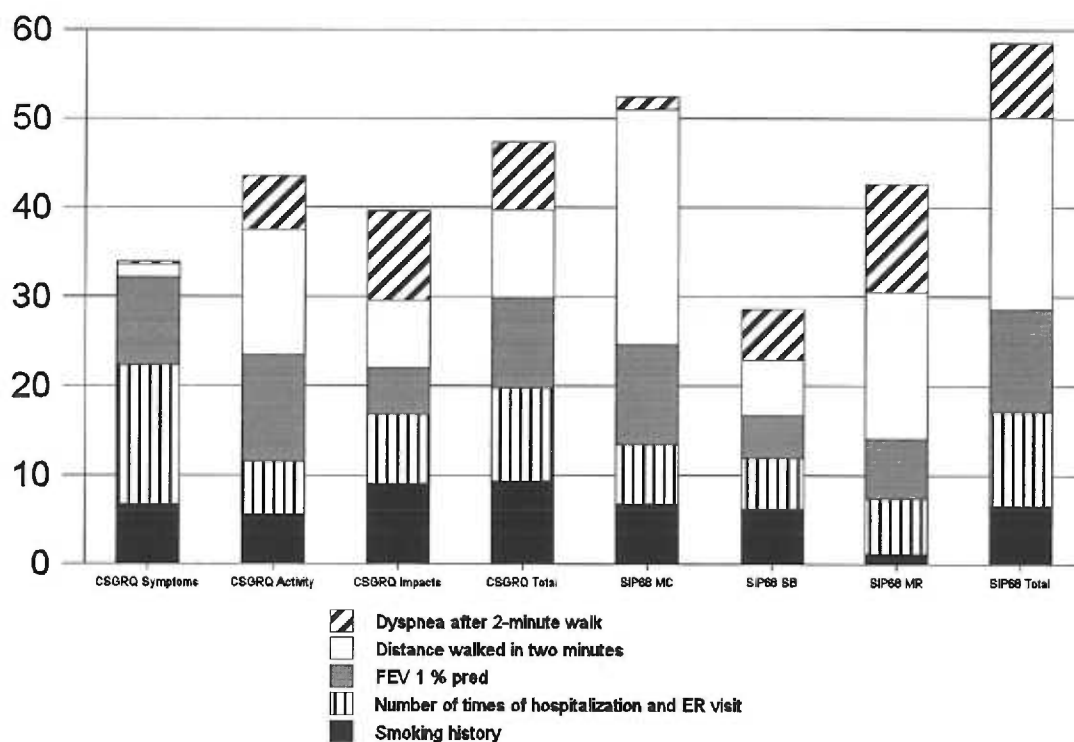
6MWD: distance walked in 6 minutes,

Borg2: dyspnea rating after 2-minute walk on a Borg scale.

Borg6: dyspnea rating after 6-minute walk on a Borg scale.

Figure 4.1. Percentage of variance explained by each of five sequentially entered predictors in MODEL 1 in which the dependent variables were each section of the CSGRQ and the SIP68 subscales (N=100)

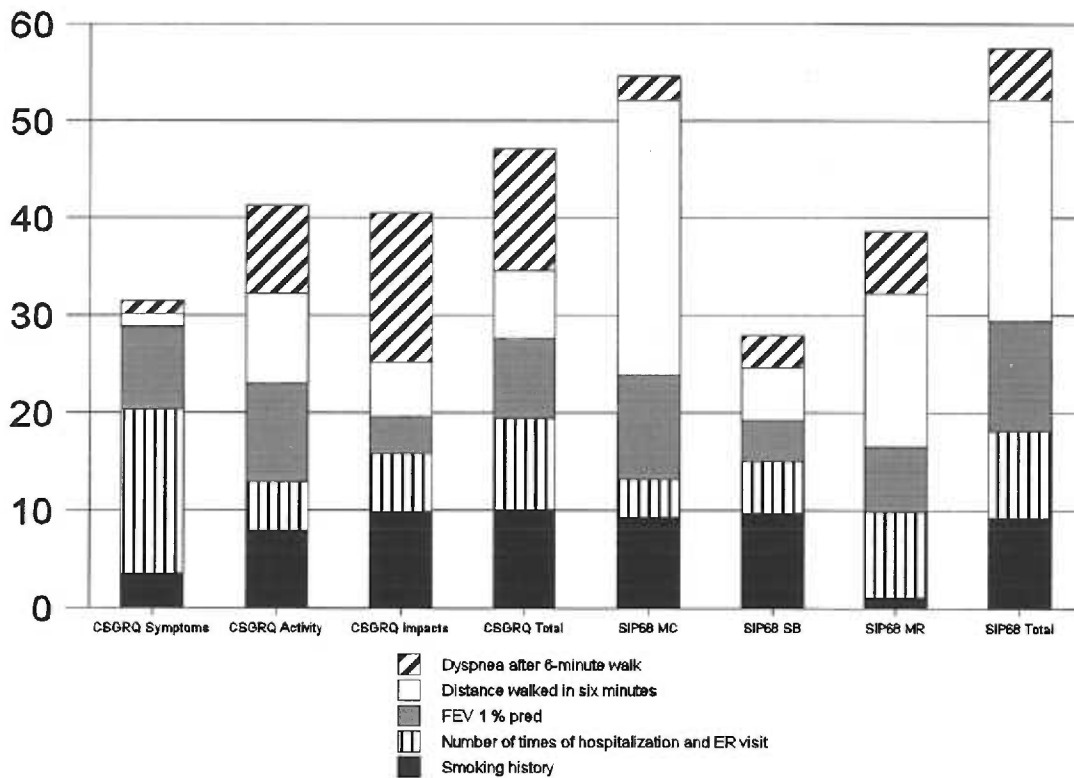
% of variance



CSGRQ: Chinese version of the St. George's Respiratory Questionnaire,
 SIP68: Sickness Impact Profile, short form;
 MC: mobility control, SB: social behavior, and MR: mobility range.
 FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

Figure 4.2. Percentage of variance explained by each of five sequentially entered predictors in MODEL 2 in which the dependent variables were each section of the CSGRQ and the SIP68 subscales (N=85)

% of variance



CSGRQ: Chinese version of the St. George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, SB: social behavior, and MR: mobility range.

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

Table 4.9. R^2 change and standardized β coefficients at final step of predictors in each regression analysis in MODEL 1 of the SGRQ, the SIP68, and their subscales (N=100)

Predictors	Dependent Variables												
	CSGRQ					SIP68							
	Symptoms	Activity	Impacts	Total	MC	SB	MR	Total	MC	SB	MR	Total	
Smoking history	ΔR^2	.067	.056	.090	.093	.068	.062	.011	.066	.068	.062	.011	.066
	β	.19*	.14*	.22**	.21**	.16*	.17*	.003	.14*	.16*	.17*	.003	.14*
Hospitalized times	ΔR^2	.156	.059	.078	.105	.066	.057	.063	.105	.066	.057	.063	.105
	β	.27**	-.02	.03	.07	.03	.03	-.04	.03	.03	.03	-.04	.03
FEV ₁ % pred	ΔR^2	.099	.120	.052	.101	.112	.048	.067	.115	.112	.048	.067	.115
	β	-.25**	-.07	.04	-.06	-.07	.002	.08	-.01	-.07	.002	.08	-.01
2MWD	ΔR^2	.014	.140	.076	.098	.264	.062	.164	.215	.264	.062	.164	.215
	β	-.12	-.38**	-.25**	-.30**	-.56**	-.24**	-.39**	-.47**	-.56**	-.24**	-.39**	-.47**
Borg2	ΔR^2	.003	.060	.100	.076	.014	.057	.121	.084	.014	.057	.121	.084
	β	.08	.33**	.42**	.37**	.16*	.32**	.46**	.38**	.16*	.32**	.46**	.38**

*p-value < .05; ** p-value < .01.

CSGRQ: Chinese version of the St. George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, SB: social behavior, and MR: mobility range.

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

2MWD: distance walked in two minutes,

Borg2: dyspnea rating after 2-minute walk on a Borg scale.

Table 4.10. R^2 change and standardized β coefficients at final step of predictors in each regression analysis in MODEL 2 of the SGRQ, the SIP68, and their subscales (N=85)

Predictors	Dependent Variables										
	CSGRQ						SIP68				
	Symptoms	Activity	Impacts	Total	MC	SB	MR	Total			
Smoking history	ΔR^2	.035	.080	.099	.101	.093	.098	.011	.093		
	β	.15	.18*	.22**	.22**	.17*	.24**	-.01	.18*		
Hospitalized times	ΔR^2	.168	.049	.059	.093	.039	.052	.088	.088		
	β	.30**	.03	.08	.12	-.02	.10	.11	.08		
FEV ₁ % pred	ΔR^2	.086	.101	.038	.082	.107	.042	.066	.113		
	β	-.21*	-.08	.07	-.04	-.08	-.05	-.01	-.07		
6MWD	ΔR^2	.012	.092	.056	.070	.282	.054	.157	.228		
	β	-.08	-.22*	-.11	-.16	-.53**	-.19	-.34**	-.44**		
Borg6	ΔR^2	.014	.091	.153	.125	.025	.033	.064	.053		
	β	.15	.39**	.50**	.45**	.20*	.23*	.32**	.30**		

*p-value < .05; ** p-value < .01.

CSGRQ: Chinese version of the St. George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, SB: social behavior, and MR: mobility range.

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

6MWD: distance walked in 6 minutes,

Borg6: dyspnea rating after 6-minute walk on a Borg scale.

Table 4.11. Comparison of R² explained by two models, which differ on two predictors on the CSGRQ and SIP68 subscales

	MODEL 1: Smoking history, hospitalized times, FEV₁ % pred, 2MWD, and Borg 2 R ² explained (N=100)	MODEL 2: Smoking history, hospitalized times, FEV₁ % pred, 6MWD, and Borg 6 R ² explained (N=85)
CSGRQ Symptoms	.34	.32
CSGRQ Activity	.44	.41
CSGRQ Impacts	.40	.40
CSGRQ Total	.47	.47
SIP MC	.52	.54
SIP SB	.29	.28
SIP MR	.43	.39
SIP Total	.58	.58

CSGRQ: Chinese version of the St. George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, SB: social behavior, and MR: mobility range.

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

2MWD: distance walked in two minutes,

6MWD: distance walked in six minutes,

Borg2: dyspnea rating after 2-minute walk on a Borg scale.

Borg6: dyspnea rating after 6-minute walk on a Borg scale.

Characters in bold highlight differences in regression models.

Hypothesis-Testing Procedures on the CSGRQ

A hypothesis-testing procedure was performed to assess construct validity of the CSGRQ. Hypotheses based on the literature review for this study included:

1. CSGRQ scores will be negatively related to lung measurement (FEV₁ % of predicted).
2. CSGRQ scores will be negatively related to distance walked in 6 minutes.
3. CSGRQ scores will be positively related to ratings on the Borg scales at rest.
4. CSGRQ scores will be positively related to the SIP68.

Pearson's product-moment correlation coefficients and ANOVA were used to examine these hypotheses. The level of probability was set at $p < .05$.

Hypothesis 1. Correlations between CSGRQ and its three sections with FEV₁ % of predicted and the ratio of FEV₁/FVC were computed. Both FEV₁ % of predicted and the ratio of FEV₁/FVC showed negative correlations with the CSGRQ total score and its three sections ($r = -.32$ to $-.44$) (see Table 4.6). The correlations between the FEV₁/FVC and the CSGRQ scores were higher than those with FEV₁% predicted except for the Activity section of the CSGRQ. This hypothesis was further examined by dividing the sample into three stages according to various degree of FEV₁% predicted: Stage I (N=64) whose FEV₁ % of predicted was greater or equal to 50%, Stage II (N=25) whose FEV₁ % of predicted fell between 35% and 49.9%, and Stage III (N=11) whose FEV₁ % of predicted was less than 35%. These categories were determined by the criteria of stages of COPD severity by the American Thoracic Society (1995). One-way analysis of variance (ANOVA) was used to compare differences in the mean scores on the CSGRQ among

three stages. Patients in Stage 3 demonstrated significantly higher scores (worse quality of life) in the CSGRQ Impacts and total scores than those in Stage 1 and Stage 2. Patients in Stage 3 also demonstrated significantly worse quality of life in the CSGRQ Symptoms and Activity scores than patients in Stage 1. Comparison of the three stages were also done for the SIP68 scores, distance walked, and dyspnea ratings after walk test. Five of eight ANOVAs had significant F values. Stage 2 had worse quality of life scores than Stage 1 on SIP68 total and SIP68 mobility control. Stage 3 walked shorter distance in 2 minutes and experienced more difficulty in breathing after 2 and 6 minutes' walk test than than Stage 1 (see table 4.12). These findings lend additional support to Hypothesis 1.

Table 4.12.

