Quality of life in asthma and COPD: development of a disease-specific questionnaire
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Chapter 1

General Introduction:
Quality of Life in Asthma and COPD
Background

This thesis deals with the development and validation of the Quality of Life for Respiratory Illness Questionnaire (QoL-RIQ), a disease-specific quality of life questionnaire for patients with asthma and chronic obstructive pulmonary disease (COPD). This work is a direct consequence of the results of the study "Coping with Chronic Non-Specific Lung Disease (CNSLD) - Research in asthma and COPD, a social science perspective". In the report of this study a research agenda for future behavioural research was presented, which was based on a survey of the literature from 1980 to 1990 of behavioural research on asthma and COPD. In addition, recommendations of interviewed specialists in the field of asthma and COPD were used.

In this research agenda quality of life was considered one of the most important topics for future research. Between 1980 and 1990 considerable attention was paid to the consequences of asthma or COPD for patients' daily lives. However, most of the studies did not have the broad quality of life perspective as a main objective. Relatively few disease-specific instruments existed at the time, so the results of the studies were not as detailed, as one would have wished.

Over the last decade addressing patients' quality of life, in addition to biomedical outcomes, has gained importance enormously: As a consequence, much attention has been paid to the development and validation of instruments assessing this new concept.

Before discussing the development and validation of one of these instruments - the QoL-RIQ-, definitions, recent pathophysiological developments and prevalence of asthma and COPD will be presented. A short review will be given of the psychological views on asthma and COPD as well as of topics of behavioural research and psychological guidance and treatment of patients with asthma and
COPD. This is followed by a short introduction into the concept of quality of life in general and more specifically in asthma and COPD and, finally an outline of the thesis will be given.

**From chronic non-specific lung disease to asthma and COPD**

*Introduction*

Chronic non-specific lung disease (CNSLD) encompasses asthma, chronic bronchitis and emphysema. All three illnesses concern chronic ailments of the airways and the patient suffers for shorter or longer periods of time from shortness of breath due to airflow obstruction. Asthmatic patients occasionally have breathing problems over short periods of time. For patients with COPD (chronic obstructive pulmonary disease) however, breathing difficulties are a more constant problem, as the airway obstruction is mostly irreversible. Until recently, no clear distinction was made between asthma and chronic obstructive pulmonary disease (COPD, combining chronic bronchitis and emphysema) in the Netherlands. This was based on the ‘Dutch Hypothesis’ which proposed that a predisposition for atopic disease, airway hyperresponsiveness, and eosinophilia (a so called ‘asthmatic constitution’) underlay the development of chronic airflow obstruction. Recently gained insight into the pathophysiological aspects of asthma showed that inflammation with participation of complex cellular and chemical mediators could be considered the salient characteristic of this disease. Due to differences in pathogenesis, asthma and COPD are nowadays considered separate entities, also in the Netherlands.
**Definitions**

Asthma is defined as “a clinical syndrome characterised by increased responsiveness of the tracheobronchial tree to a variety of stimuli.” Asthma is nowadays considered a chronic inflammatory disorder of the airways in which many cells play a role, in particular mast cells, eosinophils, and T-lymphocytes. In susceptible individuals this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness, and cough, particularly at night and/or in the early morning. These symptoms are usually associated with widespread but variable airflow limitation. This airflow limitation is at least partly reversible, either spontaneously or with treatment. The inflammation also causes an associated increase in airway hyperresponsiveness to a variety of stimuli.

COPD is a disorder with the presence of airflow obstruction as the main characteristic. This obstruction is caused by chronic bronchitis or emphysema, it is generally progressive and may be accompanied by airway hyperreactivity. The airway obstruction may be partly reversible. Chronic bronchitis is defined as “the presence of chronic productive cough for 3 months in each of two successive years. This chronic cough can not be attributed to other pulmonary or cardiac causes.” Emphysema is defined as “abnormal permanent enlargement of the airspaces distal to the terminal bronchioles, accompanied by destruction of their walls but without obvious fibrosis.” Airway hyperresponsiveness to a variety of constrictor stimuli is common in patients with COPD. The most difficult diagnostic problem is distinguishing COPD from the persistent airflow limitation of chronic asthma in older subjects.
Pathophysiology

