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

Maillé, A.R.

Citation for published version (APA):

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: https://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.

UvA-DARE is a service provided by the library of the University of Amsterdam (http://dare.uva.nl)
Chapter 6

General Discussion
Introduction

The aim of this study was the development and validation of a disease-specific quality of life questionnaire for patients with mild to moderately severe asthma and COPD. In this final chapter the main result of this study, the Quality of Life for Respiratory Illness Questionnaire (QoL-RIQ) will be summarised, specifically the way in which it was developed and validated. The developed instrument, the QoL-RIQ, will be placed in the context of other asthma and/or COPD-specific questionnaires. Its merits and demerits and clinical relevance will be discussed. Ongoing research in which the QoL-RIQ is used will be mentioned briefly. Recent developments and future directions in quality of life research are discussed, and more specifically, recommendations for future research concerning the result of this study - the QoL-RIQ - are presented.

The Quality of Life for Respiratory Illness Questionnaire (QoL-RIQ)

The development of the QoL-RIQ was prompted by developments in the area of quality of life research in health care reflecting a growing interest in this topic in chronic illness, as well as the need for a quality of life questionnaire in the Dutch language for patients with asthma and COPD. As in the Netherlands most of the diagnosed asthma and COPD patients are treated by general practitioners, it was decided to design the questionnaire for patients in GP-settings. Based on the literature on the concept of quality of life, it was decided that the questionnaire should address physical (symptoms and activities), emotional and social aspects of daily life.

When developing the questionnaire a large item-pool was generated, using a variety of sources (e.g. information from experts in psychosocial and clinical
care and research in asthma and COPD, generic quality of life instruments, patient interviews). The initial item-pool consisted of 221 items. For the questions focussing on patients' experiences, items were formulated in terms of ‘how much trouble’ they had experienced from the mentioned symptom or emotion. For items about activities, questions were stated in terms of how much patients were impeded by their disorder in carrying out that specific activity. Patients were asked to score their answer on a 7-point Likert-type scale ranging from ‘not at all’ to ‘extremely’ troubled or impeded.

After the item-selection procedure, based on impact as well as on clearly defined psychometric analysis, the questionnaire evolved to 55 items divided into seven domains: Breathing problems (9 items), physical problems (9 items), emotions (9 items), situations triggering/enhancing breathing problems (7 items), general activities (4 items), daily and domestic activities (10 items), social activities, relationships and sexuality (7 items).

In the second phase of the study evidence was gathered for its psychometric properties such as, construct validity, internal consistency, test-retest reliability and responsiveness to change. Based on its psychometric qualities it was concluded that the QoL-RIQ was useful for clinical trials as well as for the individual screening and monitoring of patients in routine medical care. In addition, the questionnaire was shown to be suitable for asthma as well as COPD patients with varying degrees of disease severity. In an explorative way, intercorrelations between quality of life, objective and subjective disease severity, and personalities were studied in order to gain some insights into the determinants of quality of life. This showed that subjective illness severity in combination with mood (depression and anxiety), and in asthma patients also in combination with self-efficacy, seem to play an important role in experienced quality of life.
Methodological Considerations

The methods used to develop and to validate the QoL-RIQ as well as aspects of the design of the study will be reviewed and discussed.

The development of the questionnaire: item generation, item style and item selection

Item generation

The applied multi-source approach in the item generation phase is used by several research groups developing disease-specific quality of life questionnaires in respiratory illness. As pointed out by Hyland, the method of item-generation strongly influences the content of the final instrument, and reflects what the researchers understand by content validity of quality of life instruments. By using such a multifaceted approach in item generation, the content of the questionnaire is not restricted to what patients identify as important aspects but is also influenced by the perspective of health professionals/researchers.

