Methodologies for the Development of the Management of Cough
CHEST Guideline and Expert Panel Report

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BACKGROUND: This series of guidance documents on cough, which will be published over time, is a hybrid of two processes: (1) evidence-based guidelines and (2) trustworthy consensus statements based on a robust and transparent process.

METHODS: The CHEST Guidelines Oversight Committee selected a nonconflicted Panel Chair and jointly assembled an international panel of experts in each clinical area with few, if any, conflicts of interest. PICO (population, intervention, comparator, outcome)-based key questions and parameters of eligibility were developed for each clinical topic to inform the comprehensive literature search. Existing guidelines, systematic reviews, and primary studies were assessed for relevance and quality. Data elements were extracted into evidence tables and synthesized to provide summary statistics. These, in turn, are presented to support the evidence-based graded recommendations. A highly structured consensus-based Delphi approach was used to provide expert advice on all guidance statements. Transparency of process was documented.

RESULTS: Evidence-based guideline recommendations and consensus-based suggestions were carefully crafted to provide direction to health-care providers and investigators who treat and/or study patients with cough. Manuscripts and tables summarize the evidence in each clinical area supporting the recommendations and suggestions.

CONCLUSIONS: The resulting guidance statements are based on a rigorous methodology and transparency of process. Unless otherwise stated, the recommendations and suggestions meet the guidelines for trustworthiness developed by the Institute of Medicine and can be applied with confidence by physicians, nurses, other health-care providers, investigators, and patients.

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ABBREVIATIONS: CHEST = American College of Chest Physicians; COI = conflict of interest; FDA = US Food and Drug Administration; GOC = Guidelines Oversight Committee; PICO = population, intervention, comparator, outcome; RCT = randomized controlled trial
The American College of Chest Physicians (CHEST) has been developing clinical practice guidelines since 1986. Since then, the science of guideline development has expanded, and the CHEST methodologies have advanced along with it. From the early "guidelines," which were not much more than consensus-based documents, to the rigorous and trustworthy guidelines of the present, CHEST processes have evolved to meet or exceed the current standards. CHEST guidelines are distinguished by the level of dedication, expertise, and careful supervision provided by the members of the Guidelines Oversight Committee (GOC) and the contributions of the volunteer health-care providers who lend their expertise and time to ensure the quality of the guidelines and derivative products.

The CHEST Cough guidelines, first published in 1998, were recreated with established methodologies in 2006. These guidelines received considerable attention in both the medical and lay press, impacting several US Food and Drug Administration (FDA) rulings relative to over-the-counter cough and cold medications, especially in children. The 2006 guidelines called for an empirical integrated approach to the diagnosis and management of cough and proposed future directions for research on cough. That iteration also defined two new terminologies: upper airway cough syndrome and unexplained cough.

Since that publication, the science of guideline development has further evolved, and CHEST has embarked on a new model of creating living guidelines to continually update recommendations as new evidence, pharmacotherapies, or medical technologies become available. CHEST also now uses a more rigorous approach to grading evidence resulting in the downgrading of much of the cough research in some clinical areas. Where there are insufficient levels of evidence to create guideline recommendations based on a systematic search of the literature, consensus suggestions are developed and revised using a modified Delphi approach. CHEST’s new consensus-based approach, combined with the evidence-based model, results in a hybrid of these two processes to provide the best clinical guidance supported by both evidence and expertise.

Composition of the Panel and Conflict-of-Interest Reviews

For practitioners to adhere to guideline or consensus statement recommendations, they must have confidence that the convened experts represent all relevant stakeholders and do not harbor biases that might influence the discussions and resulting clinical recommendations or suggestions. This is even more important when guidance includes consensus of a panel of experts. The chair of this project was vetted and determined to be free of conflicts of interest (COIs). The GOC Policies and Procedures Subcommittee and the full GOC, in accordance with explicit rules regarding COI and expertise, carefully reviewed all nominees. Greater explanations of these and other evidence-based processes are published separately.

The panel is predominantly free of relevant COIs. A few individuals with moderate conflicts, whose expertise was highly valued and who could not be easily replaced, were selected. These panelists were given individualized management plans and restricted from writing and voting on clinical content areas related to current conflicts and participation in future activities that could be perceived as conflicts. For this project on cough, 64 individuals were nominated to panel positions. Of these, 56 were approved and eight were disapproved due to substantial conflicts. Because three withdrew at the time of the writing of this article, this panel consists of 53 individuals, eight of whom were approved with specific management terms. As the work of the panel proceeds, we envision that other individuals will be added because their expertise is needed.

