

# Respiratory Symptoms Questionnaire

## User Guide

### Introducing the Respiratory Symptoms Questionnaire

#### What is the Respiratory Symptoms Questionnaire?

The Respiratory Symptoms Questionnaire (RSQ) is an instrument that assesses the frequency of respiratory symptoms and their impact on patients' activity over the previous four weeks, without requiring a specific diagnostic label of asthma or chronic obstructive pulmonary disease (COPD). The RSQ is patient reported and includes questions about respiratory symptoms common to both asthma and COPD and their impact on the patient's activity.

The four questions (items 1–4) assess the frequency of respiratory symptoms (shortness of breath, wheezing, coughing and/or chest tightness) during the day and, in response to (or as a result of) these respiratory symptoms, frequency of rescue inhaler use, activity limitations and frequency of night-time awakenings.<sup>1</sup>

Each of the four RSQ items has a 5-point Likert response scale (scored 0–4). The RSQ score is calculated as the sum score of all four responses; RSQ scores range from 0 to 16, with higher scores indicative of worse symptoms.<sup>1</sup>

The RSQ has been developed and cross-sectionally validated in patients with asthma and/or COPD.<sup>1</sup>

#### Why has the RSQ been developed?

Respiratory symptoms are common and troublesome across the spectrum of obstructive lung disease.<sup>2,3</sup> Despite the well-recognised overlap between the symptoms and diagnostic criteria of asthma and COPD,<sup>4</sup> and the increasing interest in developing more specific classifications of obstructive lung disease,<sup>5</sup> most existing patient-reported outcome (PRO) questionnaires that assess the frequency, impact or control of respiratory symptoms are designed specifically for patients with a confirmed diagnosis of either asthma or COPD.<sup>2,3</sup>

At the time of RSQ development, few PRO tools for recording respiratory symptoms had been established for use in both asthma and COPD. Although the Airways Questionnaire 20 (AQ20)<sup>6,7</sup> and St George's Respiratory Questionnaire (SGRQ)<sup>8,9</sup> include questions about respiratory symptoms and have been validated for use in both conditions, they are intended for assessing health status rather than respiratory symptoms and their impact on the patient's activity. Furthermore, the SGRQ is significantly longer, comprising 50 items and taking 10–15 minutes to complete.<sup>9</sup> As such, there is a need for brief PRO measures of respiratory symptoms that can be used across the spectrum of obstructive lung disease.<sup>1</sup>

## Development and validation of the RSQ

### How was the RSQ developed?

The questions included in the RSQ were conceptually based on clinical guidelines for assessing symptoms of asthma and of COPD.<sup>2,3</sup> As such, the RSQ is designed to assess the frequency of respiratory symptoms and the extent to which these impact the patient's activity.<sup>1</sup> It loosely follows the structure of the Global Initiative for Asthma (GINA) symptom control criteria in that it includes questions about daytime symptoms, rescue medication use, activity limitation and night-time awakenings; in addition, it incorporates a 4-week recall, which is also in line with GINA criteria.<sup>2</sup> Furthermore, the specific symptoms included in the RSQ (shortness of breath, wheezing, coughing and chest tightness) reflect the three symptom types that are common to both asthma and COPD (breathing, coughing and chest symptoms).<sup>10-12</sup>

Cognitive debriefing interviews were conducted to test patients' understanding of the RSQ and to ensure that the instructions, questions and response options were clear. RWS Life Sciences employed a qualified recruiter to select a diverse sample of patients with asthma (n=5) and patients with COPD (n=5) from the USA. All patients were either native English speakers or were literate and fluent in English. A trained interviewer (selected by RWS Life Sciences) carried out cognitive interviews, in English, with each individual patient.<sup>1</sup>

Cognitive debriefing results indicated that, overall, patients with asthma or COPD were able to understand and use the RSQ.<sup>1</sup> Experts in linguistic validation from RWS Life Sciences provided translations of the original English questions into 19 languages, though cognitive debriefing was not carried out for these translated versions.<sup>1</sup> The steps for translation included:

- Two independent edits of client-provided translation
- One harmonised forward translation
- One independent back translation
- Reconciliation of back translation and harmonised translation
- Review of back translation by Survey Research Analyst
- Desktop publishing of harmonised translation into RAPIDS format
- Proofreading of harmonised translation after conversion to web screens.