This multi-source approach may cause criticism as it does not purely reflect topics that patients view as the domain of quality of life, and this may cause bias. However, patients' experiences were the most important source of information for our questionnaire; albeit indirectly, as the items were gathered by experts in clinical and psychosocial care and research in asthma and COPD. Furthermore, before starting the item-selection procedure we asked a group of patients to review the produced item-pool critically and add topics important for them that had not been included in the questionnaire. We also asked them to select items that did not apply to their situation at all or that lacked clarity.
Style of items

In some quality of life questionnaires (Juniper and Guyatt\textsuperscript{1,2}), patients are asked to produce or select specific -activity- questions themselves, which increases patient-relevance, enhances content validity and possibly increases sensitivity to change. However, these personalised items decrease the comparability between patients. In the QoL-RIQ standardised questions are used, that all have to be answered by the patients.

To focus on patients' experiences, items were formulated in terms of 'how much trouble' patients had experienced due to that particular symptom, complaint or emotion. In the case of items focussing on activities, questions were stated in terms of 'how much they were impeded' by their respiratory problems in carrying out that specific activity. This item style was considered best in order to get subjective information on patients' experiences. A 7-point Likert-type answer scale was chosen, for sensitivity reasons. Likert-type scales reflecting 5 to 7 possibilities for reply are considered to be more sensitive, as they reflect small changes, than, for example, dichotomous (yes/no) answer categories.

Item selection and categorisation

Research groups apply different methods for item selection. In general, two 'schools of thoughts' may be distinguished in item selection procedures: The so called 'clinical impact or clinical sensibility' method versus the 'psychometric - factor analysis-' method.\textsuperscript{4,5} In case of the clinical impact method each item is rated by the patient in terms of frequency of occurrence and of importance. After calculating the product of frequency and importance, items which have the most significance (highest score) are selected in the final questionnaire. Generally, when using this item-selection method, items are categorised by the researchers in \textit{domain}-subscales according to their content and definition of quality of life.

In the psychometric method, factor analysis is used to guide item-selection and scale construction. Items that do not correlate with any other item are rejected,
as they are likely to be ambiguous or to lack communality of meaning with other items. In case of very high inter-item correlations, these items are combined or one of the items is selected. Generally, this method is combined with other item reduction methods, i.e. regarding skewness in distribution of responses, discriminative properties (i.e. > 70% of subjects choose the same response category), or item-total correlations. Items are in this case generally categorised by using psychometric analysis (factor-analysis); or they are categorised on theoretical grounds, creating valid constructs (subscales). It is stated that construct-subscale reflect the perceptions of patients of the way quality of life is organised, whereas domain-subscale reflect the perceptions of researchers.6

The item selection method used in the construction of the QoL-RIQ is primarily based on the impact method in combination with aspects of the psychometric method. By using the 7-point Likert-type scale, asking how much trouble patients had experienced or how much they had been impeded by chest problems in carrying out activities, frequency and importance were captured in one measure. According to the clinical impact method, items that were answered by more than 70% of the respondents as ‘not applicable’ were removed. In fact, these items had a low frequency of occurrence for this group of patients. Subsequently, the inter-item correlations were studied, a selection step also used by researchers from the psychometric approach. The items that correlated more than .80 were considered as items with similar meaning. As most of them were very briefly formulated these were put together pair-wise. For example, the separate items on ‘chest tightness’ and ‘shortness of breath’ showed to have an inter-item correlation higher than .80, and were combined into one item on ‘chest tightness, shortness of breath’. In the third and last step factor-analysis was applied, not for the total item pool but per domain. This was done because the items had been grouped, based on theoretical considerations regarding the
definition and content of quality of life, reflecting physical -symptoms and activities- as well as emotional and social aspects.
Factor-analysis per domain-subscale resulted in a final item set of 55 items, grouped in seven domain-subscalses, the Quality of Life for Respiratory Illness Questionnaire (QoL-RIQ).