Mean scores (Standard Deviation) and ANOVA tests for the CSGRQ and the SIP68 scores on three stages of various degree of FEV₁ % of predicted

	Stage I (N=64)	Stage II (N=25)	Stage III (N=11)	F	Significant Pairwise Differences#
CSGRQ Total	24.4 (16.2)	30.1 (14.1)	47.2 (13.4)	10.43**	III > I, II
CSGRQ Symptoms	35.4 (21.1)	44.0 (15.5)	57.8 (23.3)	6.46**	III > I
CSGRQ Activity	26.0 (18.8)	33.2 (20.5)	49.3 (16.9)	7.42**	III > I
CSGRQ Impacts	20.1 (17.4)	24.0 (14.2)	42.8 (12.5)	9.13**	III > I, II
SIP68 Total	3.6 (3.1)	5.8 (4.3)	6.9 (3.6)	6.49**	II, III > I
SIP68 MC	1.8 (1.6)	2.8 (1.4)	2.8 (1.6)	4.71*	II > I
SIP68 SB	1.3 (1.4)	1.8 (1.5)	2.3 (1.3)	2.85	
SIP68 MR	.5 (.7)	1.2 (2.2)	1.4 (1.2)	3.77*	
Borg 2	.9 (.8)	1.7 (1.3)	3.4 (1.4)	31.4**	III > II > I
Borg 6	(N=57) 1.8 (1.3)	(N=23) 3.0 (1.6)	(N=5) 4.6 (2.3)	12.20**	II, III > I
2MWD meter	119.5 (26.1)	106.6 (28.7)	96.0 (22.6)	4.95**	III < I
6MWD meter	(N=57) 360.2 (78.6)	(N=23) 327.2 (80.4)	(N=5) 317.1 (66.7)	1.88	

*p-value < .05; ** p-value < .01.

The mean difference by Scheffe test is significant at the .01 level

CSGRQ: Chinese version of the St George's Respiratory Questionnaire,

SIP68: Sickness Impact Profile, short form;

MC: mobility control, SB: social behavior, and MR: mobility range.

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second,

2MWDmeter: distance walked in 2 minutes in meters,

6MWDmeter: distance walked in 6 minutes in meters.

Borg2: dyspnea rating after 2-minute walk on a Borg scale.

Borg6: dyspnea rating after 6-minute walk on a Borg scale.

Hypothesis 2. Correlations between the CSGRQ scores and distance walked in 6 minutes were computed. There were 15 participants who could not complete the 6-minute walk test, but they did complete the walking test for 2 minutes. The CSGRQ scores were negatively correlated with distance walked. The Activity section of the CSGRQ showed the highest correlation ($r=-.48$) and the Symptoms section of the CSGRQ showed the lowest correlation ($r=-.33$) with distance walked in 6 minutes. Moreover, there were slightly stronger correlations between the CSGRQ scores and 2 minutes' walk distance than that with 6 minutes' walk distance (r ranged from $-.35$ to $-.55$ for the 2-minute walk distance compared to $-.33$ to $-.48$ for the 6-minute walk distance) (see Table 4.6). The findings supported Hypothesis 2.

Hypothesis 3. Correlations between the CSGRQ scores and dyspnea ratings on a Borg scale were computed. The researcher collected patients' dyspnea rating after a 2-minute walk break and after the completion of the 6-minute walk test as well as dyspnea ratings at rest. Dyspnea ratings on the Borg scale showed moderate positive correlations with the CSGRQ scores. The total score of the CSGRQ showed the highest correlation ($r=.48$) and the Symptoms section of the CSGRQ showed the lowest correlation ($r=.39$) with dyspnea rating at rest. The correlations became slightly stronger as patients spent a longer time performing the walk test (see Table 4.6). The findings supported Hypothesis 3.

Hypothesis 4. Correlations between the CSGRQ scores and the SIP68 scores were computed. Table 4.7 shows correlations between subscales of the CSGRQ and the SIP68 scores. The correlation between the CSGRQ total score and the SIP68 total score was $.69$

($p < .01$). The Activity section of the CSGRQ showed the highest correlation ($r = .72$) with the SIP68 total score and the Symptoms section of the CSGRQ showed the lowest correlation ($r = .22$) with the Mobility Range subscale of the SIP68. The CSGRQ Activity score also showed moderate to high correlations ($r = .49-.66$) with Mobility Control, Social Behavior, and Mobility Range subscales of the SIP68. The Emotional Stability subscale of the SIP68 showed low correlation coefficients ($r = .26-.32$) with the CSGRQ scores. The Psychological Autonomy and Communication subscale of the SIP68 did not show any significant correlations with the CSGRQ scores. The findings supported Hypothesis 4.

Researcher's Observation

During the interview for data collection, the researcher asked the patients what they thought the problem of their disease was. Various responses were given. Table 4.13 lists the percentage of patients who gave various answers. Some participants responded by giving some specific event or reason about their chest problem (e.g., hemoptysis 21 years ago; genetic predisposition; thick sputum; inhaled some fine powder in work place; allergy to cooking smoke; had pulmonary tuberculosis; bronchiectasis; pleural effusion; respiratory failure; and empyema). These responses by individual subjects were not listed in Table 4.13. Twelve participants said that they did not know what the problem is in their chest; two participants said that they have COPD because they smoked.

During the walk test, some participants were sweating, had hot flushes, used pursed-lip breathing, took off their coat, or reported feeling dizzy; one participant needed

Table 4.13.

Responses and percentage of patients' statements about problems of their diseases

	Percentage
Emphysema	30
Asthma	24
Dyspnea on exertion	21
Don't know	12
Cough	7
Repeated episodes of influenza	6
Pneumonia	3
Bronchitis	3
Smoking	2
Physical injury to chest	2

*The sum of the percentage is greater than 100 because some participants gave more than one response.

to inhale one puff of Berotec during the 2-minute walk break.

After they completed all research instruments, participants were asked about how the disease had affected their life. They expressed their worries and concerns. Statements included lots of “I can not...” and “I’d like to...if I can” and “I am afraid...”. Table 4.14 summarizes patients’ statements and their percentage.

Some participants asked the researcher where they could get a flu shot. Some were worried if regular use of inhalors made their body become addictive to the medication. Others shared with the researcher about how they keep their health condition stable by walking 1 hour every day, by jogging, by practicing Tai-Chi Chuan, or by eating healthy food.

Table 4.14.

Summary of patients' statements and their percentage about how they were affected by

COPD

	Percentage
I can't walk fast	5
I can't carry heavy stuff or do labored work	4
I don't have energy, don't want to move	4
I am afraid to get a flu	3
I'd like to go abroad, go out for fun	3
I can't speak loudly, I can't get angry	2
I can't walk stairs, climb mountains	2

*Percentage is less than 100 because not all participants responded to the question.

CHAPTER V

DISCUSSION AND CONCLUSION

This chapter is organized into four sections. The first section discusses the validity and reliability of the newly translated CSGRQ. The next section examines the usefulness of the CSGRQ for Chinese COPD patients. This section includes its feasibility, length of time for patients to use it, and what it does and does not tell us. Anecdotal data are provided regarding salient content not included in the questionnaire. The third section discusses the limitations of the study. The final section considers the implications of the findings for theory development, clinical practice, and future research. Conclusions are drawn and a brief summary of this research is provided.

The author would like to present the similarities and differences regarding sample characteristics between different language versions of the SGRQ first. Table 5.1 shows comparison of sample characteristics from different studies.

The current study was done with Chinese population to evaluate the reliability and validity of the SGRQ in COPD patients in Taiwan. The sample of this study is significantly older than those reported in the Swedish (Engstrom, Persson, Larsson, Sullivan, 1998) study; the disease severity in this study in terms of FEV₁ % of predicted was less severe than that in the Swedish study. Accordingly, the distance walked in 6 minutes by the Chinese participants was longer than that in the Swedish study. The average hospitalized days was similar between the current study and the Swedish study. This is probably due to the health care expense in Taiwan being relatively cheaper than it is in Sweden or due to patients who were hospitalized needing similar amount of care from the hospital in both

Table 5.1.

Comparison of mean (SD) of sample characteristics from different studies

	Taiwan (Yeh, 1998)	Spain (Ferrer et al., 1996)	Sweden (Engstrom and coworkers, 1998)	England, Finland, Holland, Italy, Thailand, & the U.S. (Jones and co-workers, 1989)
Number of subjects	100	318	68	141
Age: mean (SD)	71.5 (7.9)	NA	64.6 (6.8)**	63
Gender: % of male	81	100	63	NA
FEV ₁ % pred	60.7 (20.9)	44 (18)**	39.9 (17.0)**	47 (23)**
Hospitalized days	7.4 (14.1)	NA	6.1 (16.3)	NA
Distance walked in six minutes in meters	348.8 (79.4)	NA	260.7 (95.7)**	367

SD: standard deviation, NA: Not Available

*Data from Jones, Baveystock, & Littlejohns (1989).

** p-value < .01 significant differences compared to Chinese SGRQ mean scores by t-test.

FEV₁ % pred: percentage of predicted value of forced expiratory volume in one second

countries. Overall, the sample for this study is significantly different from that for the Swedish (Engstrom, Persson, Larsson, Sullivan, 1998) study.

There is not enough information in the Spanish (Ferrer et al., 1996) article to compare the sample characteristics across studies. The only information provided is that all of the participants in the Spanish version study were male, and the average FEV₁ % of predicted was 39.9%, which was significantly lower than the average FEV₁ % of predicted in the current study. Based on this information, the researcher would conclude that the study samples of the Chinese patients and the Spanish patients are likely quite different, too. Nevertheless, the current study demonstrated the same direction and was of similar strength to the correlations between the CSGRQ scores and clinical indicators regarding COPD-related characteristics. Table 5.2 shows corresponding values presented in published articles using the SGRQ in different languages. The correlation between the SGRQ total score and the 6-minute walk test ($r = -.46$) was lower than that in the Engstrom et al. ($r = -.61$) (Engstrom, Persson, Larsson, Sullivan, 1998) and Jones and coworkers ($r = -.61$) (Jones, Baveystock, & Littlejohns, 1989). However, the correlation between the SGRQ total score and FEV₁ % of predicted, SIP total score, and Global Health Rating were similar in these studies.

Table 5.2.

Corresponding correlations with the SGRO total score presented in published articles in different countries

	Taiwan (Yeh, 1998)	Spain (Ferrer et al., 1996)	Sweden (Engstrom et al., 1998)	England, Finland, Holland, Italy, Thailand, & the U.S. (Jones and co-workers, 1989)
FEV ₁ % predicted	-.41**	-.45**	-.42**	-.30**
6MWD	-.46**	NA	-.61**	-.61**
SIP total score	.69**	NA	.69**	.71**
Health rating	.64**	NA	.50**	.63**

** p-value < .01. NA: not available.

*Data from Jones, Baveystock, & Littlejohns (1989).

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second

6MWD: distance walked in 6 minutes,

SIP68: Sickness Impact Profile, short form;

Validity of Newly Translated CSGRQ

The validity of the newly translated CSGRQ (Chinese version of the St George's Respiratory Questionnaire) was evaluated using hypothesis-testing procedures and convergent, discriminant, and construct validity.

Hypothesis-Testing Procedures

Pulmonary function and exercise tolerance are the two most frequently used clinical indicators for assessing patients' condition and evaluating the effect of intervention efforts and have been empirical focal points in attempts to understand variations in functional performance in COPD patients. Symptoms, particularly dyspnea, are regarded as important factors underlying functional difficulties in people with COPD and are a key target of intervention efforts (Leidy & Traver, 1995). Hypothesis 1 stated that the CSGRQ scores will be negatively related to lung measurement (FEV_1 % of predicted). The more impaired the patient's lung function, the higher the CSGRQ scores; a higher CSGRQ score reflects a lower quality of life. The hypothesis was supported in this study, and it is similar to the correlations found in the literature (Okubadejo, Jones, & Wedzicha, 1996; Ketelaar et al., 1996; Wilson, Jones, O'Leary, Cole, & Wilson, 1997; Renwick & Connolly, 1996, and Ferrer et al., 1996). However, in another study of 79 patients with a variety of chronic lung diseased patients in Switzerland (63% of the subjects have COPD), Janssens et al. (1997) found that there were no significant relationships between FEV_1 (% of predicted) with the SGRQ scores (Janssens et al., 1997). Table 5.3 summarizes the correlations between the FEV_1 and the SGRQ scores from different studies.

Table 5.3.

