Health Related Quality Of Life (HRQOL) In COPD
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Abstract
Over the past decade, more and more research on the development and validation of questionnaires has been undertaken to quantify the impact of disease on daily life and well-being from the COPD subject's point of view. Health-related quality of life is an important outcome of medical care. HRQOL incorporates several dimensions experienced by the patient that are affected by disease and health. COPD patients come to physicians seeking relief of symptoms that include breathlessness, cough, sputum production, and functional limitation due to exertional dyspnea. Therefore interventions that would reduce these symptoms and improve function of patients are of prime importance. HRQoL measures do not substitute for physiologic parameters, but can complement these by incorporating aspects of health and disease that are directly perceived by the patient.

INTRODUCTION
In the past three decades, a number of important advances have been made in the treatment of patients with chronic obstructive pulmonary disease (COPD) (Pauwels RA et al., 2001). For example, supplemental oxygen therapy and smoking cessation have resulted in improved traditional outcome measures, such as mortality (Nocturnal Oxygen Therapy Trial Group, 1980) and rate of forced expiratory volume in one second (FEV1) decline (Anthonisen NR et al., 1994). Although these end-points are important to clinicians and patients alike, survival and physiological measures do not fully represent the experiences of patients with COPD. Relying exclusively on mortality and physiological outcomes for evaluating treatment effectiveness could result in the decision that some treatments offer no benefits, when in fact they provide significant and important benefits to patients and their families. A treatment that has no effect on mortality or FEV1, for example, may significantly improve the patient’s vitality or other functional areas of daily living. Needless to say, reducing the personal and social burden of disease by improving patient’s symptoms, functional status and quality of life are important goals. Self-perceived health outcomes are often most relevant and important to patients and their loved ones because they capture the patient’s experiences and perspectives.

Increasingly, it has been recognised that health status, especially health-related quality of life, is an important outcome of medical care (Guyatt GH et al., 1993). The development of reliable and valid tools that measure health status has contributed to a substantial increase in the use of these instruments. Since more of these tools are being used and reported, it is important for clinicians and researchers to understand their strengths and limitations.

HRQOL - TERMS, DEFINITION AND CONCEPTS
Health outcomes represent a broad group of end-points used in clinical research to assess the efficacy or effectiveness of interventions and to assess disease outcomes (Clancy CM & Eisenberg JM, 1998). Traditional health outcomes include mortality, number of hospital admissions and FEV1. More recently, there has been a growing body of research concerning endpoints that are assessed directly by patients and can be termed “patient-reported health outcomes” (PRO). It is an umbrella term used for all patient-based assessments. PROs are by definition subjective and multidimensional. Examples of PROs are outcomes such as health status, health utilities, adherence to treatment and patient satisfaction with healthcare. Health status can be defined as the impact of health on a person’s ability to perform and derive fulfilment from the activities of daily life. A patient’s self-reported health status thus includes health related quality of life and functional status.

Various definitions of HRQOL exist. The World Health Organization (WHO) definition of health is “not merely the absence of disease, but complete physical, psychological, and social well-being” (WHO, 1958). HRQOL refers to the physical, psychological and social domains of health that are
unique to each individual (Testa MA & Simonson DC, 1996). Each of these domains can be measured by the objective assessments of functioning or health status and the subjective perceptions of health. Other valued aspects of life exist that are not generally considered as “health,” including income, freedom, and the environment. It has been defined as follows: “HRQL is defined as the value assigned to duration of life as modified by impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy” (Patrick DL, Erickson P, 1996). Another definition is “HRQL can be defined as the functional effect of an illness and its consequent therapy upon a patient, as perceived by a patient” (Schipper H et al, 1996).

Conceptually, HRQOL incorporates several dimensions experienced by the patient that are affected by disease and health (Figure 2.5). This includes symptoms, physical function, cognitive performance, psychosocial condition, emotional status, and adaptation to disease. Though the severity of disease is an important determinant of the patient's health, patient perception and adaptation largely define the overall quality of life.