Recently gained insights into the pathology of asthma show that a chronic inflammatory response in the airways plays a key role in this disease. This airway inflammation is associated with airway hyperresponsiveness (an exaggerated bronchoconstrictor response to a variety of endogenous and exogenous stimuli), with airflow limitation and respiratory symptoms. Airflow limitation can be caused, due to acute bronchoconstriction, by oedematous swelling of the airway wall, increased mucus secretion and airway wall remodelling. Even in the absence of symptoms and overt airflow limitation, asthma continues to exist in the form of a mild airway inflammation and airway hyperresponsiveness.\textsuperscript{12}

Pathological changes in COPD can take place in the central airways, the peripheral bronchi, bronchioles and alveoles. In the central airways most of the hypersecretion of mucus takes place (expressed clinically as chronic bronchitis), partly due to the enlargement of tracheobronchial submucosal glands. In these glands a larger proportion of mucus is acidic. Recently it has been found that an airway wall inflammation is also present. In addition, an increase in the number of globet cells in the peripheral bronchi, increased intraluminal mucus, inflammation, and increased wall muscle mass may be found.\textsuperscript{3,11,13}

Epidemiology

The prevalence of asthma in the Netherlands, registered in general practice is about 11.6 per 1,000 for women and 10.8 per 1,000 for men. The prevalence of COPD in the Netherlands is higher than of asthma, especially for men; 24.2 per 1,000 versus 13.8 per 1,000 for women.\textsuperscript{14} The mortality rate for asthma in the Netherlands was 0.4 for men and 0.3 for women in 1994. For COPD the mortality rates are much
higher; 50.2 for men and 23.5 for women.\textsuperscript{15} Despite the introduction of new treatment modalities, the prevalence of asthma and COPD is increasing and they cause a rise in morbidity and mortality in Western countries.\textsuperscript{16,17,18} The increase in prevalence of these diseases especially concerns patients with mild forms of asthma or COPD.\textsuperscript{19}

\textit{Risk factors}

The strongest identifiable risk factor for the development of asthma seems to be atopy. Atopy can be defined as the propensity to produce abnormal amounts of IgE in response to exposure to environmental allergens. Atopy is at least partly under genetic control.\textsuperscript{20} Gender and race are often mentioned as possible risk factors, although environmental factors may be more important in the development of asthma. The onset of asthma may be caused by exposure to allergens. A distinction can be made between indoor allergens (i.e., domestic mites, animal allergens), and outdoor allergens (i.e., pollens, fungi). Aspirin and occupational sensitizers are also considered important causal factors in the onset of asthma. Contributing factors which enhance the likelihood of developing asthma upon exposure to causal factors and may even increase the susceptibility to asthma, are: smoking, active as well as passive; air pollution, outdoor as well as indoor; diet (food allergy in childhood); small size at birth and respiratory infections. Finally, more individually coloured factors may be distinguished that may trigger an asthma exacerbation by inducing inflammation and/or acute broncho-constriction. These triggers vary from person to person and even from time to time. They vary from allergens, respiratory infections, hyperventilation and exercise to weather, foods, drugs, emotions, etc.\textsuperscript{21,22,23}
The only known genetic cause for COPD is a deficiency, known as alpha-1-antitrypsin, although this only accounts for 1% of the prevalence of COPD in the United States. The primary cause of COPD is exposure to tobacco smoke. Overall, tobacco smoking is responsible for about 80 to 90% of the risk developing COPD in the United States. Although the relationship between passive smoking and the development of COPD is unclear, it is known that in children with parents who smoke the prevalence of respiratory symptoms as well as of respiratory disease is higher than in children of non-smokers. Air pollution, airway hyperresponsiveness, sex, race and socio-economic status, and occupational factors are mentioned as other possible risk factors.

**Medical management**

The goal of asthma management is to achieve control over the disease. Patients should be able to play a crucial role, which means: control of symptoms, prevention of asthma exacerbations, maintaining a pulmonary function as close to normal levels as possible, no limitations in activities including exercise, avoiding adverse effects of medications and preventing development of irreversible airflow limitation. In asthma management this partnership of patients and physicians is considered more and more important. Patient education is therefore an important component of asthma management.