*Psychometric properties of the questionnaire: reliability and validity*

**Reliability: internal consistency and test-retest reliability –reproducibility**

*Internal consistency.* The internal consistency assessed by Cronbach’s alpha for the QoL-RIQ total score was high in all three study populations (GP-setting, outpatients and Inpatient Pulmonary Rehabilitation). For the domain-subscalses, most correlation coefficients were in the eighties. Based on these results it can be concluded that the QoL-RIQ can be used for groups and for individual assessment for asthma as well as for COPD patients.7

*Test-retest reliability.* The reproducibility was considered good, for the QoL-RIQ total score and for most subscale scores; only the subscale ‘emotions regarding chest problems’ showed some random measurement error between both assessments. This suggests that emotions regarding the disease might also be sensitive to other influences than health status itself. This test of reproducibility was done with one month in between both assessments, because the questions in the QoL-RIQ regarded patients' quality of life in the last four weeks. GP-patients who indicated at the first assessment that they were in a rather stable phase of their illness were selected for a second assessment a month later. After data-collection of the second assessment, the data were screened for visits to the GP because of breathing problems (no visits) and checked on possible changes in frequency and severity of attacks.

The test-retest reliability with one month in between for the QoL-RIQ total scale is good. For most of its subscales the stability of responses is also very
acceptable to good. Only the emotions subscale shows some random measurement error. In this study two commonly advocated methods were used to assess test-retest reliability values: the Pearson product moment-correlation between the scores on both assessments, and the Intra-class correlation coefficient (ICC). The latter method was used because, in contrast to the Pearson correlation, the ICC is sensitive to variation in systematic changes in scores as well as relative sequencing of different respondents. The test-retest reliability may be influenced in several ways, i.e. the length of time between the administrations, conditions of administration, testing effects, specific factors affecting the patients in their daily life. Regarding the good results of the test-retest reliability of the QoL-RIQ it may be concluded that the questionnaire is a robust test for these factors.

Validity - Construct validity and sensitivity to change - responsiveness-

Construct Validity. Correlations of the QoL-RIQ total and subscale scores with generic quality of life questionnaires, overall questions on satisfaction with life as well as with the SCL-90 anxiety and depression subscales, questions on frequency and subjective severity of attacks and the MRCQ-score are high, providing evidence of its construct validity.

As no 'gold standard' exists for quality of life, the construct validity of instruments on this topic is usually measured by relating the instrument to other, well validated questionnaires, addressing the same concept. In this study two generic quality of life instruments were used, the Sickness Impact Profile (SIP)\(^9,10\) and a short-list from the RAND-studies the MOS-20.\(^11,12\) Correlations between the QoL-RIQ total and subscale scores were studied on the one hand and SIP and MOS-20 scales as well as the above mentioned subscales and 'overall scales' reflecting similar domains on the other hand (convergent validity). Moderate to strong correlations were found, proving the construct validity of the QoL-RIQ. However, some comments should be made. Nowadays
it is known that the validity of the SIP and MOS-20 are not perfect, especially not in the target population of patients with mild to moderately severe respiratory illness. At the time of the design of the study, it was the best known generic quality of life instrument validated for the Dutch language. The same goes more or less for the MOS-20. Although its psychometric characteristics are reasonable to good, it is not used very often nowadays because of the introduction and validation of its 'taller sister' the RAND-SF 36.

Additional information on the correlation of the QoL-RIQ with quality of life instruments comes from some ongoing research in the Netherlands. In a study in pulmonary rehabilitation patients the QoL-RIQ was strongly correlated with another disease-specific quality of life questionnaire; the St. George's Respiratory Questionnaire. In another study in asthma and COPD patients included in an inpatient pulmonary rehabilitation programme, meaningful convergent correlations were found between subscales of the QoL-RIQ on the one hand and of the RAND-36 on the other hand.