Over the past decade, more and more research on the development and validation of questionnaires has been undertaken to quantify the impact of disease on daily life and well-being from the COPD subject's point of view. This is because of recognition of the following factors:

- Individual patients are most concerned about their symptoms (e.g., dyspnea) and their function (e.g., ability to perform physical tasks), rather than objective measures such as expiratory airflow;
- HRQOL is a unique construct that is different from physiologic measures or survival (Feinstein AR, 1983);
- The goals of therapy have been expanded to include relief of symptoms and improvement in HRQOL in addition to the standard physiologic outcomes. (Guyatt, GH et al, 1987)

**WHY MEASURE HEALTH-RELATED QUALITY OF LIFE IN COPD?**

Specific outcomes, such as spirometric measurements, may have greater appeal because of their relative simplicity and apparent link with pathophysiology. Besides, the combined effect of different treatments presumed to improve a particular physiologic parameter may not necessarily lead to better patient comfort and quality of life. Miravitlles et al. observed worse HRQL in patients who received three or more drugs for COPD despite adjustment for severity of disease and comorbidities. Though the possibility of confounding by indication exists, this can also be due to unwanted side effects of overzealous treatment. Even from a physiologic standpoint, a single parameter such as the FEV₁ may be a good indicator for airflow obstruction, but may not be a good indicator of dynamic hyperinflation causing dyspnea. (Belman MJ et al, 1996) Perhaps the most important, though often overlooked, reason to consider HRQoL as an outcome is the patient's perspective. COPD patients come to physicians seeking relief of symptoms that include breathlessness, cough, sputum production, and functional limitation due to exertional dyspnea. Therefore, interventions that would reduce these symptoms and improve function of patients are of prime importance. HRQoL measures do not substitute for physiologic parameters, but can complement these by incorporating aspects of health and disease that are directly perceived by the patient.

**HEALTH-RELATED QUALITY OF LIFE: INSTRUMENTS FOR MEASUREMENT**

A number of instruments have been developed to assess HRQoL. These can be classified into three main types: generic, disease-specific/situation-specific, and Preference-based questionnaires.

**GENERAL HEALTH QUESTIONNAIRES**

Generic HRQOL instruments are broadly applicable to different health problems. Generic measures are broader in scope and applicability. The strengths of generic measures are that they are capable of detecting the effects of the diverse aspects of disease beyond those captured by a disease-specific measure and they are capable of comparing health status across multiple diseases (Ren XS et al, 1988). In addition, these measures may be more likely to detect unexpected effects of an intervention that does not relate to respiratory health. No definitive evidence in head-to-head comparisons supports the use of one generic health-status measurement over another in COPD. Domains that reflect physical limitations generally share similar correlations to a 6-min walk and FEV₁ (Guyatt, GH et al, 1987).

A number of generic health-related, quality-of-life instruments have been used to characterise COPD. The following is a discussion of the instruments that are most widely used.
Sickness Impact Profile (SIP) The Sickness Impact Profile (SIP) was developed in 1972 as a result of collecting statements describing behavioural dysfunction attributable to illnesses from sick and healthy patients, as well as professional and non professional caregivers. This 136-item questionnaire covers a broad number of domains and dimensions that include physical activity (ambulation, mobility, body care and movement), psychosocial functioning (societal interactions, alertness behaviour, emotional behaviour and communication), as well as five independent domains: sleep and rest, eating, work, home management, and recreation and past-times (Bergner M et al, 1981). The SIP has been well validated and demonstrated to be reliable and responsive among patients with COPD (Engstrom EP et al, 2001). It has been used to describe the effect of COPD on patient’s health status, although it may not be discriminative of mild COPD. This instrument was designed to be either interviewer- or self-administered. Its major disadvantage is the relatively long time it takes to complete, which is 20–30 min. Another potential disadvantage is that no studies clearly demonstrate how to define the MID in scores.

Medical Outcome Study Short Form -36 The MOS questionnaire has undergone a number of revisions. The most commonly used form is the previously mentioned SF-36. This instrument has been demonstrated to be reliable and responsive in COPD (Mahler DA & Mackowiak JI, 1995). The SF-36 is divided into eight domains: physical-functioning, role-physical, bodily pain, general health, vitality, social-functioning, role emotional and general health. The SF-36 also has two summary scores, a physical component scale and a mental component scale that were developed with factor analysis. The SF-36 offers significant advantages in that it is self-administered, easily completed in 5 min and has been translated and validated in several languages. Although not originally designed to be a utility measure, attempts have been made to create a single index to be used in the calculation of QALYs (Brazier JE, et al 1998). The MID of the SF-36 is reported to be five units, although it is unclear what scoring difference counts as an MID. This instrument is self-administered and can be completed in 10–15 min.