Correlations between the FEV₁ % of predicted and the SGRQ scores from different studies

	Symptoms	Activity	Impacts	Total
Okubadejo, Jones, & Wedzicha, 1996 (N=41 British COPD)		-.34*		
Ketelaar et al., 1996 (N= 126 Dutch COPD)		-.24**		
Wilson, Jones, O'Leary, Cole, & Wilson, 1997 (N= 111 European bronchiectasis)	-.25**	-.36**		
Ferrer et al., 1996 (N= 318 Spanish male COPD)	-.29**	-.53**	-.37**	-.45**
Engstrom, Persson, Larsson, & Sullivan, 1998 (N= 68 Swedish COPD)	NS	-.49**	-.40**	-.42**
Janssens, Rochat, Frey, Dousse, Pichard, & Tschopp, 1997 (N= 79, of which 63 % Swiss COPD)	.18	.03	-.06	-.01
Yeh, 1998 (N= 100 Chinese COPD)	-.42**	-.42**	-.32**	-.41**

*p-value < .05; ** p-value < .01. NS: not significant.

SGRQ: the St George's Respiratory Questionnaire,

FEV₁% pred: percentage of predicted value of forced expiratory volume in one second.

In the present study, the correlations between FEV₁ % of predicted and the Symptoms, Activity, and Total scores were about the same. Although the mean FEV₁ % of predicted in this study was higher (higher FEV₁ % of predicted means better lung function) than other studies (Ferrer et al., 1996; Engstrom, Persson, Larsson, & Sullivan, 1998), the correlation between FEV₁ and the Symptoms section of the CSGRQ was higher than other studies ($r = -.42$). It would be necessary and useful to conduct a qualitative research study designed to explore the meaning of symptoms, activity, and impact in Chinese COPD patients.

Hypothesis 2 stated that the CSGRQ scores will be negatively related to distance walked in 6 minutes. This hypothesis was supported, reflecting the findings reported by Ketelaar et al. (1996) and Janssens et al. (1997). In the present study, the correlations between the CSGRQ scores and distance walked in 2 minutes demonstrated a slightly stronger relationship than that with distance walked in 6 minutes. This probably due to disproportional missing data for the 6-minute walk from Stage III (55% dropped after 2-minute walk).

In their study, Ketelaar et al. (1996) found that the 12-minute walking test was significantly correlated ($p < .001$) with the SGRQ Activity score ($r = -.39$) and Impact score ($r = -.36$) in 126 Dutch COPD patients. They concluded that the 12-minute walking test is one of the determinants of HRQL in patients with severe COPD. However, exercise capacity failed to account for all the variability in HRQL. Emotional reaction and FEV₁ were other variables that had independent influence on HRQL in patients with severe COPD in this study (Ketelaar et al., 1996). In the present study, the 6-minute walking test

accounted for 1.2 to 9.2% of the variance in the CSGRQ scores.

Janssens et al. (1997) found that the average daily distance walked was significantly correlated ($p < .05$) with Activity ($r = -.59$), Impact ($r = -.51$) and Total score ($r = -.55$) of the SGRQ in 32 Switzerland chronic lung diseased patients (Janssens et al., 1997).

In validating the Swedish version of the SGRQ, Engstrom et al. (1998) found that distance walked in 6 minutes was significantly correlated with Symptom ($r = -.37$), activity ($r = -.63$), Impacts ($r = -.53$), and Total ($r = -.61$) scores of the SGRQ (Engstrom, Persson, Larsson, & Sullivan, 1998). In the current study, the Chinese version of the SGRQ also demonstrated significant correlations between distance walked in 6 minutes and Symptom ($r = -.33$), Activity ($r = -.48$), Impacts ($r = -.39$), and Total ($r = -.46$) scores of the SGRQ. The correlations between distance walked in 6 minutes and the CSGRQ scores are lower in this study as compared to those in other studies. This may be due to the fact that the missing data for 6-minute walk test for stage III was disproportional. Selection bias cannot be ignored regarding this study variable.

Hypothesis 3 stated that the CSGRQ scores will be positively related to ratings on the Borg scales at rest. The correlations of the dyspnea ratings on the Borg scale in this study are similar in direction and but slightly lower in strength to findings from other studies (Ferrer et al., 1996; Janssens et al., 1997). Table 5.4 shows correlations between dyspnea and the SGRQ scores from different studies. This may be due to that the mean FEV₁ % of predicted in this study was higher (higher FEV₁ % of predicted means better lung function) than other studies (Ferrer et al., 1996; Janssens et al., 1997).

Table 5.4.

Correlations between dyspnea# at rest and the SGRO scores from different studies

	Symptoms	Activity	Impacts	Total
Ferrer et al., 1996 N=318 Spanish male COPD	.43**	.56**	.56**	.59**
Janssens, Rochat, Frey, Dousse, Pichard, & Tschopp, 1997 N=32 European COPD	NS	.43**	.65**	.58**
Yeh, 1998 (N=100 Chinese COPD)	.39**	.42**	.45**	.48**

#dyspnea: dyspnea rating at rest on a Borg scale

*p-value < .05; ** p-value < .01. NS: not significant.

SGRQ: the St George's Respiratory Questionnaire,

Hypothesis 4 stated that the CSGRQ scores will be positively related to the SIP68. Both the CSGRQ and the SIP68 employ a standard weighting system for all subjects, regardless of their lifestyle or personal preferences. The correlations between the CSGRQ and the SIP68 are comparable to those found in the literature using the generic SIP in terms of the SIP total score (Jones, Quirk, & Baveystock, 1991; Engstrom, Persson, Larsson, & Sullivan, 1998) (see Table 5.2). In a study designed to measure improvement in quality of life of patients with asthma, the SGRQ and SIP were used in a year long double-blind, placebo-controlled, group comparative study with Nedocromil sodium in a multicenter trial from six countries. When country was introduced as a factor into the analysis, the interaction between country and general health assessment was not significant with the SGRQ or SIP scores ($p > .05$). This suggests that cultural or linguistic factors may not have influenced the patients' responses to quality of life measures (Jones et al., 1994).

In the same study, the SGRQ and SIP were administered among many other reference measures. The correlations between representative reference variables and the SIP and the SGRQ total scores were very similar. The Symptom section exhibited low but significant correlations ($p < .01$) with the SIP total ($r = .11$). The Activity section significantly correlated ($p < .0001$) with the SIP total ($r = .38$). The Impact section also significantly correlated ($p < .0001$) with the SIP total ($r = .54$) (Jones, Quirk, & Baveystock, 1991)

The SIP136 was translated into Chinese and used in COPD patients (Hsu & Yin, 1988). Two items from Sleep and Rest and two items from Recreation were removed after

pilot study (132 items left, as SIP132). The remaining 11 categories of the SIP132 had Cronbach's coefficient α ranging from .64 to .80 in 98 COPD patients in Taiwan. In the current study, the Cronbach's α was .82 for the SIP68. The correlation between the CSGRQ total score and the SIP68 total score was .69, which is the same correlation coefficient as in the Swedish version of the SGRQ and the SIP total. This provides additional evidence to the validity of the CSGRQ .

Convergent, Discriminant, and Construct Validity

Convergent and discriminant validity were assessed by corrected item-total correlations. The mean correlations of item-convergent validity and item-discriminant validity were relatively lower than the Swedish (Engstrom, Persson, Larsson, Sullivan, 1998) and Spanish versions (Ferrer et al., 1996) of the SGRQ. The Symptoms section of the CSGRQ and the Swedish SGRQ have the highest mean item-convergent validity ($r=.47$ and $.55$, respectively) and item-discriminant validity ($r=.34$ and $.40$, respectively) among the three sections of the SGRQ scores (Engstrom et al., 1998). Mean item convergent and discriminant validity data were not reported for the Spanish sample (Ferrer et al., 1996). If the average item-convergent correlations differ from the average item-discriminant correlations by around .10, this is typically accepted as adequate evidence of convergent and discriminant validity (Barbara J. Stewart, personal communication, December 5, 1998). The present study was near this criterion. Future research using combined qualitative and quantitative methods to explore items whose item-total correlation coefficients were negative or near to zero in the CSGRQ is needed.

Eight hierarchical multiple regression models were built to examine the construct validity of the CSGRQ and the SIP68. Smoking history, hospitalized times for chest problems, FEV₁ % of predicted, distance walked in 6 minutes, and dyspnea after the 6-

problems, FEV₁ % of predicted, distance walked in 6 minutes, and dyspnea after the 6-minute walking test were used to predict the CSGRQ total and its three section scores as well as the SIP68 total and three subscale scores. These five independent variables explained 47% of the variance in CSGRQ total score compared to 58% of the variance in SIP68 total score. FEV₁ % of predicted accounted for about 4 to 10% of the variance in CSGRQ scores (see Table 4.10) in the regression models which is consistent with that found in the literature (Jones, Baveystock, & Littlejohns, 1989; McSweeney, Grant, Heaton, Adams, & Timms, 1982; Weaver & Narsavage, 1992). The ratings of dyspnea after the 6-minute walking test on a Borg scale accounted for 1 to 15% of the variance in the CSGRQ scores as compared to 3 to 6% of the variance in the SIP68 scores (see Table 4.10). The sensation of dyspnea is a major problem that interferes with COPD patients' daily activities. The distance walked in 6 minutes in these models accounted for 1 to 9% of the variance in the CSGRQ scores as compared to 5 to 28% of the variance explained in the SIP68 scores.

Furthermore, the ANOVA tests showed that the CSGRQ total score and Symptom section differentiate patients with severe COPD from those who are mildly and moderately affected. In contrast, the SIP68 scores on three groups of various degree of FEV₁ % of predicted could not show differences among patients on the Social Behavior and Mobility Range subscales by the ANOVA tests (see Table 4.12). Such findings illustrate the differences in the nature of the CSGRQ and the SIP68. These demonstrate that for COPD patients, the CSGRQ is a more disease-specific measure than the SIP68, in terms of the FEV₁ % of predicted and the rating of dyspnea after 6-minute walking test on a Borg scale. The SIP is a measure of "health-related changes in behavior associated with the carrying out of one's daily activities." (Bergner, Bobbit, Carter, & Gilson, 1981). The

SIP68 is more about the impact of disease on patients' daily activity whereas the CSGRQ focuses on the impact of COPD on patients' lives. Distinctions may exist not only in specific functional areas, but also in the type and effect of predictors. In an extensive review of the literature on the SIP and COPD studies, Leidy (1995) concluded that further consideration should be given to the meaning of the SIP scores and the suitability of the SIP as a measure of functional performance, particularly in the COPD population (Leidy, 1995).

While comparing and contrasting the CSGRQ subscales and the SIP68 subscales, the researcher observed that the PAC subscale of the SIP68 showed consistently low correlations with the CSGRQ subscales as well as all clinical indicators. The PAC subscale describes behavior associated with the level at which an individual is able to operate without help in areas of mental functioning, including the ability to communicate verbally. This PAC subscale was irrelevant to this study group of COPD patients whose disease severity was mostly mild and moderate. The ES subscale of the SIP68 also showed low correlations with the subscales of the CSGRQ as compared with the other subscales of the SIP68. The ES subscale assesses the effect of the respondent's health status on his or her emotional status. Items concern irritability and/or acting disagreeably with oneself or others. These low correlations with the ES subscale may also be due to the fact that the subjects in this study did not have severe COPD and had family support.

It is noteworthy that the correlations between the Activity subscale of the CSGRQ with all subscales of the SIP68 were the highest among other subscale correlations between the CSGRQ and the SIP68. This finding is reasonable because the SIP68 focuses on the impact of disease on patients' daily activity. As mentioned earlier, traditional Chinese culture values interdependence. Family members remind COPD patients not to

exert themselves and family members do whatever the patient does not do.

Interdependence might influence the results from the SIP68 more than the CSGRQ. The SIP68 included activities like banking and housework, which were no longer in the elderly COPD patients' routine lives as long as they had family members around. For the CSGRQ, similar questions were not included. In addition, some activities that Chinese elderly do value, for example, traveling and enjoying leisure time, were listed in the CSGRQ but not the SIP68. This adds additional support to the usefulness of using the CSGRQ rather than the SIP68 in Chinese culture.

Summary

The validity of the CSGRQ was assessed using hypothesis-testing procedures and convergent, discriminant, and construct validity. The findings suggest that the CSGRQ can be used to measure health-related quality of life in Chinese COPD patients. Additionally, the findings direct attention to related research areas which will enhance the usefulness of the CSGRQ with Chinese populations.

Reliability of the CSGRQ

The reliability of the CSGRQ was assessed in terms of internal consistency reliability. The Cronbach's α for the CSGRQ total score and each section score were greater than .70 thereby reaching an acceptable level for research purposes (Nunnally, 1978). Although the Activity section of the CSGRQ had a lower Cronbach's α (.79) than that was found in the Spanish (Ferrer et al., 1996) or Swedish (Engstrom, Persson, Larsson, Sullivan, 1998) versions (Cronbach's α = .89 and .88, respectively), this finding might be due to several cultural differences in lifestyle. The activities that elder Chinese people want to pursue are enjoying leisure time and going out/abroad for sight seeing.