Approved panelists were assigned to writing committees covering topics related to their areas of expertise. Each writing committee’s lead was responsible for identifying additional GOC-approved experts, as necessary, and supervising the manuscript with associated recommendations and/or suggestions. Writing committees were assigned a volunteer or staff methodologist who facilitated the development of PICO (population, intervention, comparator, outcome) questions and conducted the systematic reviews according to CHEST-approved methods.

All relevant stakeholder groups were included. This interprofessional panel included experts in adult and pediatric pulmonology and respirology, internal medicine, allergy, sleep medicine, psychology, neurology, adult and pediatric speech pathology, otolaryngology, gastroenterology, gerontology, infectious disease, nursing, anatomy, physiology, thoracic oncology, palliative care, and pharmacology. Methodologists, representatives for lay consumers, and the FDA also contributed as authors and members of the panel.
Panel members identified other professional societies in which they maintained memberships. A total of 18 organizations with expertise overlapping with cough were invited. Association appointees represented the following societies:

- American Academy of Allergy, Asthma & Immunology (AAAAI)
- American College of Allergy, Asthma & Immunology (ACAAI)
- American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)
- American Academy of Pediatrics
- American Association for Respiratory Care (AARC)
- American Bronchoesophagological Association
- American Thoracic Society (ATS)
- Asia Pacific Society of Respirology (APSR)
- Canadian Thoracic Society (CTS)
- Congres International de Pulmonaire Pediatrie
- Irish Thoracic Society (ITS)
- The Joint Task Force on Practice Parameters (JTFPP)

Panelists doubling as association representatives have a single vote on the recommendations or suggestions. Other association representatives not vetted by GOC were not permitted to vote on or author the clinical statements, but served in an advisory capacity. There were three association-appointed representatives in the latter category. In addition, an FDA representative was approved as a panel member and will contribute to pharmacology-focused articles as well as other articles.

GOC policy values the perspective and participation of consumers educated in evidence-based medicine. Patient advocates are not permitted as they harbor biases by definition. For this panel, a consumer, who completed the Consumers United for Evidence-based Healthcare medicine curriculum, was approved by GOC as a consumer representative. This individual was provided with project materials and oriented to the project by The Cough Executive Committee.

A frontline clinician assisted in defining those important topics for which practicing physicians need advice. He was included in development of the key questions prior to the literature searches and asked to provide feedback on the usability and feasibility of the final recommendations and suggestions.

**Funding**

Per CHEST policy, there was no industry funding for this guidance project. All expenses were covered by CHEST.

**PICO Refinement/Inclusion and Exclusion Criteria**

Each topic-specific committee drafted key clinical questions that a frontline clinician and consumer representative agreed would provide important guidance for physicians, health-care clinicians, investigators, and patients with cough. With a methodologist, these key questions were then formulated to examine descriptors of the relevant PICO. These also included information about study designs, settings of care, or time frames, when relevant. These PICO elements then informed the search strategies, including synonyms, and inclusion and exclusion criteria for study screening and acceptance.

**Searches**

Searches were conducted in the National Guidelines Clearinghouse and Guidelines International Network Library for guidelines related to the identified topics. Additional searches for published systematic reviews were conducted in PubMed and the Cochrane Library. When no reasonable quality systematic reviews were identified, primary literature searches were conducted in at least two databases using the predefined search strategies. Medline and the Cochrane Library were always searched for relevant English language studies and, depending on the topic, other databases (eg, EMBASE, Scopus, and CINAHL) were searched. Identified English-language articles were initially screened by title and abstract, using the predefined inclusion and exclusion criteria followed by full-text screening of qualified articles. In the methods section of each topic, the specific databases searched, search results, and study selections are addressed. Search strategies are available upon request at science@chestnet.org.

**Quality Assessments**

Unless otherwise stated, systematic reviews and meta-analyses were preferentially assessed using DART, a tool for clinical settings developed as an improvement to existing tools. DART was adopted in 2011 for CHEST guidelines and consensus statements.