*Discriminative properties - applicability to subgroups with different illness-severities*. The QoL-RIQ is sensitive for differences in experienced quality of life between patients from different treatment settings. It was concluded that the QoL-RIQ total scale and the majority of its subscales reflected a lower quality of life in patients who were undergoing more intensive treatment (GP versus outpatients versus IPR), in asthma as well as COPD patients. The main objective of studying the QoL-RIQ in subgroups of asthma and COPD-patients treated in other than the GP-setting however was to test its internal consistency in these populations. Designed as a questionnaire for asthma and COPD-patients in GP-settings, its reliability in terms of internal consistency was also proved in outpatients and patients in the Inpatient Pulmonary Rehabilitation Programme (IPR). This also gave us the opportunity to study and compare the mean scores
on the subscales and total QoL-RIQ in these populations, as a result providing an impression of its discriminative properties. In future research the discriminative properties of the QoL-RIQ can be studied in a more controlled way, by selecting patients from even more distinct treatment-settings as well as by using clear measures for disease-severity. Although differences in demographic characteristics, medication use and disease severity measures between patients from GP-settings and outpatients on the one hand and patients in the IPR on the other were quite clear, this was not always true for GP versus outpatients. The distinction might have been clearer if clinical patients had been selected.

*Sensitivity to change – responsiveness.* The QoL-RIQ was shown to be a responsive outcome measure in a three-month Inpatient Pulmonary Rehabilitation, except for its situations subscale. This subscale addresses aspects of hyperreactivity and allergy, which are less likely to change in IPR. Apart from the paired t-statistics and effect-sizes used in this study, following some other researchers (i.e. Juniper et al.; Redelmeier et al.,\textsuperscript{18,19}), a ‘responsiveness statistic’ was used to consider the clinical relevance of these changes (Minimal Important Differences). Although this corroborated the clinical relevance of the changes in scores on the QoL-RIQ, prudence is called for. Although Juniper and Guyatt state that their conclusions on Minimal Importance Differences should hold for other questionnaires with 7-point scales,\textsuperscript{18} this should be tested in future research.

Sensitivity to change is a type of validity that refers to the ability to detect a significant change in quality of life over time and is an essential requirement of an outcome measure. As no gold standard exists for quality of life, it is unclear whether patients indicating changes in quality of life have in fact really changed. Quality of life changes can be compared to for instance a change in clinical status, interventions of known or expected efficacy, direct reports of change by
patients or providers. In the design of the study on the psychometric properties of the QoL-RIQ, no intervention was included, for practical reasons (only access to GP-patients and outpatients). The use of the QoL-RIQ in a study on the effects of the Inpatient Rehabilitation Programme (IPR) in Asthmacentre Heideheuvel made it possible to study its responsiveness in a part of the population of this study. A more extensive study of the responsiveness of the QoL-RIQ and its relationships to other effect measures is currently taking place. In a pilot phase of this study the responsiveness of the QoL-RIQ was endorsed. Additional information on the responsiveness to change of the QoL-RIQ comes from another pulmonary rehabilitation programme study. This study aimed at comparing the responsiveness of the QoL-RIQ and the St. George’s Respiratory Illness Questionnaire in patients following a six-week pulmonary rehabilitation programme. It was concluded that the QoL-RIQ was more responsive to detect rehabilitation-induced changes in quality of life than the St. George’s Respiratory Questionnaire.

Assessing quality of life in asthma and COPD: The QoL-RIQ in relation to other disease-specific questionnaires

As mentioned in Chapter 3, quality of life research in asthma and COPD was rather underdeveloped for some time. At the start of the nineties several research groups decided to develop disease-specific questionnaires. In Table 6.1 an updated review of disease-specific quality of life questionnaires for adult patients with asthma and/or COPD is presented, including the QoL-RIQ and other recently developed instruments. Their main characteristics on content and validation are covered in this table. The review is based on a Medline literature-search as well as on personal files. Questionnaires assessing functional status or activities only (i.e. the Life Activities Questionnaire for Adult Asthma - Cree and the Pulmonary Functional Status & Dyspnoea Questionnaire - Lareau) are
not included, although they sometimes come very close to the scope of quality of life instruments. After the introduction of the first disease-specific quality of life questionnaire for respiratory illness (CRQ – Guyatt\(^1\)) many research-groups felt the need to develop disease-specific quality of life instruments for this patient-group as may be concluded from Table 6.1.