Effective control of asthma may be accomplished by assessing and monitoring asthma severity (by symptom registration and lung function measurement), by avoiding or controlling asthma triggers, establishing individual medication plans and plans to cope with exacerbations. As asthma is a chronic inflammatory disorder of the airways, the prevention of inflammation by the elimination of causal factors is crucial.
In pharmacological treatment, anti-inflammatory agents, i.e. inhaled corticosteroids, form the cornerstone. Asthma medication can be divided in ‘controllers’, taken daily on a long-term basis in order to get and keep asthma under control (e.g. inhaled corticosteroids), and in ‘relievers’, agents that act quickly to relieve bronchoconstriction and accompanying acute symptoms such as cough, wheezing, chest tightness (e.g. inhaled beta2-agonists). In COPD patients treatment is directed at the prevention of symptoms and exacerbations in combination with the preservation of an optimal lung function and the improvement of quality of daily life. Prevention of smoking and stopping smoking are the main preventive therapeutic options, next to influenza vaccination and condition improvement. Stopping smoking reduces a further decline in lung function in patients that have already developed COPD. Interventions in pulmonary rehabilitation for COPD patients have mainly focused on physiological and conditional improvements. Apart from non-pharmacological therapy (e.g. smoking cessation, flu-vaccination, and condition improvement), medication is also used in the treatment of COPD. Bronchodilator therapy is important. Although inhaled corticosteroids play a crucial role in the pharmacological treatment of asthma, their role in the treatment of COPD is less clear. It seems that FEV1 is initially enhanced in COPD because of the use of inhaled corticosteroids, and that this improvement lasts for some years.

Psychological views on asthma and COPD, behavioural research and psychological treatment of asthma or COPD patients

About three decades ago, the psychological view on asthma started to change markedly, and as a result, the topics of behavioural research and psychological
guidance or treatment of patients with asthma or COPD. Up to about 1960 asthma was considered a psychosomatic disease, and its cause was explained on psychoanalytic grounds. At the beginning of the seventies, great emphasis was laid on the psychological and day to day consequences of these diseases. It was found that adult patients experienced problems in many fields of daily life. Examples of the direct physical consequences of asthma and COPD are wheezing, shortness of breath, coughing, problems with physical exercise and daily activities. Apart from that, it was found that patients experienced several emotional problems, such as shame, anxiety, depression, and in addition anger and helplessness. It was found that patients might become socially isolated or might not be able to perform their work. Individual variations exist in the reaction to or experience of the consequences of these diseases, depending on the patient's personality, attitude and behaviour. As a consequence of this shift in the psychological views on asthma and COPD, patients' participation and patients' behaviour have become crucial aspects in the treatment and management of these diseases. Much attention is now paid to illness behaviour or the way patients deal with their chronic illness (coping behaviour).

The change in psychological views on asthma has also markedly influenced the psychological treatment of patients with asthma and COPD. It has resulted in the development of intervention methods such as patient-education and self-management programmes. These programmes were intended to improve the patient's ability to control his/her symptoms and improve compliance with prescribed medication. As a result of the increased interest in the way in which asthma and COPD patients learn to live with this chronic disease, research into the consequences of these diseases for daily life, as well as the perceived psychological and social health has been gaining importance. It has been increasingly recognised that the evaluation of health care should also include outcomes important to
patients, like quality of life.²

Quality of Life

Definitions and measurement

As early as 1947 the World Health Organisation defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity".²⁷ In the following years, the daily functioning and well-being of people was more and more conceptualised by the term 'quality of life'. This concept, however, was rather elusive; quality of life was defined, conceptualised and operationalised in various ways. One of the best known definitions of quality of life is the one from Schipper et al.²⁸ "Quality of life represents the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient"(p. 16). From the WHO definition, as well as from publications by Spilker et al.²⁹, it can be concluded that the physical, mental and social dimension of health should be covered in quality of life research.

So, although the term "quality of life" is not unequivocally defined, it is generally assumed that a good approximation is provided by measures which deal with at least the following areas of daily life: physical and functional status, psychological status and social functioning. With regard to assessing "quality of life" in clinical medicine, a distinction is generally made between 'generic' and 'disease-specific' questionnaires. Generic instruments measure general characteristics and consequences of sickness, and have the advantage of being broadly applicable to people with different disorders. They allow comparisons between individuals or groups with different illnesses, or comparisons between patients and healthy
controls. However, they may not touch on the most relevant topics of a specific illness. To take into account the characteristic problems and consequences on daily functioning, disease-specific questionnaires are used. The potential responsiveness of disease-specific questionnaires to change over time, compared to generic instruments, is also an important advantage.\textsuperscript{30}

Over the past decade the development, validation and translation of quality of life instruments as well as the implementation of quality of life in clinical research and patient care has been of enormous influence. Nowadays 'quality of life' is a very important issue in health research and health care. Many professionals with different scientific backgrounds contribute to quality of life research: psychologists; physicians; epidemiologists; nurses etc. Research on determinants of quality of life has been initiated, theoretical models are built around the quality of life concept, including variables such as disease severity, personality characteristics, coping, illness- perceptions and self-efficacy.

