

Tools for Assessing Outcomes in Studies of Chronic Cough

CHEST Guideline and Expert Panel Report

Louis-Philippe Boulet, MD, FCCP; Remy R. Coeytaux, MD, PhD; Douglas C. McCrory, MD, MHS; Cynthia T. French, PhD, RN, FCCP; Anne B. Chang, MBBS, PhD, MPH; Surinder S. Biring, MBChB, MD; Jaclyn Smith, MBChB, PhD; Rebecca L. Diekemper, MPH; Bruce Rubin, MD, MEng, MBA; and Richard S. Irwin, MD, Master FCCP; on behalf of the CHEST Expert Cough Panel

BACKGROUND: Since the publication of the 2006 American College of Chest Physicians (CHEST) cough guidelines, a variety of tools has been developed or further refined for assessing cough. The purpose of the present committee was to evaluate instruments used by investigators performing clinical research on chronic cough. The specific aims were to (1) assess the performance of tools designed to measure cough frequency, severity, and impact in adults, adolescents, and children with chronic cough and (2) make recommendations or suggestions related to these findings.

METHODS: By following the CHEST methodologic guidelines, the CHEST Expert Cough Panel based its recommendations and suggestions on a recently published comparative effectiveness review commissioned by the US Agency for Healthcare Research and Quality, a corresponding summary published in *CHEST*, and an updated systematic review through November 2013. Recommendations or suggestions based on these data were discussed, graded, and voted on during a meeting of the Expert Cough Panel.

RESULTS: We recommend for adults, adolescents (≥ 14 years of age), and children complaining of chronic cough that validated and reliable health-related quality-of-life (QoL) questionnaires be used as the measurement of choice to assess the impact of cough, such as the Leicester Cough Questionnaire and the Cough-Specific Quality-of-Life Questionnaire in adult and adolescent patients and the Parent Cough-Specific Quality of Life Questionnaire in children. We recommend acoustic cough counting to assess cough frequency but not cough severity. Limited data exist regarding the performance of visual analog scales, numeric rating scales, and tussigenic challenges.

CONCLUSIONS: Validated and reliable cough-specific health-related QoL questionnaires are recommended as the measurement of choice to assess the impact of cough on patients. How they compare is yet to be determined. When used, the reporting of cough severity by visual analog or numeric rating scales should be standardized. Previously validated QoL questionnaires or other cough assessments should not be modified unless the new version has been shown to be reliable and valid. Finally, in research settings, tussigenic challenges play a role in understanding mechanisms of cough.

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ABBREVIATIONS: AHRQ = Agency for Healthcare Research and Quality; CB = consensus-based; CER = comparative effectiveness review; CHEST = American College of Chest Physicians; COI = conflict of interest; CQLQ = Cough-Specific Quality-of-Life Questionnaire; LCQ = Leicester Cough Questionnaire; PCQ = Pediatric Cough Questionnaire; PC-QOL = Parent Cough-Specific Quality of Life Questionnaire; PICOTS = population of interest, interventions, comparators, outcomes, timing of outcomes, and settings; QoL = quality of life; VAS = visual analog scale

Summary of Recommendations

1. In adult and adolescent patients (≥ 14 years of age) complaining of chronic cough, we recommend that validated and reliable health-related quality of life (QoL) questionnaires be used as the measurement of choice to assess the impact of cough on patients (Grade 1B).

2. In adults and adolescents with chronic cough, we recommend the Cough-Specific Quality-of-Life Questionnaire and Leicester Cough Questionnaire, as they are the most extensively studied and commonly used previously validated and reliable cough-specific health-related QoL questionnaires to assess the impact of cough (Grade 1B).

3. In children (< 14 years of age) with chronic cough, we recommend that validated and reliable health-related QoL questionnaires be used as the measurement of choice to assess the impact of cough (Grade 1B).

4. In children (< 14 years of age) with chronic cough, we recommend the Parent Cough-Specific Quality of Life Questionnaire, the most extensively studied and commonly used previously validated and reliable health-related QoL questionnaire, as the measurement of choice to assess the impact of cough (Grade 1B).

5. To standardize the development, utilization, and reporting of cough-specific QoL questionnaires, we suggest that cough counting alone not be used to establish validity of the questionnaires (consensus based [CB]).

6. To standardize the development, use, and reporting of cough severity by visual analog scales (VASs) or numeric rating scales, we suggest that they be used in standard fashion (CB).

7. To ensure the integrity of health-related QoL questionnaires and other patient-reported outcomes that have been shown to be valid and reliable, we

suggest that a modified version should not be used and reported unless the modified version has been shown to be reliable and valid (CB).

8. In adult and adolescent patients with cough of any duration, we suggest that tussigenic challenges have a role in research settings to understand mechanisms of cough (CB).

9. In patients of all ages, we recommend acoustic cough counting to assess cough frequency but not cough severity (Grade 1B).

Cough, particularly chronic cough, is a common symptom.¹ Although the possible causes of this symptom are numerous, assessment of its etiologic factors should follow a systematic approach, as stated in previous guidelines.²⁻⁴ Furthermore, it is recognized that the assessment of antitussive medications should follow specific rules and use valid instruments.⁵ Research outcomes often measured in studies of cough include one or more of the following concepts: cough severity, cough impact on quality of life (QoL), cough frequency, or cough sensitivity. Most often, measures of frequency and severity of cough and cough impact on QoL have not been based on the use of standardized or valid measures. Therefore, more-precise assessments could help to determine the actual impact of cough on patients and allow for valid evaluation of outcomes, providing reliable measurement of the effect of antitussive therapies.

In this regard, the American College of Chest Physicians (CHEST) Expert Cough Panel initially reviewed the 2006 cough guidelines on this topic to develop the current updated recommendations and suggestions.² In the former guideline, recommendations stressed the need for optimally evaluating chronic cough and the efficacy of cough-modifying agents by using both subject self-reporting and objective methods because they have the potential to measure different aspects of

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AFFILIATIONS: From the Institut universitaire de cardiologie et de pneumologie de Québec (Dr Boulet), Quebec City, QC, Canada; Department of Community and Family Medicine (Dr Coeytaux), Duke University School of Medicine, Durham, NC; Duke Evidence-based Practice Center (Dr McCrory), Duke Clinical Research Institute, Duke University, Durham, NC; Pulmonary, Allergy and Critical Care Medicine (Dr French), UMass Memorial Medical Center, Worcester, MA; Department of Respiratory Medicine (Dr Chang), Royal Children's Hospital, Herston, QLD, Australia; Division of Asthma, Allergy and Lung Biology (Dr Birring), King's College London, London, England; University Hospital of South Manchester (Dr Smith), Manchester, England; American College of Chest Physicians (Ms Diekemper), Glenview, IL; Virginia Commonwealth University (Dr Rubin), Richmond, VA; and Division of Pulmonary, Allergy, and Critical Care Medicine (Dr Irwin), University of Massachusetts Medical School, Worcester, MA.

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CORRESPONDENCE TO: Louis-Philippe Boulet, MD, FCCP, Institut universitaire de cardiologie et de pneumologie de Québec (IUCPQ), Centre de Pneumologie 2725, chemin Sainte-Foy, Quebec City, QB G1V 4G5, Canada; e-mail: lpboulet@med.ulaval.ca

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