As a result several instruments were developed at the start of the nineties. Results on 7 disease-specific quality of life questionnaires were published between 1991 and 1994. Publications on ten instruments were traced, and it can be concluded that in the period 1990 to 2000 an impressive amount of knowledge and experience has been gained in the development and use of disease specific quality of life instruments in asthma and COPD.

The contents of these questionnaires (number of items, item style and domains/constructs) show a tremendous diversity. The number of items varies from 20 (C(R)DQ\(^1\)) to 76 (St. George’s\(^3\)) for the original questionnaires. More compact versions were developed for three of these instruments, with 10, 15 and 20 items respectively (mini Asthma Quality of Life Questionnaire\(^39\), Breathing Problem Questionnaire\(^46\), RIQ-MON-10\(^49\), Airways Questionnaire\(^53\)). The style varies from 'tick if applicable'\(^54\) to 7 point Likert-type scales,\(^1,2,38,51,55\) but the Likert-type scales form a majority. Note that the C(R)DQ\(^1\) as well as the AQLQ\(^2\) have individualised activity items, but a more recent version of the AQLQ has standardised activity items.\(^38\)

The diversity in subscales, domains versus constructs and the variety in content, reflects researchers’ different opinions on the definition and operationalisation of quality of life. Most researchers use domains to group items based on intuition. A minority uses subscales based on factor analysis (constructs). In a study on the two different methods for item selection (clinical impact versus psychometric – factor analysis) Juniper showed that these methods resulted in almost the same questionnaires.
<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>items (n) and item style</th>
<th>Domains / Constructs</th>
<th>Validation</th>
<th>test-retest</th>
<th>sensitivity to change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Respiratory (Disease) Questionnaire - Guyatt* - 1987</td>
<td>20 items 7-point Likert</td>
<td>four domains</td>
<td>COPD, FEV&lt;sub&gt;1&lt;/sub&gt; &lt;70% pred&lt;sup&gt;1&lt;/sup&gt;</td>
<td>walk test global ratings&lt;sup&gt;1&lt;/sup&gt;</td>
<td>0.55 - 0.60&lt;sup&gt;2&lt;/sup&gt; dyspnoea r 0.77 other: 0.90-0.93&lt;sup&gt;16&lt;/sup&gt; yes, i.e. treatment modification 2-6 wks , inpts rehab, 12 wks rehab at home&lt;sup&gt;16&lt;/sup&gt;</td>
</tr>
<tr>
<td>Living with Asthma Questionnaire - Hyland* - 1991</td>
<td>68 items 3-point Likert and not applicable</td>
<td>eleven domains -colds, -mobility, -sex -work/other activities -dysphoric states &amp; attitudes, -sports; -holidays; -social/ leisure; -sleep; -effects on others; -medication usage two constructs -functional limitation -distress</td>
<td>asthma patients in GP-setting and Asthma Society recruits yes, i.e. -factor analysis -generic QoL (SIP)&lt;sup&gt;29&lt;/sup&gt; -symptoms and clinical efficacy&lt;sup&gt;29&lt;/sup&gt;</td>
<td>Not reported r 0.95, two months&lt;sup&gt;28&lt;/sup&gt;, ICC 0.85, three weeks&lt;sup&gt;28&lt;/sup&gt; yes, i.e. medical trials medication trial (salmeterol) effect size total scale 0.69&lt;sup&gt;19&lt;/sup&gt; Other&lt;sup&gt;11,12&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>St. George's Respiratory Questionnaire - Jones* - 1991</td>
<td>76 items 5-point Likert (symptoms) yes/no (other)</td>
<td>three constructs -symptoms -activity -impacts</td>
<td>Asthma and COPD wide range of illness severity -symptoms -lung function -6 minute walk test -MRCPQ -depression/ anxiety -generic QoL (SIP)&lt;sup&gt;29&lt;/sup&gt;</td>
<td>ICC 0.88 - 0.92 two weeks&lt;sup&gt;23&lt;/sup&gt; yes, clinical trials mean change scores assessed for treatment efficacy</td>
<td></td>
</tr>
<tr>
<td>Asthma Quality of Life Questionnaire - Juniper* - 1992 -version with standardised activity items* - 1999</td>
<td>32 items 7-point Likert</td>
<td>four domains -symptoms -emotional function -environmental stimuli -activity limitations</td>
<td>Asthma, wide range of airway responsiveness -clinical asthma measures and -generic QoL (SIP,RAND,HUI)&lt;sup&gt;46,47&lt;/sup&gt;</td>
<td>ICC 0.89 - 0.94 four weeks&lt;sup&gt;40&lt;/sup&gt;, ICC 0.81-0.93 two weeks&lt;sup&gt;42&lt;/sup&gt; yes, clinical trials, clinical sensitivity, minimal important difference (MID) assessed for clinical relevance of changes&lt;sup&gt;48,49&lt;/sup&gt; responsiveness good&lt;sup&gt;49&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Mini AQLQ&lt;sup&gt;40&lt;/sup&gt; - 1999</td>
<td>15 items</td>