\textit{Quality of life in asthma and COPD}

At the start of our project in 1989-1990, quality of life had been examined in life-threatening diseases such as oncology and cardiology.\textsuperscript{31,32,33} In these areas the importance of quality of life was increasingly recognised when considering treatments in experimental studies, as well as in decision-making regarding patient treatment and patient care.

Quality of life research addressing asthma or COPD-patients, however was rather under developed. In the eighties, various studies established that asthma and COPD have great consequences on the daily functioning of the patient, depending in part on the frequency and severity of symptoms. Besides breathing problems, coughing, allergic reactions and the like, which arise directly from the disorder, fatigue,
sleeping difficulties, and limitations in physical and daily activities have also been identified as consequences of asthma and COPD.\textsuperscript{34,35,36,37} A variety of emotional problems also result from these diseases, such as fear, shame, helplessness, dependence and depression.\textsuperscript{38,39,40} In addition, asthma and COPD can also have many effects on relationships and social contacts; social isolation and loneliness are often cited.\textsuperscript{41,42}

Although these studies showed the effects of asthma or COPD on daily life, most studies did not have the broad quality of life perspective as a main objective, and examined, as a consequence only parts of daily functioning. In addition, many instruments to assess quality of life in these studies were not disease-specific, due to which the results of the studies were not always as detailed as one would wish.\textsuperscript{43} The only disease-specific quality of life questionnaire for respiratory patients that existed at that time was the Chronic Respiratory Disease Questionnaire of Guyatt et al., developed for patients with chronic bronchitis and emphysema.\textsuperscript{34,35} The study of the quality of life of patients with asthma and COPD was considered to be one of the most important areas and recognised as such in a research agenda for future behavioural research by Dutch medical and behavioural science experts in 1991.\textsuperscript{1,2} Prompted by the developments in the area of quality of life in health care, and the need for the development of a questionnaire in the Dutch language for asthma and/or COPD-patients we decided to develop a disease-specific questionnaire which included functional, psychological and social aspects of the quality of life of asthma and COPD-patients.

In The Netherlands 80% of the diagnosed asthma and COPD-patients are treated by general practitioners (GPs).\textsuperscript{44,45} Asthma and COPD-patients in a GP-setting are obviously more hindered in their daily activities than a healthy population\textsuperscript{45}, but relatively little research has been done into the consequences of mild and moderately severe asthma and/or COPD on daily functioning. Therefore, we
decided to address patients with asthma and COPD from GP-settings first. In the last decade, several disease-specific quality of life questionnaires have been developed, especially for children and adults with asthma. COPD-specific quality of life questionnaires are gaining attention very recently. This thesis addresses the development and validation of the Quality of Life for Respiratory Illness Questionnaire (QoL-RIQ).

Outline of the thesis

In Chapter 2 part of the results of a study on the state of the art of behavioural research between 1980 and 1990, and topics for future research in this field are presented. The research agenda with recommendations for future behavioural research is the main topic of this chapter. In this research-agenda quality of life was considered to be one of the most important and the development of the Quality of Life for Respiratory Illness Questionnaire (QoL-RIQ) is a direct consequence of these recommendations. The state of the art of behavioural research between 1980 and 1990 has been published as "Coping with Chronic Non-Specific Lung Disease (CNSLD) - research in asthma and COPD, a social science perspective".¹

In Chapter 3 a review of empirical research on quality of life in asthma and COPD-patients between 1980 and 1994 is presented. Special attention has been paid to the definitions and operationalisations of the concept of quality of life in this field of research, as well as to the questionnaires used to assess quality of life, and the specific aims of quality of life research in asthma and COPD patients.

Chapter 4 describes the first stage of our research project: the construction of the QoL-RIQ - a disease-specific quality of life questionnaire for patients with asthma or COPD in general practice. The questionnaire itself is presented and a first indication is given of some of its psychometric qualities. As a next step, the validity
of the QoL-RIQ was investigated in more detail.

In Chapter 5 the results of the study on the psychometric characteristics of the questionnaire, its internal consistency and suitability for patients in different treatment settings, its test-retest reliability, construct validity and responsiveness to change are presented. To get more insight into the possible mediating role of psychological characteristics of patients (e.g., coping resources, self-efficacy, and anxiety) between objective and subjective disease severity and patients’ quality of life in respiratory illness, the relative contribution of subjective and objective illness severity measures as well of specific personality characteristics to quality of life were investigated in an explorative way.

Finally, a general discussion and recommendations for future research are presented in Chapter 6.

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