Quality Well Being (QWB) The QWB is a health-status instrument that was developed as part of the Health Status Index (Fanshel S & Bush J. 1970). It contains three scales: mobility, physical activity and social activity. Questions determine the functional level of each scale. Weighted values for the different combinations of functional level and symptomatology on each scale were assigned from a randomly selected population-based sample. Responding to questions were assigned values derived from the population based sample. This method of scoring allows for the QWB to be transformed to a scale from zero to one and has the unique advantage of being able to be used to calculate QALYs in cost-effectiveness analysis, meaning that the QWB is the only health-status measure described here that allows for the calculation of QALYs. A single cross-sectional study has been performed; demonstrating validity among patients with COPD (Kaplan RM, et al 1984) and it is unclear what scoring difference counts as an MID. This instrument can be either interviewer or self-administered and takes 20 min to complete.

DISEASE SPECIFIC QUESTIONNAIRES

The disease- or condition-specific instruments focus on one condition and attempt to define its effects on a patient’s health status.

Chronic Respiratory Disease Questionnaire (CRDQ) CRDQ was developed more than 10-yrs-ago through qualitative interviews of patients with chronic lung disease and it has been used comprehensively in examining health status of COPD patients (Guyatt GH et al, 1987). An interviewer administered questionnaire, it contains 20 items that cover 4 domains: dyspnea (five item) fatigue (four item) emotional function (seven items) and mastery (a domain that explores how patients cope with their illness (four items). The CRDQ individualizes the dyspnea domain by asking this patient to identify the activities that make them dyspnoeic and to rate the degree of dyspnea. In order to assist their selection, patients are offered a list of 26 activities. The structure of the
other domains is conventional, each patient being asked identical questions. The respondents are asked to grade their function in each item using seven point Likert scale. The total for each domain is divided by number of items, yielding a potential score of one to seven with high number representing better function. The CRQ has been used to assess the effects of bronchodilators and to make comparisons between bronchodilators or aerosol delivery mechanisms, modes of ventilation, long-term oxygen therapy and pulmonary rehabilitation.

SGRQ is a standardized, self-administered questionnaire for measuring impaired health and perceived HRQL in airways disease. It contains 50 items with 76 weighted responses that cover three domains: symptoms, activity and impact. In addition to the domain scores, a total score is calculated. Each item has an empirically derived weight. The SGRQ is scaled from zero to 100 (with zero representing the best health-related quality of life). This instrument has been demonstrated to be valid, reliable and responsive among patients with COPD (Jones PW et al 1991).

Seattle Obstructive Lung Disease Questionnaire (SOLDQ) The SOLDQ, a relatively new instrument, was designed to examine patients with asthma or COPD (Tu SP, et al 1997). The instrument contains 29 items that cover three health domains and a satisfaction with care domain. These domains are the physical function, emotional function, coping skills and treatment satisfaction. Each domain score is transformed (but not normalised) on a scale of one to 100. The MID in the score of the physical function domain, adapted from the SF-36 physical function domain, has been estimated to be six points. The SOLDQ instrument has been demonstrated to be valid and responsive to change among American veterans, but has yet to be used extensively outside this population. Overall, the SOLDQ physical function score had greater predictive validity than the SF-36 physical component score. The SOLDQ is self-administered and can be completed in 10–15 min.

The Quality of Life for Respiratory Illness Questionnaire (QLRIQ) It is a disease-specific, quality-of-life measure designed for patients with reversible and fixed airway obstruction. Patients are asked how much of a problem each item has been during the past year. This instrument contains seven domains and 55 items and each item is rated on a seven-point Likert scale. The domains are breathing problems, physical problems, emotions, situations triggering or enhancing breathing problems, daily and domestic activities, social activities, relationships and sexuality, and general activities. Although test/retest reliability and responsiveness have not been reported, the instrument shows internal consistency and constructs validation (Maille AR, et al 1994).

Finally, there is an additional health-status instrument that was developed for use among a subset of patients with COPD, those with chronic respiratory failure. The Maugeri Foundation Respiratory Failure Questionnaire-28 has 28 items and was developed in Italian but has been translated into many languages. Although this instrument is only validated in this subset of patients with severe COPD, in this group, the instrument has been shown to be reliable, valid and responsive to change with treatment with non invasive ventilation (Carone M et al 1997).