Chinese elder people usually live with other family members beside their spouses. They do not need to do most of the housework or any daily routine work if they choose. Usually, family members will do whatever work is left. The items comprising the Activity section include more vigorous-intensive work which is not common in Chinese elderly people's daily life. Additionally, competitive sports are not popular among Chinese elderly people. In spite of these differences, the CSGRQ worked well with the current sample in terms of internal consistency reliability. Results of the study suggest that the Chinese version of the CSGRQ is conceptually equivalent to the original version, and similarly reliable and valid.

Usefulness of the CSGRQ in Chinese COPD patients

This section will discuss the feasibility of the CSGRQ, length of time for health professionals to use it, and what it does and does not tell us. Anecdotal data are provided regarding pertinent content that is not included in the questionnaire.

It took about 8 to 15 minutes for the researcher to collect data from Chinese COPD patients using CSGRQ. During the interview, many patients commented on how COPD has affected their lives (these are translated from original Chinese responses):

“I have no energy, no power to live; there is no drive in life, I don't feel like to move, I am waiting to die.”

“If you have a good lung, life is shining, colorful, if you had a bad lung, life is dark, only black and white; there are too many things that I can't do because of this disease.”

“I feel vulnerable psychologically.....my emotions have become weak.”

“I don't feel well psychologically, if I talked too much, spoke louder, I felt

dyspnea.”

“To me, quality of life means I can walk around, do something that I want to do without dyspnea.”

“I can’t afford to get mad or speak loudly; I can’t behave like anyone else.”

These findings and data suggest that the capacity or opportunity to engage in self-actualizing and self-entertaining activities may be limited in COPD patients. As Covino and colleagues (1982) stated that those with COPD have a unique pattern of depression. They fell into a pattern of denial of impulsiveness. Thus they avoided spontaneity in life (Covino, Dirks, Kinsman, & Seidel, 1982). The outlook of life in COPD patients was affected by the impacts of disease on their ability to show emotions in their daily lives. Patients become fragile and vulnerable in this regard. DeVito (1990) explored COPD patients’ perceptions of dyspnea by a qualitative approach and found that five themes commonly faced by them were fear, helplessness, loss of vitality, preoccupation, and legitimacy. For instance, the comment “I have no energy, no power to live; there is no drive in life, I don’t feel like to move, I am waiting to die.” in the present study reflects loss of vitality and helplessness found in DeVito’s data. She further proposed that acknowledging the potential for these perceptions and validating their presence with individual patients may be therapeutic in and of itself (DeVito, 1990). Nicholas and Leuner (1992) stated that it is important to carefully assess the patient with COPD, knowing that functional limitations that occur as a result of COPD will require adaptation on the part of the patient. This period of adjustment could potentially be negative and may require interventions to facilitate positive alterations for the patients. Kaptein et al. (1993) argued

that reporting of respiratory symptoms, absence from work, and hospitalization in patients with COPD is a matter both of physiology and psychology (Kaptein, Brand, Dekker, Kerstjens, Postma, Sluiter, & the Dutch CNSLD study group, 1993). Other researchers also suggested that a direct focus on psychological interventions to ameliorate depression and improve mastery is likely to improve quality of life with some resultant positive effect on functional status (Moody, McCormick, & Williams, 1990). Leidy also argued that psychosocial factors seem to influence functional performance, independent of the physiologic effects. It is important for health care providers to clearly understand the factors influencing functional performance in people with COPD (Leidy, 1995). This relates to conceptualization of quality of life in Chinese COPD patients. To understand this phenomenon further, a qualitative research designed to explore what are the constituents of quality of life in Chinese COPD patients is needed in future research.

Items in the Symptoms section were somewhat difficult to answer for COPD patients with asthmatic component. When they were asked about the frequency of wheezing attacks, they had a hard time to decide which category to choose. Because of industrialization of Taiwan, there are few people who live in Taipei who still have a place to do gardening. Apartments with elevators are more common in Taipei city than other cities in Taiwan. Items listed in the Activity section like gardening, walking stairs, and competitive sports are less common for participants of this study to be engaged in, not to mention to shovel snow for participants from subtropical area (i.e., Taiwan).

Additionally, the weights attached to each item for calculating the SGRQ score are cumbersome. According to Nunnally (1978), items with fancy weights correlate well with

raw scores (Nunnally, 1978). The researcher computed the correlations between weighted and unweighted CSGRQ scores and found that except for the Symptom section ($r = .93$), which had relatively lower correlation coefficient than other SGRQ scores, the rest of the CSGRQ scores had very high correlations: Activity ($r = 1.0$), Impacts ($r = .99$), and the total score of the CSGRQ ($r = .97$). This leads to additional support for the usefulness of the unweighted CSGRQ in clinical practice in Taiwan.

Smoking history, hospitalized times for chest problems, FEV₁ % of predicted, distance walked in 6 minutes, and dyspnea after the 6-minute walking test were used to predict the CSGRQ total in this study. These five independent variables explained 47% of the variance in the CSGRQ total score. What the CSGRQ tells us that measuring these five predictors do not tell is about the frequency of cough, sputum production, wheeze, breathlessness, and the duration and frequency of attacks of breathlessness or wheeze; activities that were either caused or were limited by breathlessness; and a range of aspects concerned with social functioning and psychological disturbances resulting from airway diseases, such as employment, being in control of health, panic, stigmatization, the need for medication and its side effects, and expectations for health and disturbance of daily life. The CSGRQ brings together a number of different aspects of a disease and give a robust summary of a patient's symptoms and their impact on daily life and activities. Although some revision may be needed before applying the CSGRQ to Chinese COPD patients, the findings demonstrate the usefulness of the CSGRQ for clinical research. More evidence, for example, a longitudinal design to examine the sensitivity of the CSGRQ to detect difference within subjects, is needed to determine the applicability of the CSGRQ for

keeping track of individual patients' progress, and for group comparison regarding the effects of different intervention efforts.

Limitations of the Study

Four potential limitations have been identified for the current methodological study.

1. Its cross-sectional design limits the ability to describe how progression of disease severity relates to changes in health-related quality of life, in this case, the CSGRQ.
2. Because of collecting data at 2-minute mark of the 6-minute walk test, the 6-minute walk test in this study is different from other studies in this regard.
3. The reference values for the SGRQ were obtained from populations who use different languages.
4. Sample may not be representative of COPD patients in Taiwan.

First, because the researcher recruited patients from outpatient respiratory clinic in one medical center in Taipei, the study sample may not represent patients who do not go to this clinic.

Second, only patients who were able and willing to perform the walk test were enrolled in the study, and therefore some of the more severe patients may have been excluded.

Third, the missing data for 6-minute walk test for each stage is 10.9% from Stage I ($FEV_1 \geq 50\%$ predicted), 8.0% from Stage II (FEV_1 35 to 49.9% predicted), and 54.5% from Stage III ($FEV_1 < 35\%$ predicted). This posed a potential selection bias for this study variable. Among those who did not complete the 6-minute walk test, some

refused to walk more after the 2-minute walk mark, and some were unable to walk further. There is no information available about the walking ability of the participants who did not complete the walk test.

Finally, there is concern about generalizability of the findings to all COPD patients in Taiwan. External validity refers to generalizability of findings to the target population, in this case to all COPD patients in Taiwan. Threats to external validity can be mitigated by using a probability sample that ensures each COPD patient has an equal chance of being selected to participate. However, in this study, a convenience sample was used. There is no sufficient data about the population of COPD patients in Taiwan. A comparison of the study sample with target population cannot be made. Therefore, generalizability of findings of this study to all COPD patients in Taiwan cannot be made.

Implications for Research, Practice, and Theory

Significant and strong correlations were found between the Chinese SGRQ and a widely used, generic health status questionnaire, the SIP68. Significant, but more modest, correlations were found between the Chinese SGRQ and the spirometric data. The CSGRQ also correlated with the patients' own global health rating and with the assessment of exercise capacity and dyspnea ratings. Thus, this study confirms the validity of the Chinese SGRQ. The good agreement between correlations found in this study and those presented previously from different language versions of the SGRQ confirms the measurement equivalence among different versions of the SGRQ.

The results demonstrated a satisfactory internal consistency reliability (alpha levels above .76) of the CSGRQ, although there seem to be many items in the Activity and

Impacts sections not contributing to the reliability of the measure for patients with COPD. In order to confirm the findings for the current study, further research is needed with Chinese COPD patients. Also, additional research is required to further instrument development on the quality of life in COPD patients. Correlational studies are needed to examine the relationship between selected variables using valid and reliable measures with COPD patients. Moreover, combining qualitative and quantitative data examining quality of life in the COPD patients in Taiwan should be conducted. This design would be stronger than a quantitative study in explicating the impact of disease in COPD patients' lives.

Although methodological studies like the current study are limited in their direct application to clinical nursing practice, it is hoped that the results do offer preliminary recommendations. The four hypotheses on the correlations between the CSGRQ and clinical indicators were supported in this study. That is, the CSGRQ shows significant relationship with clinical indicators. The 6-minute walking test and dyspnea rating after 6-minute walking test are simple, low-cost tests that can provide valuable data to health care professionals. The CSGRQ does not take long time to complete and can supplement the physiological data of the patient and provide a holistic view of the impact of COPD on those patients.

Outcome assessment and management has become a major focus as the costs of health care have escalated over the past decade. Careful outcome assessment is currently an expected activity for determining the effectiveness of nursing interventions and programs. The ultimate goal of nursing is to make a positive difference in the state of

health of people (Strickland, 1997). Health-related quality of life (HRQL) measures are increasingly being used in clinical trials in the western societies to provide standardized global assessment of the patient's health status and to quantify the size of health gain from therapy. Such measures bring together a number of different aspects of a disease and give a robust summary of a patient's symptoms and their impact on daily life and activities (Wilson, 1998). Therefore, nursing interventions to improve quality of life in outpatient clinics could be developed and the CSGRQ could be used by health care providers to follow up the effectiveness of nursing interventions.

The findings of this study do not have direct implications for the development of theory. However, as previously discussed, the findings of this study do contribute to understanding of the HRQL. They also have implications to future research that can guide the development and refinement of quality of life theory in Chinese culture.

Summary

The purpose of this study was to translate the St. George's Respiratory Questionnaire (SGRQ) into Chinese and to assess the feasibility, reliability, and validity of the translated instrument. The SGRQ was selected because it is similar to the questions asked by pulmonary doctors in Taiwan.

A convenience sample of 100 Chinese COPD patients was recruited from an outpatient clinic in Taipei, Taiwan. These participants completed a lung function test on a spirometer, responded to the CSGRQ and SIP68, a 6-minute walk test (15 of them completed only a 2-minute walk test), marked their ratings of dyspnea on modified Borg scales at rest, at 2-minute walk break (a break after 2 minute of the 6-minute walk), and at

the completion of 6-minute walk.

The validity of the newly translated CSGRQ (Chinese version of the St George's Respiratory Questionnaire) was evaluated using hypothesis-testing procedures and convergent and discriminant validity. All hypotheses were supported in the study. The CSGRQ scores were negatively correlated with distance walked. Dyspnea ratings on the Borg scale showed moderate positive correlations with the CSGRQ scores. The correlations became stronger as patients spent longer time performing walking test. The correlation between the CSGRQ total score and the SIP68 total score was .69 ($p < .01$).

The construct validity was demonstrated by building hierarchical multiple regression models with the CSGRQ total score and section scores as well as the SIP68 and its subscales as the dependent variables. Smoking history, hospitalized times for chest problems, FEV₁ % of predicted, distance walked in 6 minutes, and dyspnea after the 6-minute walking test were used to predict the CSGRQ total and its three section scores as well as the SIP68 total and three subscale scores. These five independent variables explained 47% of the variance in CSGRQ total score compared to 58% of the variance in SIP68 total score. FEV₁ % of predicted accounted for about 4 to 10% of the variance in CSGRQ scores in the regression models which is consistent with that found in the literature (Jones, Baveystock, & Littlejohns, 1989; McSweeny, Grant, Heaton, Adams, & Timms, 1982; Weaver & Narsavage, 1992). The ratings of breathlessness after the 6-minute walking test on a Borg scale accounted for 1 to 15% of the variance in the CSGRQ scores as compared to 3 to 6% of the variance in the SIP68 scores (see Table 4.10). The sensation of dyspnea is a major problem that interferes with COPD patients

daily activities. The distance walked in 6 minutes in regression analyses accounted for 1 to 9% of the variance in the CSGRQ scores as compared to 5 to 28% of the variance in the SIP68 scores.

The ANOVA tests on various degree of FEV₁ % of predicted showed that the CSGRQ differentiates patients with severe COPD from those who are mildly and moderately affected (see Table 4.12). Such findings illustrate the differences in the nature of the CSGRQ and the SIP68. The SIP68 is more about the impact of disease on patients' activity whereas the CSGRQ focuses on the impact of COPD on patients' lives.