Quality was assessed for individual studies and the body of relevant evidence. Based on the PICO questions and volume of available literature, multiple study designs were included in the systematic reviews. Randomized controlled trials (RCTs) primarily indicate benefits, but observational studies are often helpful in identifying harms. Observational studies were also examined when RCTs were not available to answer a particular PICO question. Including multiple study
designs resulted in a need for multiple quality assessment tools. Tools were chosen for assessing RCTs, observational studies, and diagnostic studies. Ms Diekemper developed a quality assessment tool for intervention studies, including RCTs and observational studies. This tool was based upon principles developed in an RCT tool created by Ms Diekemper; Belinda K. Ireland, MD, TheEvidenceDoc, St. Louis, Missouri; and Liana R. Merz, PhD, MPH, Center for Clinical Excellence, BJC HealthCare, St. Louis, Missouri, and those of two other published tools. Other tools such as the Newcastle-Ottawa tool could be used until a better tool for observational studies becomes available. The Cochrane Risk of Bias Tool was also used to assess the quality of new RCTs identified through updates of published systematic reviews. Diagnostic studies were assessed using the QUADAS tool.

Extracts
Unless otherwise stated, at least two reviewers, which sometimes included a methodologist, extracted relevant data from primary studies or existing systematic reviews for inclusion in the CHEST-provided template for Cough evidence tables. These tables are maintained by CHEST and are available upon request at science@chestnet.org.

Meta-analyses and Profiles
If a recently published good-quality meta-analysis was available, it was used to inform the recommendations. When a good-quality meta-analysis was not available, guideline authors were encouraged to perform their own meta-analyses when appropriate. Meta-analyses were performed when the data were fairly homogeneous. Heterogeneity of the pooled results was assessed using a $\chi^2$ test and Higgins' $I^2$, and a forest plot was examined for consistency of the results. A Higgins' $I^2$ of 50% or higher and a $P$ value of < .05 indicated statistically significant heterogeneity. The random effects model was chosen a priori as the appropriate model for pooling the data because it accounts for heterogeneity among the included studies. Results from the meta-analyses are available in the supplemental materials downloadable from the CHEST website under the corresponding article in the Table of Contents or available upon request at science@chestnet.org.

Evidence table templates were produced a priori and tailored to the specific PICO questions to present data on study design, setting, population, intervention, comparators, measured outcomes, results, and overall quality assessment for each included study. Evidence tables or evidence profiles were produced, when appropriate, to present the data from included studies. Evidence tables present data on individual studies, whereas evidence profiles present pooled data on each outcome examined and allow the reviewer to assess the quality of the body of evidence for each outcome. Evidence tables and profiles are available in the supplementary materials or available upon request at science@chestnet.org.

Evidence profiles were produced using the GRADE profiler software customized specifically for CHEST. The CHEST-modified software ranked the quality of the body of evidence using three categories: high, moderate, and low, as opposed to the four GRADE categories (high, moderate, low, and very low), as CHEST sets a minimal threshold of peer-reviewed publication. The body of evidence was summarized by outcome for each PICO question and assessed, based on limitations in the design or execution of the included studies (risk of bias), imprecision, inconsistency or heterogeneity of results across the studies, indirectness (relative to the PICO question), and reporting or publication bias. Generally, RCTs begin as high-level evidence but can be downgraded based on these criteria. Observational studies start as lower level evidence but can be upgraded if they are not deficient in the other areas, there is a large magnitude of effect, there is a statistically significant effect even with the presence of bias, or there is a dose-response gradient. Evidence profiles include a quality assessment table summarizing the quality of the body of evidence and a summary of findings table that includes the relative and absolute effect for each critically important outcome.

Recommendations and Suggestions
The evidence reviews, meta-analyses, and evidence profiles provided the foundation for the graded recommendations. The term “recommendation” only applies when the body of evidence permits an evidence-based guideline methodology. All other guidance statements are called suggestions, are consensus-based, and not graded. Because in some areas the available literature did not meet the predetermined threshold for an evidence-based guideline, any existing evidence, as well as the experiences of the carefully constructed panel, were permitted to inform the drafted suggestions.

Following the systematic reviews of the structured PICO questions, nonconflicted content experts drafted the recommendations and suggestions, as well as the
corresponding strengths of each proposed recommendation (refer to Grading section). All recommendations and suggestions were entered into the modified Delphi process to refine the language and achieve consensus of the panel (see Consensus Achievement section). Final refinements to these guidance statements emerged from this process.

Grading

Only recommendations can be graded because they are based on sufficient evidence for an evidence-based guideline. For transparency, consensus-based statements are not graded and are designated CB (consensus-based). Both forms of guidance documents are written to be actionable with as much specificity as the evidence and expertise allow. They have been crafted to provide as much clarity as possible with regard to who, what, when, where, and how. Performance measures should not be derived from consensus-based suggestions and caution should be taken with recommendations of weak grades due to lower confidence in the magnitude of benefits and harms.