**PREFERENCE BASED QUESTIONNAIRES**

Euro Qol 5D The Euro Qol 5D (EQ-5D) is a generic, preference-based utility questionnaire and consists of two parts, the EQ-5D VAS and the EQ-5D index (Kind P. 1996). The EQ-5D VAS is a visual analogue scale ranging from 0=death/worst possible health to 100=best possible health. The EQ-5D index is a five-item questionnaire. The items consist of mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each item has three levels: no problem, some problem and severe problem. For the EQ-5D index, 0.03 has been regarded as the MID.

Short Form 6D The Short Form 6D (SF-6D) is a health-state classification system constructed post hoc from 11 selected items from the SF-36 generic HRQL questionnaire. The SF-6D is composed of six HRQL domains: physical functioning, role limitations, social functioning, pain, mental health and vitality, and is based on 11 selected items from the SF-36 instrument. The number of response options varies between four and six, depending on domain. In practice, subjects fill in the SF-36 questionnaire and their responses are then used to determine SF-6D scores.

Time Trade-Off The Time Trade-Off (TTO) includes a direct question offering a choice between twenty years in current health or shorter length of life in perfect health (Torrance GW. 1976).

Feeling Thermometer with Health Marker States for COPD (HS-COPD) A future instrument for preference-based utilities may be the Feeling Thermometer using pre-defined Health Marker States or Clinical Marker States. The HS-COPD is being developed using Health Marker States relevant for COPD, and the instrument to complete is a
visual analogue scale. This gives the HS-COPD a possibility to be used as a utility instrument, which has to be a generic instrument in order to compare various diseases/conditions.

The characteristics of selected general and disease-specific questionnaires for measuring HRQOL in patients with COPD are listed in Table 2.8

**HEALTH-RELATED QUALITY OF LIFE - LINGUISTIC VALIDATIONS**

With a few exceptions, most questionnaires have been developed in English. There are many examples in the literature of the translation of HRQOL questionnaires, but few publications describe the guidelines to be followed (Hunt SM 1988). In recent years a standardised procedure has been worked out, comprising three main steps. The first step is the production of a culturally and linguistically adapted version of the source questionnaire. The second step is the comparison of the source and the target versions. The third step is the comparison of all target versions (international harmonisation). Each translation should follow the same established forward-backward translation procedure, with independent translations and counter-translations (Aaronson NK et al 1992).

**USES OF HRQOL QUESTIONNAIRE IN COPD**

There are at least three ways in which an HRQoL questionnaire can be used, namely as an evaluative, discriminative or predictive measure.

The number of publications on the use of HRQOL questionnaires to measure the effect of interventions is increasing (evaluative measure). The term evaluative means that the instrument has the ability to detect within-subject changes over time that occur either spontaneously or as a result of treatment or other intervention. COPD is a disease characterised by a faster decline in FEV₁ than the physiological decline with increasing age that occurs in healthy subjects (Burrows B, et al 1987). Papers include evaluation of HRQOL after rehabilitation programmes (Wijkstra PJ, et al 1994).

The usage of HRQoL questionnaires as a discriminative measure in COPD has been considered. This means that a questionnaire has the ability to differentiate between subjects, or groups of subjects, with different levels of impairment, i.e. those with mild, moderate or severe impairment of HRQoL. One group of researchers (van den Boom G, et al 1998) showed that many subjects are not likely to visit their doctor until their HRQL is heavily affected.

A predictive measure can be explained as having the ability to predict a future event or disease prognosis. The option of using HRQoL questionnaires as a predictive measure is demonstrated in a study where poor scores on the SGRQ were associated with re hospitalisation for COPD and increased use of resources, such as nebulisers. Another study concluded that improving physical performance and teaching adequate coping strategies should be considered in order to improve HRQL (Ketelaars CA, et al 1996).

In summary, HRQoL questionnaires in COPD may have a value to evaluate changes after intervention.

HRQoL and mortality One possible use of HRQoL measures is for prognostication. Previous studies show a correlation between measures for quality of life and mortality independent of disease severity. Anxiety, nutritional status, and psychosocial factors such as marital support have been implicated as predictors of mortality (Anthonisen NR, et al 1996).

Health-Related Quality of Life and Resource Utilization Worsening health status may lead to increased health resource utilization. Thus, evaluating HRQoL may be useful in identifying patients at risk of precipitous decline for which preventive measures may be instituted.

**References**

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