Internal consistency of each section score of the CSGRQ was assessed by the Cronbach's α coefficient. The Cronbach's α coefficient was .76 for the Symptoms section, .79 for the Activity section, .86 for the Impacts section, and .92 for the total CSGRQ score. The Cronbach's α coefficient of the SIP68 was .82 in this sample. These α values were greater than .70 and reached an acceptable level (Nunnally, 1978). The findings of these procedures suggest that the CSGRQ can be used to measure health-related quality of life in Chinese COPD patients. However, additional research should be undertaken to develop further our understanding of the CSGRQ performance within the Chinese culture.

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APPENDIX A
Oregon Health Sciences University
Consent Form

TITLE: Evaluating Reliability and Validity of the Chinese Version of the St. George's Respiratory Questionnaire in Patients with Chronic Obstructive Pulmonary Disease in Taiwan

PRINCIPAL INVESTIGATOR: Shiow-Yih Yeh, R. N., M. N. S. (011-886)-2-2546-8126.

CO-INVESTIGATORS: Barbara J. Stewart, Ph.D.(503) 494-3835.

Linda Felver, Ph.D.,R. N.(503) 494-3723.

PURPOSE: You have been invited to participate in this research study because we are interested in how your disease has affecting the quality of your life. The St. George's Respiratory Questionnaire (SGRQ) is a health-related quality of life measure specific for asthma and COPD patients. The purpose of this study is to evaluate the reliability and validity of the Chinese version of the SGRQ in Taiwanese COPD patients. It will probably take 45 minutes for you to be involved with the study.

PROCEDURES: If you agree to participate, you will be interviewed for approximately 30 minutes by the investigator named above. You will answer questions about the following: your occupational and educational history; the severity of your shortness of breath and how it affects your daily activities, the impact of your chest problem on your daily life; some of the questions may be of a sensitive nature, such as questions about your sexual life (one in the SGRQ, one in the Sickness Impact Profile).

You will be asked to perform a simple test of your lung function on a spirometer, known as a forced expiratory volume. You will also be asked to walk twice for 6 minutes each at your own pace as a measure of your exercise capacity.

RISKS: In this study, sensitive questions may cause some psychological discomfort. A forced expiratory volume maneuver may cause temporary shortness of breath. Walking for 6 minutes may cause muscle fatigue and temporary shortness of breath. Rest periods will be provided as needed. Data collection will occur at times that you feel comfortable and capable of doing those tests.

BENEFITS: You will not personally benefit from participating in this study. However, by serving as a subject, you may contribute new information which may benefit

patients in the future.

ALTERNATIVES: You may choose not to participate in this study.

CONFIDENTIALITY: All of your answers will be seen only by the investigators and used only for research purposes. However, if the investigators find evidence of severe mental or physical illness, they will discuss this information with you and your physician. The published report of the research will not show your individual results, but will show data that are combined with those of other participants. Neither your name nor your identity will be used for publication or publicity purposes.

COSTS: There are no costs involved in participating in this research study.

LIABILITY: The Oregon Health Sciences University, as a public corporation, is subject to the Oregon Tort Claims Act, and is self insured for liability claims. If you suffer any injury from this research project, compensation would be offered to you only if you establish that the injury occurred through the fault of the University, its officers or employees. However, you have not waived your legal rights by signing this form. If you have further questions, please call the Medical Services Director at (011-886-2) 2365-9055.

PARTICIPATION: Shioh-Yih Yeh (011-886-2-2546-8126) has offered to answer any other questions you may have about this study. If you have any questions regarding your rights as a research subject, you may contact the Tri-Service General Hospital Institutional Review Board at (011-886-2) 2368-0282. You may refuse to participate, or you may withdraw from this study at any time without affecting your relationship with or treatment at the Tri-Service General Hospital.

You have been given a copy of this form and have had a chance to read it. Your signature below indicates that you have read the foregoing and agree to participate in this study.

Signature: _____

Date: _____

Witness: _____

Date: _____

Signature of the investigator: _____

Date: _____

親愛的

先生：
女士：

您好！此研究的目的是了解慢性阻塞性肺部疾病對您生活品質所造成的影響，並希望知道您呼吸喘對您生活品質影響的程度，期由研究結果可以提供日後護理照顧的依據。

本研究不會對您目前的治療及照顧有任何的影響，且僅供臨床的學術研究，絕不對外公開個人資料，請您放心據實作答。您的意見將會對護理的改進有極大的幫助。您所提供的資料在資料分析後會立即銷毀，若您願意參與，請簽名於下面的橫線上，謝謝您的合作！

葉秀逸敬上

簽名：_____

APPENDIX B
STUDY INSTRUMENTS AND PROTOCOL
Validation of the CSGRQ
Subject Screening Tool

Subject ID _____

Hospital identification number _____

Date and time _____

Inclusion criteria:

- age 40-90 (Subject's birthdate, age _____)
- understands Mandarin
- diagnosed of symptomatic COPD, chronic bronchitis, or emphysema
- FEV₁ of predicted < 75% or FEV₁/FVC < 75%
- is willing and able to complete the study measures

Exclusion criteria:

YES NO

- legally blind or deaf
- cancer diagnosis,
- uncontrolled diabetes,
- uncontrolled hypertension,
- psychiatric illness,
- Class 2 or greater New York Heart Association criteria for heart failure,
dyspnea
- is not able to walk,
- ventilator-dependent,
- has unstable angina pectoris

PROTOCOL FOR QUESTIONNAIRES

Subject ID _____

Now I have a series of questionnaires (*the CSGRQ and SIP68 are in random order*) that I would like to read to you.

Please mark the answer that is most appropriate for you.

(Seat yourself next to the respondent, and proceed by reading questions to him/her.

The St. George's Respiratory Questionnaire (SGRQ)

PART 1

QUESTIONS ABOUT HOW MUCH CHEST TROUBLE YOU HAVE HAD OVER THE LAST YEAR.
PLEASE TICK IN ONE BOX FOR EACH QUESTION.

	most days a week	several days a week	a few days a week	only with chest infections	not at all
1) Over the last year, I have coughed:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) Over the last year, I have brought up phlegm (sputum) :	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) Over the last year, I have had shortness of breath :	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4) Over the last year, I have had attacks of wheezing :	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5) During the last year, how many severe or very unpleasant attacks of chest trouble have you had :					
				more than 3 attacks.....	<input type="checkbox"/>
				3 attacks.....	<input type="checkbox"/>
				2 attacks.....	<input type="checkbox"/>
				1 attack.....	<input type="checkbox"/>
				no attacks.....	<input type="checkbox"/>
6) How long did the worst attack of chest trouble last: (Go to Question 7 if you had no severe attacks)					
				a week or more.....	<input type="checkbox"/>
				3 or more days.....	<input type="checkbox"/>
				1 or 2 days.....	<input type="checkbox"/>
				less than a day.....	<input type="checkbox"/>
7) Over the last year, in an average week, how many good days (with little chest trouble) have you had:					
				no good days.....	<input type="checkbox"/>
				1 or 2 good days.....	<input type="checkbox"/>
				3 or 4 good days.....	<input type="checkbox"/>
				nearly every day is good.....	<input type="checkbox"/>
				every day is good.....	<input type="checkbox"/>
8) If you have a wheeze, is it worse in the morning:					
				no.....	<input type="checkbox"/>
				yes.....	<input type="checkbox"/>

PART 2SECTION 1

HOW WOULD YOU DESCRIBE YOUR CHEST CONDITION? (PLEASE TICK IN ONE BOX ONLY)

- the most important problem I have.....
- causes me quite a lot a problems.....
- causes me a few problems.....
- causes no problem.....

IF YOU HAVE EVER HAD PAID EMPLOYMENT, PLEASE TICK ONE OF THESE:

- my chest trouble made me stop work.....
- my chest trouble interferes with my work or made me change my work....
- my chest trouble does not affect my work.....

SECTION 2: QUESTIONS ABOUT WHAT ACTIVITIES USUALLY MAKE YOU FEEL BREATHLESS THESE DAYS.

FOR EACH ITEM, PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU .

- | | TRUE | FALSE |
|------------------------------------|--------------------------|--------------------------|
| Sitting or lying still..... | <input type="checkbox"/> | <input type="checkbox"/> |
| Getting washed or dressed..... | <input type="checkbox"/> | <input type="checkbox"/> |
| Walking around the home..... | <input type="checkbox"/> | <input type="checkbox"/> |
| Walking outside on the level..... | <input type="checkbox"/> | <input type="checkbox"/> |
| Walking up a flight of stairs..... | <input type="checkbox"/> | <input type="checkbox"/> |
| Walking hills..... | <input type="checkbox"/> | <input type="checkbox"/> |
| Playing sports or games..... | <input type="checkbox"/> | <input type="checkbox"/> |

SECTION 3 : SOME MORE QUESTIONS ABOUT YOUR COUGH AND BREATHLESSNESS THESE DAYS.

FOR EACH ITEM, PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU.

- | | TRUE | FALSE |
|--|--------------------------|--------------------------|
| My cough hurts..... | <input type="checkbox"/> | <input type="checkbox"/> |
| My cough makes me tired..... | <input type="checkbox"/> | <input type="checkbox"/> |
| I am breathless when I talk..... | <input type="checkbox"/> | <input type="checkbox"/> |
| I am breathless when I bend over..... | <input type="checkbox"/> | <input type="checkbox"/> |
| My cough or breathing disturbs my sleep..... | <input type="checkbox"/> | <input type="checkbox"/> |
| I get exhausted easily..... | <input type="checkbox"/> | <input type="checkbox"/> |

SECTION 4 : QUESTIONS ABOUT OTHER EFFECTS THAT YOUR CHEST TROUBLE MAY HAVE ON YOU THESE DAYS.

FOR EACH ITEM, PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU.

	TRUE	FALSE
My cough or breathing is embarrassing in public.....	<input type="checkbox"/>	<input type="checkbox"/>
My chest trouble is a nuisance to my family, friends or neighbours.....	<input type="checkbox"/>	<input type="checkbox"/>
I get afraid or panic when I cannot get my breath.....	<input type="checkbox"/>	<input type="checkbox"/>
I feel that I am not in control of my chest problem.....	<input type="checkbox"/>	<input type="checkbox"/>
I do not expect my chest to get any better.....	<input type="checkbox"/>	<input type="checkbox"/>
I have become frail or an invalid because of my chest.....	<input type="checkbox"/>	<input type="checkbox"/>
Exercise is not safe for me.....	<input type="checkbox"/>	<input type="checkbox"/>
Everything seems too much of an effort.....	<input type="checkbox"/>	<input type="checkbox"/>

SECTION 5 : QUESTIONS ABOUT YOUR MEDICATION. IF YOU ARE RECEIVING NO MEDICATION GO STRAIGHT TO SECTION 6.

TO COMPLETE THIS SECTION PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU.

	TRUE	FALSE
My medication does not help me very much.....	<input type="checkbox"/>	<input type="checkbox"/>
I get embarrassed using my medication in public.....	<input type="checkbox"/>	<input type="checkbox"/>
I have unpleasant side effects from my medication.....	<input type="checkbox"/>	<input type="checkbox"/>
My medication interferes with my life a lot.....	<input type="checkbox"/>	<input type="checkbox"/>

SECTION 6 : THESE ARE QUESTIONS ABOUT HOW YOUR ACTIVITIES MIGHT BE AFFECTED BY YOUR BREATHING.

FOR EACH QUESTION, PLEASE TRUE IF ONE OR MORE PARTS APPLIES TO YOU BECAUSE OF YOUR BREATHING. OTHERWISE TICK FALSE.

	TRUE	FALSE
I take a long time to get washed or dressed.....	<input type="checkbox"/>	<input type="checkbox"/>
I cannot take a bath or shower, or I take a long time.....	<input type="checkbox"/>	<input type="checkbox"/>
I walk slower than other people, or I stop for rests.....	<input type="checkbox"/>	<input type="checkbox"/>
Jobs such as housework take a long time, or I have to stop for rests.....	<input type="checkbox"/>	<input type="checkbox"/>
If I walk up one flight of stairs, I have to go slowly or stop.....	<input type="checkbox"/>	<input type="checkbox"/>
If I hurry or walk fast, I have to stop or slow down.....	<input type="checkbox"/>	<input type="checkbox"/>
My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, play bowls or play golf.....	<input type="checkbox"/>	<input type="checkbox"/>
My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim.....	<input type="checkbox"/>	<input type="checkbox"/>
My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports.....	<input type="checkbox"/>	<input type="checkbox"/>

SECTION 7 : WE WOULD LIKE TO KNOW HOW YOUR CHEST TROUBLE USUALLY AFFECTS YOUR DAILY LIFE.

PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU BECAUSE OF YOUR CHEST TROUBLE (REMEMBER THAT TRUE ONLY APPLIES TO YOU IF YOU CAN NOT DO SOMETHING BECAUSE OF YOUR BREATHING)

	TRUE	FALSE
I cannot play sports or games.....	<input type="checkbox"/>	<input type="checkbox"/>
I cannot go out for entertainment or recreation.....	<input type="checkbox"/>	<input type="checkbox"/>
I cannot go out of the house to do the shopping.....	<input type="checkbox"/>	<input type="checkbox"/>
I cannot do housework.....	<input type="checkbox"/>	<input type="checkbox"/>
I cannot move far from my bed or chair.....	<input type="checkbox"/>	<input type="checkbox"/>

HERE IS A LIST OF OTHER ACTIVITIES THAT YOUR CHEST TROUBLE MAY PREVENT YOU DOING. (YOU DO NOT HAVE TO TICK THESE, THEY ARE JUST TO REMIND YOU OF WAYS IN WHICH YOUR BREATHLESSNESS MAY AFFECT YOU) :

- GOING FOR WALKS OR WALKING THE DOG
- DOING THINGS AT HOME OR IN THE GARDEN
- SEXUAL INTERCOURSE
- GOING OUT TO CHURCH, OR PLACE OF ENTERTAINMENT
- GOING OUT IN BAD WEATHER OR INTO SMOKY ROOMS
- VISITING FAMILY OR FRIENDS OR PLAYING WITH CHILDREN

PLEASE WRITE IN ANY OTHER IMPORTANT ACTIVITIES THAT YOUR CHEST TROUBLE MAY STOP YOU DOING:

NOW, WOULD YOU TICK IN THE BOX (ONE ONLY) WHICH YOU THINK BEST DESCRIBES HOW YOUR CHEST AFFECTS YOU:

- It does not stop me doing anything I would like to do.....
- It stops me doing one or two things I would like to do.....
- It stops me doing most of the things I would like to do.....
- It stops me doing everything I would like to do.....

THANK YOU FOR FILLING IN THIS QUESTIONNAIRE. BEFORE YOU FINISH WOULD YOU CHECK TO SEE THAT YOU HAVE ANSWERED ALL THE QUESTIONS.

SYMPTOMS COMPONENT

This consists of all the questions in Part 1. The weights for Questions 1-8 are summed. It will be noted that the questionnaire requests a single response to Questions 1-7. If multiple responses are given to a question then averaging the weights for the positive responses for that question are acceptable. We feel that is a better approach than losing an entire data set and have used this technique in calculating the results used in our validation studies. (Clearly a better approach is to prevent such multiple response occurring, but it is difficult to prevent occasional accidents).

ACTIVITY COMPONENT

This is calculated from the summed weights for the positive responses to Section 2 and Section 6 in Part 2 of the questionnaire.

IMPACTS COMPONENT

This is calculated from Sections 1; 3; 4; 5; 7. Again it will be noted from the questionnaire that a single response is required for the two parts of Section 1 and the last part of Section 7. In the case of multiple responses we have adopted the approach of meaning the weights for any multiple responses to these parts.

TOTAL SCORE

The Total score is calculated by summing the all positive responses in the questionnaire and expressing the result as a percentage of the weights for all items in the questionnaire (as shown on previous page).

HANDLING MISSED ITEMS

It is better not to miss items and any missing items are the fault of the experimenter, not the patient. We have examined the effect of missing items and recommend the following methods:

Part 1

Missed items are treated as if the answer was in the negative.

Part 2

The following approach may be used. Items in Sections 2,3,4,5,6, and first part of section 7 all require a response of either 'True' or 'False'. If neither box is ticked, the item should be coded as 'missing'. If this approach is to be used, the scoring program should be written so that when an item is coded as 'missing', the weight for that item is subtracted from the total possible weight for that component of the questionnaire (ie either the Impacts or the Activity component) and from the Total weight.

We have very carefully tested this method of handling missing data and found that it is reliable for up to 10 missed items in Part 2 of the questionnaire.

4. QUESTIONNAIRE ITEM WEIGHTS
PART 1

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QUESTIONS ABOUT HOW MUCH CHEST TROUBLE YOU HAVE HAD OVER THE LAST YEAR.
PLEASE TICK IN ONE BOX FOR EACH QUESTION.

	most days a week	several days a week	a few days a week	only with chest infections	not at all
1) Over the last year, I have coughed:	80.6	63.2	29.3	28.1	0
2) Over the last year, I have brought up phlegm (sputum) :	76.8	60.0	34.0	30.2	0
3) Over the last year, I have had shortness of breath :	87.2	71.4	43.7	35.7	0
4) Over the last year, I have had attacks of wheezing :	86.2	71.0	45.6	36.4	0
5) During the last year, how many severe or very unpleasant attacks of chest trouble have you had :					
				more than 3 attacks.....	86.7
				3 attacks.....	73.5
				2 attacks.....	60.3
				1 attack.....	44.2
				no attacks.....	0
6) How long did the worst attack of chest trouble last: (Go to Question 7 if you had no severe attacks)					
				a week or more.....	89.7
				3 or more days.....	73.5
				1 or 2 days.....	58.8
				less than a day.....	41.9
7) Over the last year, in an average week, how many good days (with little chest trouble) have you had:					
				no good days.....	93.3
				1 or 2 good days.....	76.6
				3 or 4 good days.....	61.5
				nearly every day is good.....	15.4
				every day is good.....	0
8) If you have a wheeze, is it worse in the morning:					
				no.....	0
				yes.....	62.0

PART 2SECTION 1

HOW WOULD YOU DESCRIBE YOUR CHEST CONDITION? (PLEASE TICK IN ONE BOX ONLY)

the most important problem I have.....	83.2
causes me quite a lot a problems.....	82.5
causes me a few problems.....	34.6
causes no problem.....	0

IF YOU HAVE EVER HAD PAID EMPLOYMENT, PLEASE TICK ONE OF THESE:

my chest trouble made me stop work.....	88.9
my chest trouble interferes with my work or made me change my work....	77.6
my chest trouble does not affect my work.....	0

SECTION 2: QUESTIONS ABOUT WHAT ACTIVITIES USUALLY MAKE YOU FEEL BREATHLESS THESE DAYS.

FOR EACH ITEM, PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU .

Sitting or lying still.....	90.6
Getting washed or dressed.....	82.8
Walking around the home.....	80.2
Walking outside on the level.....	81.4
Walking up a flight of stairs.....	76.1
Walking hills.....	75.1
Playing sports or games.....	72.1

SECTION 3 : SOME MORE QUESTIONS ABOUT YOUR COUGH AND BREATHLESSNESS THESE DAYS.

FOR EACH ITEM, PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU.

My cough hurts.....	81.1
My cough makes me tired.....	79.1
I am breathless when I talk.....	84.5
I am breathless when I bend over.....	76.8
My cough or breathing disturbs my sleep.....	87.9
I get exhausted easily.....	84.0

SECTION 4 : QUESTIONS ABOUT OTHER EFFECTS THAT YOUR CHEST TROUBLE MAY HAVE ON YOU THESE DAYS. FOR EACH ITEM, PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU.

My cough or breathing is embarrassing in public.....	74.1
My chest trouble is a nuisance to my family, friends or neighbours.....	79.1
I get afraid or panic when I cannot get my breath.....	87.7
I feel that I am not in control of my chest problem.....	90.1
I do not expect my chest to get any better.....	82.3
I have become frail or an invalid because of my chest.....	89.9
Exercise is not safe for me.....	75.7
Everything seems too much of an effort.....	84.5

SECTION 5 : QUESTIONS ABOUT YOUR MEDICATION. IF YOU ARE RECEIVING NO MEDICATION GO STRAIGHT TO SECTION 6.

TO COMPLETE THIS SECTION PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU.

My medication does not help me very much.....	88.2
I get embarrassed using my medication in public	53.9
I have unpleasant side effects from my medication.....	81.1
My medication interferes with my life a lot.....	70.3

SECTION 6 : THESE ARE QUESTIONS ABOUT HOW YOUR ACTIVITIES MIGHT BE AFFECTED BY YOUR BREATHING. FOR EACH QUESTION, PLEASE TRUE IF ONE OR MORE PARTS APPLIES TO YOU BECAUSE OF YOUR BREATHING. OTHERWISE TICK FALSE.

I take a long time to get washed or dressed.....	74.2
I cannot take a bath or shower, or I take a long time.....	81.0
I walk slower than other people, or I stop for rests.....	71.7
Jobs such as housework take a long time, or I have to stop for rests.....	70.6
If I walk up one flight of stairs, I have to go slowly or stop.....	71.6
If I hurry or walk fast, I have to stop or slow down.....	72.3
My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, play bowls or play golf	74.5
My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim.....	71.4
My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports.....	63.5

SECTION 7 : WE WOULD LIKE TO KNOW HOW YOUR CHEST TROUBLE USUALLY AFFECTS YOUR DAILY LIFE.

PLEASE TICK EITHER TRUE OR FALSE AS IT APPLIES TO YOU BECAUSE OF YOUR CHEST TROUBLE (REMEMBER THAT TRUE ONLY APPLIES TO YOU IF YOU CAN NOT DO SOMETHING BECAUSE OF YOUR BREATHING)

I cannot play sports or games.....	64.8
I cannot go out for entertainment or recreation.....	79.8
I cannot go out of the house to do the shopping.....	81.0
I cannot do housework.....	79.1
I cannot move far from my bed or chair.....	94.0

HERE IS A LIST OF OTHER ACTIVITIES THAT YOUR CHEST TROUBLE MAY PREVENT YOU DOING. (YOU DO NOT HAVE TO TICK THESE, THEY ARE JUST TO REMIND YOU OF WAYS IN WHICH YOUR BREATHLESSNESS MAY AFFECT YOU) :

- GOING FOR WALKS OR WALKING THE DOG
- DOING THINGS AT HOME OR IN THE GARDEN
- SEXUAL INTERCOURSE
- GOING OUT TO CHURCH, OR PLACE OF ENTERTAINMENT
- GOING OUT IN BAD WEATHER OR INTO SMOKY ROOMS
- VISITING FAMILY OR FRIENDS OR PLAYING WITH CHILDREN

PLEASE WRITE IN ANY OTHER IMPORTANT ACTIVITIES THAT YOUR CHEST TROUBLE MAY STOP YOU DOING:

NOW, WOULD YOU TICK IN THE BOX (ONE ONLY) WHICH YOU THINK BEST DESCRIBES HOW YOUR CHEST AFFECTS YOU:

It does not stop me doing anything I would like to do.....	0
It stops me doing one or two things I would like to do.....	42.0
It stops me doing most of the things I would like to do.....	84.2
It stops me doing everything I would like to do.....	96.7

THANK YOU FOR FILLING IN THIS QUESTIONNAIRE. BEFORE YOU FINISH WOULD YOU CHECK TO SEE THAT YOU HAVE ANSWERED ALL THE QUESTIONS.

BACK-TRANSLATION OF THE CSGRQ

Part I:

The following questions are regard to the levels of seriousness of the problems involving your thoracic (chest) cavity over the last year. Please check one answer for each question.

- Most of the week
- Quite a few days a week
- One or two days a week
- Only when otherwise sick from lung infectious illness
- None

- 1). How often did you cough during the past year?
- 2). How often did you cough up phlegm during the past year?
- 3). How often did you have trouble catching your breath during the past year?
- 4). How often did you have asthma during the past year?

- 5). Over the past year, how many times have you had serious or very bothersome problems involving the thoracic cavity?
 - More than three times
 - Three times
 - Twice
 - Once
 - Never

- 6). How long did the most serious incident last?
 - More than one weeks
 - Three days or more
 - One or two days
 - Less than a whole day

- 7). Over the last year, on average, how many comfortable days did you have a week?
 - None
 - One or two
 - Three or four
 - Almost every day
 - Every day

- 8). If you have asthma, is it worse in the morning?
 - Yes
 - No

Part II**Section 1:**

How would you describe the situation regarding your thoracic cavity?

- My biggest problem
- A source of much trouble
- A source of some trouble
- No problem

If you work, have these problems:

- Caused you to stop working
- Affected your work or caused you to change jobs
- Had no effect on your work

Section 2:

Have you had trouble breathing while engaging in any of the following activities lately? Please answer "yes" or "no" for each item

- When peacefully sitting or lying down
 - When in the bath or changing clothes
 - When walking about indoors
 - When walking on level ground outside
 - When climbing one flight of stairs
 - When walking uphill
 - When exercising or playing competitive sports

Section 3:

The following are questions about recent trouble you have had with coughing or breathing. Please answer "yes" or "no" for each item:

- It is very painful when I cough
 - When I cough, I feel very tired
 - I find it hard to breathe when I talk
 - When I bend down, I can't breathe
 - Because of coughing or breathing difficulties, it is hard for me to sleep
 - I easily tire

Section 4:

Which of the following statements about thoracic-cavity problems applies to your recent situation:

- Coughing or breathing problems embarrass me in public
- Problems involving my thoracic cavity bother my family, friends or neighbors
- When I can't catch my breath, I panic or feel scared
- I feel unable to control these problems

I feel the situation can't be improved
 As a result of these problems, I feel weak or have lost my ability to do things
 Exercise is unsafe for me
 Doing anything takes a tremendous amount of energy for me

Section 5:

The following questions are about medication. If you are not taking medication for your respiratory condition, please skip to Section 6.