### How has the RSQ been psychometrically validated?

The RSQ has been psychometrically validated in a cross-sectional sample of patients from the NOVELTY study (a NOVEL observational longiTudinal studY; ClinicalTrials.gov: NCT02760329). Evaluation of the longitudinal properties of the RSQ is ongoing.

The results of the cross-sectional validation analysis indicate that the RSQ demonstrated good reliability and validity in patients with asthma and/or COPD.<sup>1</sup> The full results have been reported by Karlsson N, et al. (ERJ Open Research, 2021).<sup>1</sup> Box 1 provides a summary of this analysis.

**Background** The Respiratory Symptoms Questionnaire (RSQ) is a novel, four-item patient-reported, diagnosis-agnostic tool designed to assess the frequency of respiratory symptoms and their impact on activity, without specifying a particular diagnosis. Our objective was to examine its validity in patients with asthma and/or chronic obstructive pulmonary disease (COPD).

**Methods** Baseline data were randomly sampled from patients who completed the RSQ in the NOVELTY study ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02760329): NCT02760329). The total sample (n=1530) comprised three randomly selected samples (n=510 each) from each physician-assigned diagnostic group (asthma, asthma+COPD and COPD). The internal consistency and structural validity of the RSQ were evaluated using exploratory and confirmatory factor analyses; psychometric performance was observed using Classical Test Theory and Item Response Theory analyses.

**Results** For the total sample, the mean±SD RSQ score was 5.6±4.3 (range 0–16). Irrespective of diagnosis, the internal consistency of items was uniformly adequate (Cronbach's  $\alpha$ =0.76–0.80). All items had high factor loadings and structural characteristics of the measure were invariant across groups. Using the total sample, RSQ items informatively covered the  $\theta$  score range of –2.0 to 2.8, with discrimination coefficients for individual items being high to very high (1.7–2.6). Strong convergent correlations were observed between the RSQ and the St George's Respiratory Questionnaire (0.77,  $p<0.001$ ).

**Conclusions** The RSQ is a valid, brief, patient-reported tool for assessing respiratory symptoms in patients across the whole spectrum of asthma and/or COPD, rather than using different questionnaires for each diagnosis. It can be used for monitoring respiratory symptoms in clinical practice, clinical trials and real-world studies.

**Box 1.** Abstract from Karlsson N, et al. ERJ Open Res 2021;7;00828-2020; doi: 10.1183/23120541.00828-2020. The full article can be accessed here: <https://www.doi.org/10.1183/23120541.00828-2020>.

## Who developed and validated the RSQ?

The development and validation of the RSQ was funded by AstraZeneca.

## Using the RSQ

### Why and when should I use the RSQ?

The RSQ is a validated, easy-to-administer PRO questionnaire that can be used for monitoring patient-reported respiratory symptoms in clinical practice, clinical trials and real-world studies.<sup>1</sup>

The RSQ performs well cross-sectionally and its longitudinal properties are still being evaluated. Therefore, at present, the RSQ is most suitable for exploratory objectives and hypothesis-generating research. In future, when longitudinal analyses are complete, the RSQ may prove to be useful for monitoring symptoms over time.

### Patient care

The RSQ is one of a few quick, easy-to-interpret PRO tools that are suitable for use in routine clinical care. It was developed for application in both primary and specialist care settings to assess the frequency of respiratory symptoms (shortness of breath, wheezing, coughing and/or chest tightness) during the day, frequency of rescue inhaler use in response to symptoms, activity limitations as a result of symptoms and frequency of night-time awakenings due to symptoms, without requiring a specific diagnostic label of asthma or COPD.<sup>1</sup> It is intended to foster dialogue between patients and clinicians and, ultimately, to guide patient-oriented care. Furthermore, a key feature of the RSQ is that it can be completed by patients in 1–2 minutes, which may be particularly valuable in primary care settings.<sup>1</sup>

