



# Evaluating Cough Assessment Tools

## A Systematic Review

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**Background:** Little is known about the comparative validity, reliability, or responsiveness of instruments for assessing cough frequency or impact, where the term impact encompasses both cough severity and the impact of cough on health-related quality of life.

**Methods:** We conducted a systematic review to evaluate instruments that assess cough frequency or impact in adults, adolescents, and children with acute or chronic cough.

**Results:** Seventy-eight studies were included, of which eight were randomized controlled trials and 70 were observational studies. In all age groups, audio and video electronic recording devices had good reliability compared with other methods of assessing cough frequency but had variable correlation with other cough assessments, such as visual analog scale scores, quality-of-life questionnaires, cough diaries, and tussigenic challenges. Among adult and adolescent patients, the Leicester Cough Questionnaire (LCQ) and the Cough-Specific Quality-of-Life Questionnaire (CQLQ) were valid and reliable, showing high intraclass and test-retest correlations. Among children, the Parent Cough-Specific Quality of Life Questionnaire and Pediatric Cough Questionnaire were valid and reliable.

**Conclusions:** Electronic recording devices can be valid assessments of cough frequency. The LCQ and CQLQ for adults and the Parent Cough-Specific Quality of Life questionnaire for children are valid instruments for assessing cough impact. There is limited but insufficient evidence to determine the reliability or concurrent validity of the different types of cough diaries or visual analog scale scores. There are also limited data to support the responsiveness of recording devices. There is good responsiveness data for the LCQ and CQLQ, but more evidence is needed.

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**Abbreviations:** ACOS = Adverse Cough Outcome Survey; CQLQ = Cough-Specific Quality-of-Life Questionnaire; GRC = Global Rating of Change; LCQ = Leicester Cough Questionnaire; MID = minimally important difference; PCQ = Pediatric Cough Questionnaire; PC-QOL = Parent Cough-Specific Quality-of-Life Questionnaire; VAS = visual analog scale

Cough is the most common complaint for which individuals seek medical attention in the United States.<sup>1</sup> Cough can be considered either acute or chronic (defined as lasting > 4 weeks in patients aged < 14 years or for > 8 weeks in older patients).<sup>2,3</sup> Accurate and reliable measures of cough frequency and impact are necessary for the development of effective treatment plans and assessments of change with therapy.

Cough is experienced differently by each individual, and the effect cough has on a person's life is influenced by many factors. In this review, we concentrate on two of the most commonly measured aspects of cough: frequency and impact. Cough frequency

typically is assessed by a cough recording device for research applications, but this approach is not practical in clinical settings. More commonly, cough diaries and visual analog scale (VAS) scores are used to measure cough frequency, impact, or both; however, the concurrent validity of these tools is unclear. Quality-of-life questionnaires (both cough specific and nonspecific) have also been used to evaluate cough impact.

To help improve the quality of cough assessments, we conducted a systematic review of the literature evaluating the comparative validity, reliability, and responsiveness of tools used to assess cough frequency or impact. In this context, the term impact is

understood to encompass both cough severity and the impact of cough on health-related quality of life.

## MATERIALS AND METHODS

This report summarizes key methods and findings from a comparative effectiveness review commissioned by the US Agency for Healthcare Research and Quality.<sup>4</sup> Further details of the methods, results, and conclusions can be found in the full report.

### *Literature Search and Study Selection*

We searched MEDLINE, EMBASE, and the Cochrane Database of Systematic Reviews through June 2012 to identify English-language evaluative studies of instruments used to assess the frequency or impact of acute or chronic cough. Included studies had to (1) compare one cough assessment tool to another or to clinical assessment of cough or (2) evaluate change in response to treatment over time with a given tool.

For each included article, one investigator abstracted data and assigned quality ratings. A second investigator reviewed the completed abstraction form alongside the original article to check for accuracy and completeness and independently assigned quality ratings. Disagreements were resolved by consensus or by obtaining a third reviewer's opinion if consensus could not be reached. Individual study quality was assessed with the Quality of Diagnostic Accuracy Studies-2 instrument<sup>5</sup> and reported as low or high.

### *Data Synthesis*

We evaluated the concurrent validity of cough assessment tools on the basis of their agreement with other measures (other tools or clinical assessments of cough). We considered correlation coefficients  $>0.8$  to show strong correlation, between 0.6 and 0.79 to show moderate correlation, between 0.4 and 0.59 to show fair correlation, and  $<0.4$  to show poor or no correlation. We evaluated reliability with intermethod agreement, test-retest concurrence, or intraclass correlation. In addition, for multiitem instruments, we considered internal consistency as measured by Cronbach  $\alpha$ . We evaluated responsiveness by reporting data on changes in cough measures over time associated with treatment (or no treatment) of cough symptoms or the underlying etiology of cough. A few studies reported sensitivity, specificity, positive predictive value, and negative predictive value based on the ability of an assessment

to correctly identify cough or no cough compared with human count or video recording. When evaluating sensitivity, specificity, positive predictive value, and negative predictive value, we considered  $>0.9$  to be high and 0.7 to 0.89 to be moderate.

## RESULTS

### *Description of Included Studies*

Figure 1 depicts the flow of literature through the search and screening process. Seventy-eight studies met the inclusion criteria for this review.<sup>6-83</sup> Eight studies were randomized controlled trials<sup>9,31,34,56,69,70,72,76</sup>; the remaining 70 were observational studies. Forty-two studies reported outcomes for a tool measuring cough frequency, and 56 reported outcomes for a tool measuring cough impact. Fifty-nine studies included adults and adolescents (aged  $\geq 14$  years); 15 included only children (aged  $<14$  years); and four included adults, adolescents, and children.

### *Measures of Cough Frequency*

**Adults and Adolescents (Aged  $\geq 14$  Years) and Mixed Populations (Adults, Adolescents, and Children):** Thirty-one studies focused on instruments measuring cough frequency either in adults and adolescents (29 studies, 69% of frequency studies overall) or in a mixed population of adults, adolescents, and children (two studies, 5%) (e-Table 1). Of these, all but four (13%) evaluated electronic audio recording devices. Reference standards used to validate these instruments included human cough counts, other electronic audio recording devices, video recording devices, quality-of-life questionnaires, subjective scoring, and laboratory tussigenic challenges. Table 1 summarizes the correlations found among various cough assessment tools for adults and mixed populations.

Six studies found high intraclass correlation coefficients.<sup>10-12,24,30,78</sup> The sensitivity of cough frequency tools was high when compared with human cough counts in two studies<sup>11,54</sup> and moderate in one study.<sup>10</sup> One study found moderate sensitivity when compared with video recordings.<sup>20</sup> Three studies found high specificity, with two using human cough count as a reference<sup>10,11</sup> and the other using a video recording as a reference.<sup>20</sup> One study found moderate positive predictive value and high negative predictive value with the use of video recordings as a reference.<sup>20</sup>

Five studies demonstrated significant responsiveness to treatment as follows: three with VAS score,<sup>9,34,69</sup> one with cough frequency score,<sup>32</sup> and two with electronic recording devices.<sup>34,50</sup> No significant response to treatment was found in one study looking at cough frequency score<sup>70</sup> or another study looking at an electronic device.<sup>76</sup>

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