<td>four constructs -breathlessness/ physical restriction -mood disturbance -social disruption -concerns for health</td>
<td>Asthma outpatients and community sample of asthmatics - markers of asthma severity -subscale scores vs total score</td>
<td>0.82 - 0.92&lt;sup&gt;3&lt;/sup&gt;, 0.84 - 0.94&lt;sup&gt;3&lt;/sup&gt;, 0.71 - 0.91&lt;sup&gt;14&lt;/sup&gt; ICC 0.61 - 0.80 3 weeks&lt;sup&gt;8&lt;/sup&gt; relative validity coefficient overall scale 0.52 - 1.0; breathlessness scale 0.62 - 1.0&lt;sup&gt;14&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Australian Asthma Quality of Life Questionnaire - Marks* - 1992</td>
<td>20 items 5-point Likert</td>
<td>four constructs -breathlessness/ physical restriction -mood disturbance -social disruption -concerns for health</td>
<td>Asthma outpatients and community sample of asthmatics - markers of asthma severity -subscale scores vs total score</td>
<td>0.82 - 0.92&lt;sup&gt;3&lt;/sup&gt;, 0.84 - 0.94&lt;sup&gt;3&lt;/sup&gt;, 0.71 - 0.91&lt;sup&gt;14&lt;/sup&gt; ICC 0.61 - 0.80 3 weeks&lt;sup&gt;8&lt;/sup&gt; relative validity coefficient overall scale 0.52 - 1.0; breathlessness scale 0.62 - 1.0&lt;sup&gt;14&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Questionnaire</td>
<td>First author and year</td>
<td>Items (n) and item style</td>
<td>Domains / subscales</td>
<td>Validation</td>
<td>Patient group and illness severity</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>-----------------------</td>
<td>--------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Breathing Problem Questionnaire</td>
<td>Hyland, 1994</td>
<td>33 items</td>
<td>13 domains, two constructs - problems - emotional evaluations</td>
<td>COPD</td>
<td>Exercise tolerance personality</td>
</tr>
<tr>
<td>Short Form</td>
<td>Maille, 1998</td>
<td>10 items</td>
<td>One scale score</td>
<td>COPD ambulatory pulmonary rehabilitation</td>
<td>BPQ-33, treadmill endurance, shuttle walk</td>
</tr>
<tr>
<td>Quality of Life for Respiratory Illness Questionnaire</td>
<td>Maille, 1994</td>
<td>55 items</td>
<td>Seven domains - breathing problems - physical - emotions - situations - general activities - daily &amp; domestic activities - social activities, relationships and sexuality</td>
<td>Asthma &amp; COPD GP setting, outpatients, inpatient rehabilitation</td>
<td>SIP, MOS-20 overall QoL emotions severity of attacks MRQG, SGRO</td>
</tr>
<tr>
<td>AQ - 30</td>
<td>Quirk, 1994</td>
<td>30 items</td>
<td>Yes/no/not applicable</td>
<td>Asthma patients - outpatient asthma clinic</td>
<td>Disease specific QoL scales clinical variables</td>
</tr>
<tr>
<td>Short form AQ-20</td>
<td>Lettard, 1996</td>
<td>20 items</td>
<td>Tip if applicable</td>
<td>Asthma patients - outpatient services</td>
<td>SIP overall QoL lung function severity of attacks oral corticosteroids</td>
</tr>
<tr>
<td>Asthma Impact Record</td>
<td>Trekule, 1996</td>
<td>63 items</td>
<td>Four domains - physical-activity - physical symptoms - psychological - social-relational</td>
<td>Asthma patients - outpatient services</td>
<td>- exercise capacity - lung function - disease-specific QoL</td>
</tr>
<tr>
<td>Seattle Obstructive Lung Disease Questionnaire</td>
<td>Tu, 1997</td>
<td>29 items</td>
<td>Four domains - physical function - emotional function - coping skills - treatment satisfaction</td>
<td>Asthma &amp; COPD ambulatory care; emergency room; hospitalised</td>
<td>- exercise capacity - lung function - disease-specific QoL</td>
</tr>
</tbody>
</table>
This suggests relatively small differences resulting from method of selecting items. For the way of grouping items in the final item pool, this could be somewhat different. This is shown by the research of Hyland, who grouped his final 68 item set in 11 domains. However, in a new study he used patients’ responses in factor analysis and found out that 2 subscales, or constructs, could be distinguished, a cognitive, ‘problem’ construct and an emotional, ‘evaluation’ construct. More recently these two constructs were expanded to five: activities and avoidance as cognitive constructs, distress and preoccupation as emotional constructs, and a separate ‘colds’ construct. The cognitive constructs correlated more highly with lung function and change in lung function than the emotional constructs, in addition the constructs showed differential responsiveness to change in a double blind medication trial. If sensitivity to longitudinal change largely depends on whether the subscales are domain or construct subscales, further study on the identification of underlying constructs in the developed questionnaires is recommended.