Taking medication hasn't been of much help to me
 I feel embarrassed to take medicine in public
 The side effects of taking medicine cause me discomfort
 Taking medication is a big interference in my life

Section 6:

Do problems involving your thoracic cavity affect your life in the following ways? (Yes or no):

It takes me a long time to wash, groom and clothe myself
 I can't take a bath or shower, or it takes extremely long
 I walk slower than others, or I have to stop to rest
 It takes a long time to finish simple household chores, or I have to stop in the middle to rest
 Walking up a flight of stairs takes a long time, or I have to stop in the middle to rest
 If I'm in a hurry or walking faster than usual, I often am forced to rest or slow down
 The chest problems make it difficult to do such things as walk uphill, carry things up stairs, weed the garden, dance, play balls or play golf
 The chest problems make it difficult to do such things as carry heavy objects, dig in the garden or shovel snow, jog, walk eight kilometers an hour, play tennis, or swim
 The chest problems make it difficult to do strenuous work with the hands, run, ride a bicycle, swim quickly or play competitive sports

Section 7:

Regarding the following statements about the effects of thoracic-cavity problems on your daily life, answer yes or no (please note that you should only answer yes if you are unable to participate because of problems involving the thoracic cavity):

I can't exercise or participate in competitive sports
 I can't go outside to enjoy leisure activities
 I can't go outside to shop
 I can't do household chores
 I can't go too far from my bed or chair

The following are a list of activities that those with thoracic-cavity problems avoid (there is no need to answer; the list is just provided to remind you how these problems can affect daily living)

- Going on walks or walking the dog
- Working around the house or in the garden
- Having sex
- Going to church or places where people gather in their leisure time
- Going outside during unfavorable weather conditions or entering smoky rooms
- Visiting relatives or friends, or playing with children

Now, would you please list any other important activities you can not do as a result of your respiratory problems:

Generally speaking, which of the following sentences describes the effect of these problems on your life:

- I can still do everything I want to do
- There are one or two things I would like to do that I can't
- I can't do most of what I'd like to do
- I can't do anything I'd like to do

聖喬治呼吸問卷

開始時間：_____

Part I：以下題目是關於過去一年你胸腔問題的嚴重程度。請單選。

- | | 每週大
部份時候 | 每週
數天 | 每週少
數幾天 | 只有
感染時 | 沒
有 |
|---------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1)過去一年，我咳嗽的時間： | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2)過去一年，我咳痰的時間： | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3)過去一年，我喘不過氣來的時間： | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4)過去一年，我氣喘發作的時間： | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5)過去一年，你有過幾次非常嚴重或難過的胸腔毛病： | | | | | |
| | | | 超過三次..... | | <input type="checkbox"/> |
| | | | 三次..... | | <input type="checkbox"/> |
| | | | 二次..... | | <input type="checkbox"/> |
| | | | 一次..... | | <input type="checkbox"/> |
| | | | 沒有..... | | <input type="checkbox"/> |
| 6)最嚴重的那次持續了： | | | | | |
| | | | 超過一週..... | | <input type="checkbox"/> |
| | | | 超過三天..... | | <input type="checkbox"/> |
| | | | 一或二天..... | | <input type="checkbox"/> |
| | | | 不到一天..... | | <input type="checkbox"/> |
| 7)過去一年，平均來算，一星期中你有幾天是舒服的？ | | | | | |
| | | | 沒有..... | | <input type="checkbox"/> |
| | | | 一或二天..... | | <input type="checkbox"/> |
| | | | 三或四天..... | | <input type="checkbox"/> |
| | | | 幾乎每天..... | | <input type="checkbox"/> |
| | | | 每天..... | | <input type="checkbox"/> |
| 8)如果你有氣喘，是否在早上比較嚴重？ | | | | | |
| | | | 是..... | | <input type="checkbox"/> |
| | | | 否..... | | <input type="checkbox"/> |

Section 1：你如何描述你的胸腔狀況？

- 我最大的問題.....
- 給我帶來許多麻煩.....
- 給我帶來一些麻煩.....
- 沒有問題.....

如果你有工作的話，你的胸腔問題會

- 導致你辭職.....
- 影響你的工作或導致你換工作.....
- 沒有影響.....

Section 2：以下哪些活動最近經常造成你呼吸困難？請逐項勾選：

- 靜坐或躺平不動.....
- 沐浴或穿衣.....
- 在屋裡走動.....
- 在屋外平地走動.....
- 爬一層樓梯.....
- 爬坡.....
- 運動比賽.....

Section 3：以下還有一些關於你最近咳嗽及呼吸的問題。請逐項勾選：

- 我咳嗽得很難過.....
- 咳嗽令我疲倦.....
- 我說話時無法呼吸.....
- 我彎身時無法呼吸.....
- 咳嗽或呼吸問題使我無法安睡.....
- 我很容易疲倦.....

Section 4：以下各題是關於胸腔問題最近在哪些方面對你造成影響。

- 咳嗽呼吸問題使我當眾出醜.....
- 我的胸腔問題讓家人、朋友鄰居感到很煩.....
- 我喘不過氣時會害怕或恐慌.....
- 我覺得無法控制自己的胸腔問題.....
- 我覺得自己的胸腔問題不可能改善.....
- 我因為胸腔問題而變得很虛弱或失去行為能力.....
- 對我而言運動是不安全的事.....
- 似乎做任何事都很吃力.....

Section 5：以下關於服藥方面問題，如果沒有服藥，請跳到 Section 6。

- 吃藥對我沒有多大用處.....
- 我對當眾服藥感到難為情.....
- 藥物的副作用使我很不舒服.....
- 服藥對我的生活干擾很大.....

Section 6：以下是關於呼吸方面問題影響到你活動的情形：

- 我需要花很長的時間來梳洗或穿衣.....
- 我無法洗澡和沖澡，或洗得非常慢.....
- 我走路比別人慢，或是中途得停下來休息.....
- 家事類的工作要很久才做得完，或是中途得停下來休息.....
- 如果要爬一層樓梯，我會爬得很慢或是中途得停下來休息.....
- 如果我趕路或走得快些，常被迫半途停下來休息或放慢腳步.....
- 我的呼吸問題使我很難做如爬坡、搬東西上樓、在花園中除草、跳舞、打保齡球或高爾夫一類的事.....
- 我的呼吸問題使我很難做提重物，在花園裡挖洞或剷雪、慢跑、每小時步行 8 公里，或打網球、游泳一類的事.....
- 我的呼吸問題使我很難做一些活動例如粗重的手工、跑步、騎腳踏車、快速游泳或參與運動競技的事.....

Section 7：以下題目是關於胸腔方面的問題對你的日常生活的影響，請逐項勾選（請注意：只有在因為呼吸問題而不能從事某些活動時才回答是）

- 我無法做運動或參加比賽.....
- 我無法出外從事休閒或娛樂.....
- 我無法出外購物.....
- 我不能做家事.....
- 我不能離開我的床鋪或椅子太遠.....

現在，請寫下你因胸腔問題而無法從事的活動：

整個來說，下列那一句話最能描述問題對你的影響：

- 我仍能做任何我想做的事.....
- 有一兩件我想做的事不能做.....
- 我不能做大部份我想做的事.....
- 我想做事我都不能做.....

還有什麼，是以上這些問題沒有問到，但因為這個病，使您的生活品質受影響：

當我問您(Random 1 題)：題號： _____

您想到什麼？

結束時間： _____

The Sickness Impact Profile, Short Form, SIP68

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH

- 1 ___ I get around in a wheelchair.
- 2 ___ I get dressed only with someone's help.
- 3 ___ I do not move into or out of bed by myself, but am moved by a person or mechanical aid.
- 4 ___ I stand up only with someone's help.
- 5 ___ I do not fasten my clothing, for example require assistance with buttons, zippers, shoelaces.
- 6 ___ I do not walk at all.
- 7 ___ I do not use stairs at all.
- 8 ___ I make difficult moves with help, for example, getting into or out of cars, bathtubs.
- 9 ___ I do not bathe myself completely, for example, require assistance with bathing.
- 10 ___ I do not bathe myself at all, but am bathed by someone else.
- 11 ___ I do not have control of my bladder.
- 12 ___ I am very clumsy in body movements.
- 13 ___ I do not have control of my bowels.
- 14 ___ I feed myself with help from someone else.
- 15 ___ I do not maintain balance.
- 16 ___ I use bedpan with assistance.
- 17 ___ I am in a restricted position all the time.

In short:

- Statements can concern changes that have occurred recently or some time ago.
- Mark only those statements that describe a change in behavior that is related to your state of health.
- Mark only those statements that apply to you entirely.
- Do not mark statements that only partially apply to you.

You may take a break, but it is important that you finish the questionnaire in one day. Please do not consult others on any of the statements. We are interested in what you think.

You may begin filling out the questionnaire. Read the statements carefully and determine if they describe your situation and if they are related to your state of health.

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH

- 1 ___ I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.
- 2 ___ I have difficulty doing activities involving concentration and thinking.
- 3 ___ I react slowly to things that are said or done.
- 4 ___ I make more mistakes than usual.
- 5 ___ I do not keep my attention on any activity for long.
- 6 ___ I forget a lot, for example, things that happened recently, where I put things, appointments.
- 7 ___ I am confused and start several actions at a time.
- 8 ___ I do not speak clearly when I am under stress.
- 9 ___ I have difficulty speaking, for example, get stuck, stutter, stammer, slur my words.
- 10 ___ I do not finish things I start.
- 11 ___ I am having trouble writing or typing.

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH

- 1 ___ I go up and down stairs more slowly, for example, one step at a time, stop often.
- 2 ___ I walk shorter distances or stop to rest often.
- 3 ___ I walk more slowly.
- 4 ___ I use stairs only with mechanical support, for example, handrail, cane crutches.
- 5 ___ I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg.
- 6 ___ I kneel, stoop or bend down only by holding on to something.
- 7 ___ I do not walk up or down hills.
- 8 ___ I get in and out of bed or chairs by grasping something for support, or using a cane or walker.
- 9 ___ I stand only for short periods of time.
- 10 ___ I dress myself, but do so very slowly.
- 11 ___ I have difficulty doing handwork, for example turning faucets, using kitchen gadgets, sewing, carpentry.
- 12 ___ I move my hands or fingers with some limitation or difficulty.

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH

1. ___ My sexual activity is decreased.
2. ___ I am cutting down the length of visits with friends.
3. ___ I am drinking less fluids.
4. ___ I am doing fewer community activities.
5. ___ I am doing fewer social activities with groups of people.
6. ___ I am going out for entertainment less often.
7. ___ I stay away from home only for brief periods of time.
8. ___ I am eating much less than usual.
9. ___ I am not doing heavy work around the house.
10. ___ I do my hobbies and recreation for shorter periods of time.
11. ___ I am doing less of the regular daily work around the house than I would usually do.
12. ___ I am cutting down on some of my usual inactive recreation and pastime, for example, watching TV, playing cards, reading.

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH

1. ___ I often act irritable toward those around me, for example, snap at people, give sharp answers, criticize easily.
2. ___ I act disagreeable to family members, for example, I act spiteful, I am stubborn.
3. ___ I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them.
4. ___ I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen.
5. ___ I am not joking with family members as I usually do.
6. ___ I talk less with those around me.

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH

- 1 ___ I am not doing any of the shopping that I would usually do.
- 2 ___ I am not going into town.
- 3 ___ I am not doing any of the house cleaning that I would usually do.
- 4 ___ I am not doing any of the regular work around the house that I would usually do.
- 5 ___ I stay home most of the time.
- 6 ___ I am not doing any of the clothes washing that I would usually do.
- 7 ___ I am not going out to visit people at all.
- 8 ___ I am getting around only within one building.
- 9 ___ I have given up taking care of personal or household business affairs, for example paying bills, banking working on budget.
- 10 ___ I do not get around in the dark or in unlit places without someone's help.

Table 4A

Pearson's correlation coefficients for the SIP68 total score and the category scores with various five point scales (p ≤ 0.01, total population on file with regard to criteria).

	SIP68	SA	MC	PAC	SG	ES	MR	n*
severity [†]	.48	.40	.42	.16	.32	.19	.36	1590
health [†]	.34	.08	.25	.22	.38	.21	.24	1604
physical functioning [†]	.53	.36	.46	.21	.44	.19	.39	1549
psychological functioning [†]	.26		.10	.39	.27	.42	.17	1512
interaction with others [†]	.25	.07	.12	.30	.21	.35	.14	1499
happiness [†]	.22		.08	.28	.19	.31	.17	1370

[†] self-assessment on a five point scale

* Because not all aggregated files represented the same variables, the size of the research population varies in this table.