The CHEST Grading System (Table 1) has two elements: (1) the balance of benefits to harms (risks and burdens), which also includes our confidence in the effect, and (2) the quality of the body of relevant evidence supporting the recommendation. Stronger recommendations (level 1) are those whose benefits of the advocated intervention(s) clearly outweigh whatever harms or burdens may be associated with administration of those interventions. Likewise, if the harms clearly outweigh the benefits, a strong negative recommendation (ie, do not do it) is level 1. When confidence in the effect is great, additional research studies are unlikely to change the direction of these strong endorsements. They are confidently worded “we recommend” or “we recommend against.” In weaker recommendations, worded “we suggest,” it is not as clear that the benefits outweigh the harms (or vice versa), and new research could change the direction or strength of these recommendations. Thus, level 2 recommendations signal research funders of the need for more studies in these areas.

The other element of the CHEST grading system is the quality assessment of the total body of supporting evidence (A, B, or C). A-level grades represent the highest quality but are the least common.

Cough panelists determined the balance between the benefits and harms. The methodologists weighed in on the level of evidence, which was based on the grade assigned to the body of evidence for each outcome. With the increased rigor of today’s quality assessments, most recommendations receive a C-level grade. Readers are advised that even recommendations with a lower grade of evidence can still be strong recommendations (grade 1), where strength of the recommendation is based on the balance of benefits to harms and our confidence in the magnitude of the effect.

Consensus Achievement

All guidance statements were based upon a consensus-achievement process. Consensus achievement took place either through simultaneous web-based voting or via online survey. Meeting presentations were webcasted or shared through another online service. All voting was anonymous to minimize peer pressure and lobbying. Panelists were given the opportunity to review and provide feedback on all recommendations and suggestions in advance of voting.

For evidence-based recommendations, panelists were asked to identify those recommendations that might be considered controversial for any reason or that they would like to see presented for group discussion (the process for the consensus-based suggestions is described below). Those not marked for this purpose were deemed to have panel support. Authors of recommendations selected for further discussion presented the supporting evidence for their recommendations during face-to-face or virtual meetings, followed by discussion and voting.

The total number of eligible voters varied, based on the number of managed individuals recused from voting on any particular recommendations because of their COIs. Some nonconflicted individuals were unable to attend, even virtually, and did not vote. Consensus required 80% of voters to elect “agree” or “strongly agree” with a recommendation for it to be included in the guideline without further modification. When recommendations received 67% to 79% of votes in favor, the GOC Policy on When Consensus Cannot Be Achieved permitted publication of the recommendation with a statement that consensus could not be reached, and an optional minority opinion in a section labeled, “Other Considerations.” The authors of “Other Considerations” were permitted to discuss the available evidence concerning these topics, but were required to explain that the proposed recommendations did not achieve panel agreement. This identified important evidence gaps where more research might strengthen the level of accord.

For expert opinion-based suggestions without sufficient evidence to be guideline recommendations, the consensus process differed. All suggestions, regardless
TABLE 1  CHEST Grading System

<table>
<thead>
<tr>
<th>Grade of Recommendation</th>
<th>Balance of Benefit vs Risk and Burdens (Strength of the Recommendation: Level 1 or 2)</th>
<th>Methodologic Strength of Supporting Evidence (Quality of Body of Evidence: A, B, C, or CB)</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graded evidence-based guideline recommendations</td>
<td>Benefits clearly outweigh risk and burdens, or vice versa</td>
<td>Consistent evidence from randomized controlled trials without important limitations, or exceptionally strong evidence from observational studies.</td>
<td>Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change our confidence in the estimate of effect.</td>
</tr>
<tr>
<td>Strong recommendation, high-quality evidence (1A)</td>
<td>Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence from observational studies.</td>
<td>Recommendation can apply to most patients in most circumstances. Higher quality research may well have an important impact on our confidence in the estimate of effect and may change the estimate.</td>
<td></td>
</tr>
<tr>
<td>Strong recommendation, moderate-quality evidence (1B)</td>
<td>Evidence for at least one critical outcome from observational studies, case series, or from randomized, controlled trials with serious flaws or indirect evidence.</td>
<td>Recommendation can apply to most patients in many circumstances. Higher quality research is likely to have an important impact on our confidence in the estimate of effect and may well change the estimate.</td>
<td></td>
</tr>
<tr>
<td>Strong recommendation, low or very low-quality evidence (1C)</td>
<td>Benefits closely balanced with risks and burden</td>
<td>Consistent evidence from randomized controlled trials without important limitations or exceptionally strong evidence from observational studies.</td>
<td>The best action may differ depending on circumstances or patients’ or societal values. Further research is very unlikely to change our confidence in the estimate of effect.</td>
</tr>
<tr>
<td>Weak recommendation, high-quality evidence (2A)</td>
<td>Benefits closely balanced with risks and burden</td>
<td>Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence from observational studies.</td>
<td>Best action may differ depending on circumstances or patients’ or societal values. Higher quality research may well have an important impact on our confidence in the estimate of effect and may change the estimate.</td>
</tr>
<tr>
<td>Weak recommendation, moderate-quality evidence (2B)</td>
<td>Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced</td>
<td>Evidence for at least one critical outcome from observational studies, case series, or from randomized, controlled trials with serious flaws or indirect evidence.</td>
<td>Other alternatives may be equally reasonable. Higher quality research is likely to have an important impact on our confidence in the estimate of effect and may well change the estimate.</td>
</tr>
<tr>
<td>Weak recommendation, low or very low-quality evidence (2C)</td>
<td>Uncertainty due to lack of evidence, but expert opinion that benefits outweigh risk and burdens or vice versa</td>
<td>Insufficient evidence for a graded recommendation</td>
<td>Future research may well have an important impact on our confidence in the estimate of effect and may change the estimate.</td>
</tr>
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</table>