Half the disease-specific quality of life questionnaires were developed for patients with asthma, and initially validated in outpatients. The Living with Asthma Questionnaire also included patients from GP settings at its initial validation. Two out of ten questionnaires only address COPD patients, the Chronic Respiratory Disease Questionnaire is validated in patients with more severe airway obstruction. The short version of the Breathing Problem Questionnaire was validated in COPD-patients from an ambulatory pulmonary rehabilitation. Three disease-specific quality of life questionnaires were developed for asthma as well as COPD patients. All have been validated in patients with broad ranges of illness severity; the QoL-RIQ however, seems to be the only instrument that included patients from GP-settings.

Psychometric characteristics of the questionnaires were studied and reported in various ways. For all instruments information is available on their construct-
validity, but the grounds for claiming construct validity vary from 'low relationship with markers of asthma severity'\textsuperscript{53} to positive relationships with clinical asthma severity, or other symptom measures in combination with correlations with generic and or other disease-specific questionnaires.

Concerning the reliability of the questionnaires it was found that most researchers presented data on internal consistency as well as on test-retest reliability. For some questionnaires internal consistency was claimed but no figures were reported or could be traced in literature. Although test-retest reliability is often considered a more important aspect of reliability in quality of life instruments than internal consistency, the latter gives important information on whether the items in a scale or subscale measure the same or a closely related construct in a reliable manner. In general the presented coefficients for internal consistency can be considered moderate to good. The same conclusion can be drawn from the presented figures on test-retest reliabilities. It should be noted that the period between the two assessments varied from three days\textsuperscript{54} to four months.\textsuperscript{55} For most questionnaires the sensitivity to change was studied and claimed. Some questionnaires have now been widely used in clinical trials, and their sensitivity to change has been established.