## **Research**

The RSQ can be used to assess respiratory symptoms and their impact on activity in patients with asthma and/or COPD, or those who have not yet received a specific diagnosis.<sup>1</sup> Assessing similar concepts across diagnostic groups using a single tool may be particularly useful for researching obstructive lung disease in real-world and observational settings. The RSQ may therefore be a valuable tool for studies that aim to further our understanding of obstructive lung disease beyond conventional diagnostic labels.<sup>1</sup>

### **For which patients is the RSQ suitable?**

As noted above, the RSQ can be completed by patients aged 18 and older who have asthma and/or COPD, or who have not yet received a specific diagnosis of asthma and/or COPD.<sup>1</sup>

### **How should the RSQ be completed?**

The questionnaire should be completed in a quiet, private area, free from distraction. Patients should complete the RSQ independently, answering the questions as honestly as they can. There are no right or wrong answers; the patient should simply select the answer that they feel best applies to them.

### **How do I interpret RSQ scores?**

The RSQ has a score range of 0–16, which is calculated as the sum score of the four items (each scored 0–4), with higher scores indicative of worse symptoms. All four items must be completed to score the RSQ.<sup>1</sup>

### **How do I request to use the RSQ?**

The RSQ is available by request on the AstraZeneca patient-reported outcomes website:

<https://www.astrazeneca.com/patient-reported-outcomes.html>.

The RSQ is free to use for legitimate scientific and clinical care reasons. AstraZeneca retains licensing rights.

### **How do I obtain translations of the RSQ for my study?**

Translations can be requested via the AstraZeneca patient-reported outcomes website

<https://www.astrazeneca.com/patient-reported-outcomes.html>. AstraZeneca retains translation rights.

## References

1. Karlsson N, Atkinson MJ, Müllerová H, et al. Validation of a diagnosis-agnostic symptom questionnaire for asthma and/or COPD. *ERJ Open Res* 2021; 7: 00828-2020 (<https://doi.org/10.1183/23120541.00828-2020>).
2. Global Initiative for Asthma. Global strategy for asthma management and prevention (2020 update). [https://ginasthma.org/wp-content/uploads/2020/04/GINA-2020-full-report\\_-final-\\_wms.pdf](https://ginasthma.org/wp-content/uploads/2020/04/GINA-2020-full-report_-final-_wms.pdf). Date last updated: 2020. Date last accessed: 12 August 2020.
3. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease: 2020 report. <https://goldcopd.org/wp-content/uploads/2019/11/GOLD-2020-REPORT-ver1.0wms.pdf>. Date last updated: 2020. Date last accessed: 12 August 2020.
4. Sin DD, Miravitlles M, Mannino DM, et al. What is asthma–COPD overlap syndrome? Towards a consensus definition from a round table discussion. *Eur Respir J* 2016; 48: 664–673.
5. Pavord ID, Beasley R, Agustí A, et al. After asthma: redefining airways diseases. *Lancet* 2018; 391: 350–400.
6. Hajiro T, Nishimura K, Jones PW, et al. A novel, short and simple questionnaire to measure health-related quality of life in patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1999; 159: 1874–1878.
7. Barley EA, Quirk FH, Jones PW. Asthma health status measurement in clinical practice: validity of a new short and simple instrument. *Respir Med* 1998; 92: 1207–1214.
8. Wilson SR, Rand CS, Cabana MD, et al. Asthma outcomes: quality of life. *J Allergy Clin Immunol* 2012; 129: S88–S123.
9. Cazzola M, MacNee W, Martinez FJ, et al. Outcomes for COPD pharmacological trials: from lung function to biomarkers. *Eur Respir J* 2008; 31: 416–469.
10. Gater A, Nelsen L, Fleming S, et al. Assessing asthma symptoms in adolescents and adults: qualitative research supporting development of the asthma daily symptom diary. *Value Health* 2016; 19: 440–450.
11. Leidy NK, Murray LT, Monz BU, et al. Measuring respiratory symptoms of COPD: performance of the EXACT-Respiratory Symptoms Tool (E-RS) in three clinical trials. *Respir Res* 2014; 15: 124.
12. Leidy NK, Wilcox TK, Jones PW, et al. Development of the EXacerbations of Chronic obstructive pulmonary disease Tool (EXACT): a patient-reported outcome (PRO) measure. *Value Health* 2010; 13: 965–975.