Table 4B

Pearson's correlation coefficients for the SIP68 total score and category scores with various five point scales (p ≤ 0.01, diagn. Rheumatism, n=377).

	SIP68	SA	MC	PAC	SG	ES	MR
severity [†]	.52	.44	.44	.12*	.38	.21	.46
health [†]	.25	.12	.18	.12*	.25	.18	.17
physical functioning [†]	.47	.31	.38	.15	.43	.23	.40
psychological functioning [†]	.25	—	.13*	.34	.19	.41	—
interaction with others [†]	.23	—	.20	.25	.20	.29	.11*
happiness [†]	.28	.12*	.16	.19	.21	.27	.26

* p < 0.05

[†] self-assessment on a five point scale

疾病衝擊量表 (Sickness Impact Profile, SIP68)

以下是有關您的健康狀態的敘述。如果其描述的狀態與您目前的情況吻合，請在方框內打✓（項目之間的差異不大，請提醒病患仔細作答）。

S A 身體的自主性

- 1. 您靠輪椅活動。
- 2. 您只有靠別人幫忙才能穿好衣服。
- 3. 您無法自由上下床，必須由他人幫助或利用輔助物。
- 4. 您必須由他人協助才能站起來。
- 5. 您不能自己穿好衣服，必須有人協助，譬如扣扣子、拉拉鍊、繫鞋帶等。
- 6. 您一點也不能走動。
- 7. 您完全不能走樓梯。
- 8. 難度大的活動，例如上下車、進出浴盆等，您都需要別人幫忙。
- 9. 您必須由他人協助才能完成沐浴。
- 10. 您完全不能自己沐浴，而都由他人協助。
- 11. 您小便失禁。
- 12. 您動作不協調。
- 13. 您大便失禁。
- 14. 您須由他人餵食。
- 15. 您不能保持身體平衡。
- 16. 您必須由他人協助使用便盆。
- 17. 您不能隨意變換體位。

M C 對行動的控制

- 1. 您上下樓梯很慢，只能一階一階走，還經常要停一下。
- 2. 您行走的距離比以前短，或經常要停下來，休息後再走。
- 3. 您走路比以前慢。
- 4. 您使用支撐物上下樓梯，如扶手、拐杖、手杖。
- 5. 您走路有些困難，如一瘸一拐、搖晃、摔倒、腿僵硬等。
- 6. 您必須扶住某些東西才能蹲下或彎腰。
- 7. 您不能走上下坡。
- 8. 您上下床或坐椅子必須扶住某些東西或用拐杖、助行器。
- 9. 您能站立很短的時間。
- 10. 您能自己穿衣，但穿的很慢。
- 11. 您在做一些要動手的事時覺得很困難，例如開水龍頭、作手工等。
- 12. 您的手指活動受限或有困難。

P A C 心靈的自主性及溝通

- 1. 您在推理及解決問題上有困難，例如：做計劃、做決定、學新事物。
- 2. 您集中注意力及思考有困難。
- 3. 您對言語的反應很慢。
- 4. 您比平常容易出錯。
- 5. 您對任何活動都不能保持長久的注意力。

- 6. 您最近比較健忘，例如東西放哪、剛發生過的事。
- 7. 您最近比較糊塗，經常把幾件事混在一起。
- 8. 當您有壓力時，就表達不清楚。
- 9. 您說話不清楚、結結巴巴、含糊不清。
- 10. 您做事總是有頭無尾。
- 11. 您目前寫字有困難（指以前會寫字的）。

S B 社交行爲

- 1. 您的性活動減少了。
- 2. 您與朋友見面的時間變短了。
- 3. 您喝的流質量減少了。
- 4. 您較少參加公眾活動。
- 5. 您很少參加社交活動。
- 6. 您很少參與娛樂活動。
- 7. 您在外面逗留的時間很短。
- 8. 您比以前（生病以前）吃的少。
- 9. 您無法做很繁重的家事。
- 10. 您只能短時間從事有興趣的事及娛樂。
- 11. 您現在很少做以往常做的家務，如整理書報。
- 12. 您減少了以往某些靜態的活動，如看電視、打牌、看書報。

E S 情緒的穩定性

- 1. 您很容易生氣，說話尖刻，容易損人。
- 2. 您常跟家人唱反調，也很固執。
- 3. 您常常向家人大發脾氣。
- 4. 您總是很急躁、沒耐心，也常跟自己過不去。
- 5. 您已經不像往常一樣和家人開玩笑。
- 6. 您和周圍的人說話少了。

M R 活動範圍

- 1. 您已經不再上街購物。
- 2. 您已經不再去街上辦事。
- 3. 您已經不再清理家務，如倒垃圾、掃地、擦桌椅。
- 4. 您現在不再做以往常做的家務，如整理書報、燒開水。
- 5. 您大部份時間都待在家裏，不外出。
- 6. 您不再洗衣服。
- 7. 您完全不去拜訪親戚朋友。
- 8. 我只能在同一棟樓內活動。
- 9. 您不再處理個人或家裏的事，如繳帳單、去銀行、計劃家庭收支等。
- 10. 在黑暗及照明欠佳下，若沒有人協助，您便無法行動。

PROTOCOL FOR MEASUREMENT OF DYSPNEA (Breathlessness)

Subject ID _____

(Hand subject the Borg Scales) I am going to ask you to pick a number on a line like this *(point to top line)* along with descriptives that shows how you rate your perceived breathlessness. The bottom end of the scale is anchored as the most severe degree of breathlessness experienced by you in the past. The top end of the scale is anchored as the sense of breathlessness experienced at rest. I would like you to pick a number that indicates how severe your breathlessness is now. *(Have subject point to a number on Borg Scale.)*

I will ask you to rate your perceived breathlessness again during and after the walking test later.

The Modified Borg Scale

0	Not at All
.5	Very, Very Light
1	Very Light
2	Light
3	Moderate
4	A Little Serere
5	Serere
6	
7	Very Serere
8	
9	Very, Very Serere
10	Maximum

伯格呼吸困難程度量表

0	一點也不
0.5	非常非常輕微
1	非常輕微
2	輕微
3	中度
4	有一點嚴重
5	嚴重
6	
7	非常嚴重
8	
9	非常非常嚴重
10	最大限度

PROTOCOL FOR 6 MINUTE WALK

Subject ID _____

1. After completion of questionnaires and spirometry, give subject instructions for the walk test. "This is the last part of the study. Now we will go out into the hallway and I will ask you to walk as far as you can in 6 minutes. You may rest as often and as long as you like. The goal is to cover as much ground as you can in 6 minutes."

If the subject uses oxygen, find out if he/she can carry own oxygen tank. Also, ask him/her if a higher flow rate is used with exercise. If so, set liter flow to the higher rate now.

2. In hallway, show subject start and turning points. Then say: "Start walking when I say 'go'. Remember that the goal is to cover as much ground as possible in 6 minutes.

You may rest whenever you like and for as long as you need to. I will say 'stop' when the time is up. When I say 'stop', I want you to stop walking and stay where you are.

Are you ready?"

3. Start timer and say 'go' at the same time. Now do the followings:
 - a. Walk with the subject all the way along.
 - b. At 1-minute mark and 5-minute mark of the 6-minute walk, say "You are doing well".
 - c. Use lap counter to record completion of each length.

If subject complains of chest pain, discontinue test immediately and have him/her sit down. Check vital signs and notify physician. If subject complains of shortness of breath or weakness, say "Take a rest now and when it passes, try to walk a little farther." If subject does not feel he/she can continue, stop the test; note distance walked and time elapsed.

4. At two minutes, mark the distance subject has covered; show a Borg scale to the subject and ask the subject what is the level of his/her breathlessness, note location and the direction he/she was headed.
5. At 6 minutes from the starting time, say "stop". Mark the place subject has stopped and which direction he/she was headed at the time, and show a Borg scale to the subject and ask the subject what is the level of his/her respiratory discomfort.
6. Have subject sit down. Have subject rest until he/she feels recovered, or at least 5 minutes. At end of recovery period, remind subject to turn down oxygen flow rate, if appropriate.
7. After subject leaves, measure distance covered in the 2-minute walk mark and the total distance walked.

SIX MINUTE WALK DATA RECORD

Subject ID _____

At 2 minutes:

number of laps _____ x length of lap _____ = _____ meters

length of last lap = _____ meters

Total = _____ meters

WALK2 _____

At 6 minutes:

number of laps _____ x length of lap _____ = _____ meters

length of last lap = _____ meters

Total = _____ meters

WALK6 _____

Carries own oxygen? Yes No N/A

Comments/reason for stopping/action taken:

If test stopped before 6 minutes: Distance _____ Time _____

DEMOGRAPHIC DATA RECORD

Subject ID _____

These questions ask about personal characteristics and socioeconomic status.

1. What is your marital status?
 - Married, living with spouse.....1
 - Never married.....2
 - Divorced.....3
 - Separated.....4
 - Widowed.....5
 2. What was the highest grade or year in school that you completed?
 _____ Years of education
 3. What is the name you use for your lung problem? _____
 4. Do you use oxygen because of your lung disease? Yes No
 5. Did you ever smoke cigarettes? Yes No
 If yes, ask the following:
 - a. How many packs a day did you smoke? _____ Pack(s)/day
 - b. How many years did you smoke? _____ Years
 - c. Do you still smoke? Yes No
 If no, When did you quit? _____ Years ago
 6. How do you perceive your health status?
 - a. Nothing is wrong
 - b. Mildly impaired
 - c. Moderately impaired
 - d. Severely impaired
- This is the end of the interview. I want to thank you for being willing to share your time and thoughts with me.
7. Gender Male.....1
 Female.....2
 8. Height (centimeters; without shoes) _____, Current Weight (Kilograms) _____
 9. Hospitalized times and emergency room visits over the last year: _____ times
 10. Number of days spent in hospital within past year: _____ Days
 11. Use of inhalers: Yes No
 12. Spirometry.
 FEV₁ _____ liter, FEV₁ _____ % of predicted, FEV₁/FVC _____



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Feb. 26, 1998

Attn: Institute of Review Board

School of Nursing
Oregon Health Sciences University

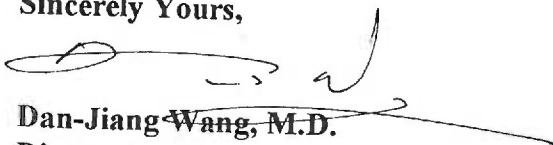
To Whom It May Concern:

Re.: Ms. Shioh-Yih Yeh's application
for collecting the data on the topic
"The Reliability and Validity of the Chinese
Version of the St. George's respiratory Questionnaire
in Patients with Chronic Obstructive Pulmonary Disease
in Taiwan"

With reference to the above, we have examined the draft plan made by Ms. Yeh, the doctoral student in gerontological nursing. We have considered the patients' rights won't be affected by her study. Thus, we agree with her in principle and would like to give her any assistance, if possible.

Best regards.

Sincerely Yours,



Dan-Jiang Wang, M.D.
Director
Tri-Service General Hospital
Deputy Director
National Defense Medical Center

MEMO

Date: July 14, 1998
To: *Shiow-Yih Yeh, Student, SN-5S, c/o Barbara Stewart PhD*
From: Gary T. Chiodo, DMD, Chair, Institutional Review Board, L106
Leslie Bevan, PhD, Director Research Support Office, L106



Subject: **4943**
Evaluating Reliability and Validity of the Chinese Version of the St. George's Respiratory Questionnaire in Patients with Chronic Obstructive Pulmonary Disease in Taiwan

Protocol/Consent Form Approval

We received your response to the IRB recommendation(s) dated 7/13/98 on 7/13/98.

Your protocol/consent form is approved for 1 year effective 7/14/98.

The IRB# and the date of this approval should be placed at the top right corner of the first page of the consent form.

Investigators must provide subjects with a copy of the consent form, keep a copy of the signed consent form with the research records, and place a signed copy in the patient's hospital/clinical medical record (if applicable).

If this project involves the use of an Investigational New Drug, a copy of the approved protocol must be forwarded to the Pharmacy and Therapeutics Committee (Pharmacy Services - Investigational Drugs, OP-16A).

If this is a cancer study, we will notify the Oregon Cancer Center (OCC) of the IRB approval. As the PI, you are responsible for providing the OCC with copies of the final approved protocol/consent form.

If other levels of review and approval are required, the project should not be started until all required approvals have been obtained. In addition, studies funded by external sources must be covered by an agreement signed by the sponsor and the Oregon Health Sciences University. Principal Investigators are not authorized to sign on behalf of the University.

Thank you.