Considering the QoL-RIQ in relation to other disease specific quality of life questionnaires it belongs, with its 55-items, to the group of longer (55-76 items) rather than shorter (20-33 items) instruments. The use of a seven point Likert-type answer category is quite common; six out of ten research-groups use five to seven point Likert-type scales in their questionnaires. The content of the QoL-RIQ reflects a broad range of topics that are relevant in quality of life research. The dimensions could just as well have been put together in wider domains (e.g. breathing problems, and physical problems combined in 'physical-symptoms': general activities and daily and domestic activities combined in 'physical-
activities’). This, however, could have reduced the specificity of the information gathered with each of the seven domains.

The QoL-RIQ is one of the few instruments developed for asthma as well as for COPD patients. Although at first specifically developed for patients from GP-settings, research shows that it can also be used in patients who are more severely ill. Its psychometric characteristics are good, although its responsiveness to change has only been studied in inpatient rehabilitation programmes.

It can be concluded that the QoL-RIQ, a disease-specific quality of life questionnaire for asthma and COPD patients, is a valid instrument in the Dutch language that can be used for patients with varying illness severity. The questionnaire is also available in English\textsuperscript{51} and French.\textsuperscript{57}

**Recommendations for future research on the QoL-RIQ and on quality of life in asthma and COPD in general**

Over the past ten years many disease specific quality of life questionnaires have been developed for patients with asthma and COPD. Most of these were developed in the English language. Some of the questionnaires have been translated and, in many instances, also validated in a wide range of languages. It can be concluded that the development of quality of life instruments for asthma and COPD patients has gained much attention. In this paragraph recommendations will be made for future research considering the Quality of Life for Respiratory Questionnaire, and for research on quality of life in asthma and COPD in general.
Recommendations for future research concerning the QoL-RIQ

- The sensitivity to change of the QoL-RIQ should be assessed in patients with mild to moderate illness severity, for asthma as well as for COPD.
- The sensitivity to change of the QoL-RIQ should also be studied in intervention studies other than pulmonary rehabilitation, i.e. medication trials.
- Reference data should be defined for patient groups with distinct illness severity, for asthma and COPD. Patients should be selected and classified according to international guidelines for the definition of illness severity.
- Apart from the short version for monitoring in general practice, a general short version should be developed for screening purposes.
- The layout of the 55-item version of the QoL-RIQ should be adapted to create a version that is easily applicable in a clinical practice setting.
- Finally, it would be interesting to study the QoL-RIQ by factor analysis for underlying constructs. The purpose of such a study would not be so much to change the content of the questionnaire but to have a closer look at the grouping of the items in subscales versus grouping them in constructs.

Recommendations for quality of life research in asthma and COPD in general

- Study on the determinants of quality of life. The concept of quality of life has to be included in theoretical models concerning personality characteristics, coping, illness perceptions including self-efficacy, adaptive tasks, social support, etcetera. More knowledge about the influence of these variables on quality of life will help to develop well-based theories about quality of life, and may steer interventions to improve patients' quality of life.
- Existing questionnaires should be compared to assess their relative relevance. This may give insight into which questionnaire is most suited for specific populations, specific purposes and specific disease. This process has already been started (i.e. 30, 58).

- Recommendations mentioned for the QoL-RIQ also apply to other quality of life questionnaires for patients with asthma and COPD; development of 'reference data' for patient groups with different degrees of illness severity, based on international guidelines; existing questionnaires may be adapted for specific situations, i.e. clinical patient care, specific interventions or trials, including the development of short-forms; study of the grouping of items, domains versus constructs.

- Lastly, it should be taken into account that even well translated versions of existing questionnaires must be validated.

References