CB = consensus based.
of their level of controversy, were presented to the panel and voted upon anonymously during the same synchronized voting activity. Many were revised during the voting rounds as a result of the independent modified Delphi process. Up to three rounds were permitted for each suggestion until consensus was achieved. The 80% threshold for “agree” or “strongly agree” prevailed, but at least 75% of the panel was required to vote. The purpose of these requirements (discussed elsewhere) is based on having a significant level of consensus among experts to provide guidance based primarily on expert opinion and insufficient evidence. Suggestions not obtaining consensus, even after three rounds were not published, but their related topics were discussed in the section on future research.

Review Process
After the Cough Executive Committee provided final approval, the NetWorks, GOC, and Board of Regents disseminated manuscripts and supporting documentation for review. The CHEST NetWorks of interested members, in the areas of Airways Disorders, Allied Health, Clinical Pulmonary Medicine, Pediatric Chest Medicine, Pulmonary Physiology Function and Rehabilitation, and Respiratory Care, reviewed the content of the manuscripts. Members from the CHEST Board of Regents and GOC reviewed both content and methods, including consistency, accuracy, and completeness. The CHEST journal peer review process overlapped with the later rounds of these reviews. All ideas for modification were marked as mandatory or suggested, responded to or justified, and tracked through the multiple rounds of review. The CHEST Presidential line of succession provided the final approval allowing submission to the journal.

Dissemination
After publication, the guidelines were promoted to a wide audience of physicians, other health-care providers, and the public through multiple avenues. Press releases were prepared for both the lay and medical media, with major outreach efforts to all relevant print, broadcast, and Internet media. Panelists located in various large media markets were identified as potential spokespersons for interviews. Social media promotion was facilitated over Twitter, Facebook, CHEST e-Communities, internal and external blogs, and other communication routes. Blast communications were sent to CHEST members with links to the publication and postings on CHEST’s website.

In addition to publication in CHEST, other derivative products were prepared to help with implementation, including slide sets, algorithms, and other clinical tools. These derivative products are posted on the CHEST website and will be made available in CHEST Guidelines. CHEST Guidelines will be the repository for the most current recommendations and suggestions from all CHEST guidelines, consensus statements, and hybrid documents. This online repository will also house a collection of related resources.

Associations that appointed representatives earlier in the process were asked to consider endorsing the approved guidelines for listing in the final publication. These organizations were requested to help promote the publication to their memberships through newsletters, Web sites, and other means.

Updating
CHEST guidelines and consensus statements are living documents, subject to updating as necessary. Annual reviews begin 1 year after publication. The GOC has established criteria to select and prioritize projects for updating, including the publication of new studies whose results might impact either the direction or strength of the existing recommendations. Other criteria focus on new interventions or changes in practice that might require updating existing recommendations. The long-term goal is to maintain the currency of the guidance documents.

Summary
The CHEST methods for development of guideline recommendations and consensus suggestions have evolved as the field of evidence-based medicine has evolved. The creation of this hybrid model is an example of the latest innovation in these methodologies. Unless otherwise stated, these guidance documents meet all of the standards of the Institute of Medicine for trustworthy clinical practice guidelines. More information on CHEST methods for the development of guidelines and consensus statements can be found in the General Methodology article.

Acknowledgments
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References