Advancing Clinical Practice and Policy through Guidelines

The Role of the American Thoracic Society

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In the face of an overwhelmingly large and growing medical literature, providers often turn to clinical practice guidelines to inform the decisions they make with patients. By systematically appraising the evidence and providing transparent recommendations for practice, guidelines have the potential to improve both bedside decision-making and health policy. This potential has not been fully realized because most guidelines lack transparency, are tainted by conflicts of interest, or fail to employ rigorous methods to appraise the evidence. To address the shortcomings of past guidelines, the Institute of Medicine (IOM) published recommendations for trustworthy guidelines, effectively setting the "gold standard" for what constitutes a high-quality guideline. Along with many other groups that develop guidelines, the American Thoracic Society (ATS) is rapidly evolving processes for development and implementation to meet many of the IOM standards. This Pulmonary Perspective describes the rapidly changing landscape of clinical practice guidelines, the role of the ATS in this landscape, and the activities the ATS is engaged in to ensure that the guidelines it produces are of the highest quality with the broadest impact.

Keywords: clinical practice variation; standards of care; evidence-based medicine; professional organizations; pay for performance

Over the last several decades, the pulmonary, critical care, and sleep communities have increasingly relied on clinical practice guidelines (CPGs) to help shape the care of its patients. The volume of medical literature is expanding at such a rapid pace that most clinicians struggle to keep abreast of developments in their field. In theory, CPGs raise awareness of best practices, and thereby facilitate evidence-based decisions about the optimal care for patients, improving patient safety and reducing inappropriate practice variation. In practice, however, some experts question their validity and, ultimately, their ability to change practice (1). Concerns about the validity of CPGs and their applicability to clinical practice stem from the lack of evidence supporting many if not most clinical decisions (2), the paucity of guidelines based on studies of *effectiveness* in real-world practice rather than studies of *efficacy* in the idealized settings of the typical randomized, controlled trial, the limited evidence that guideline-based care improves patient outcomes, and recommendations from different guidelines that are sometimes in conflict (3). Additional concerns stem from how guidelines are developed, and include the wide variability in guideline quality (4), methods for development that are unfamiliar to most clinicians or lack transparency, and the potential for conflicts of interest to introduce bias. In this pulmonary perspective, we briefly describe the evolving role of clinical practice guidelines in practice, how the standards for guideline development have advanced to address variability in the development process that impacts the quality of existing guidelines, and conclude with a discussion of how the American Thoracic Society (ATS) is specifically addressing the challenges of the rapidly evolving guideline landscape.

THE (CHANGING) ROLE OF CLINICAL PRACTICE GUIDELINES

The use of clinical practice guidelines to aid in medical decision-making is a relatively recent development (5). In the past, clinicians who sought guidance often turned to narrative reviews or expert consensus-based clinical position statements from professional societies. It is now recognized that, although useful for providing a broad introduction to a topic, narrative reviews and clinical statements are suboptimal for addressing specific questions about practice, because they typically recommend a course of action based on evidence gathered in a nonsystematic, potentially biased way. Rigorously developed CPGs, on the other hand, explicitly address this limitation by recommending a course of action based on a comprehensive and systematic review and grading of the evidence and an explicit comparison of the benefits and harms of a given test or treatment (6). Although CPGs are just one type of evidentiary knowledge one can use when making clinical decisions (7), clinicians can be confident that decisions informed by high-quality CPGs reflect current knowledge and are consistent with best practices. Ideally, the practice of evidence-based medicine should always involve the judicious application of evidence to the specific patient and health care setting.

Although CPGs were originally targeted exclusively to clinicians to help in decision-making, their target audience has grown. Because CPGs explicitly identify tests and treatments that are recommended (or not recommended), other groups, including health system administrators, disease advocates, litigators, and payers, are now using CPGs to define the standards of care. For example, insurers may base coverage decisions for patients being treated for pulmonary hypertension on which therapies are recommended in CPGs for this illness. In addition, payers and regulatory agencies seeking to measure and track health care quality are increasingly translating CPG recommendations into performance measures. For example, established developers of performance measures, such as

(*Received in original form January 2, 2013; accepted in final form January 26, 2013*)

Author Contributions: Both authors were involved in conception and design, analysis and interpretation of data, drafting and revising of article for important intellectual content, and final approval of the manuscript.

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Am J Respir Crit Care Med Vol 187, Iss. 9, pp 910–914, May 1, 2013

Originally Published in Press as DOI: 10.1164/rccm.201301-0009PP on February 7, 2013
Internet address: www.atsjournals.org

the American Heart Association and the American Medical Association's Physician Consortium for Performance Improvement, routinely identify CPGs as a particularly rich source of information that should be integrated into the evidence base that underlies a performance measure (8, 9).

THE ERA OF TRUSTWORTHY GUIDELINES

The attention of multiple stakeholders has increased the pressure to define what constitutes a high-quality CPG that is worthy of trust. Until recently, the absence of common standards that defined trustworthy CPGs resulted in substantial variability in the quality, transparency, and objectivity of published guidelines (10). It was often assumed that guidelines were high in quality simply because they were created or endorsed by professional societies. Unfortunately, most guidelines produced over the last two decades, including those created by professional societies, were plagued by conflicts of interest, and failed to synthesize the evidence underlying their recommendations objectively and transparently (11).

In an effort to improve guideline quality, in 2011 the Institute of Medicine (IOM) published recommendations for guideline development in its report, *Clinical Practice Guidelines We Can Trust*, which outlined eight broad recommendations for creating trustworthy guidelines (Table 1) (6). In the document, the IOM sets rigorous standards for assembling the guideline panel, vetting and managing conflicts of interest among panel members, performing literature reviews, formulating recommendations, coordinating reviews by both internal and external stakeholders, and assessing the document periodically for currency. Essentially, the IOM provides a "gold standard" one can now use to judge the trustworthiness of a CPG by determining how well it adheres to the outlined standards (12).

Although most agree that adhering to the IOM standards is a laudable goal, the resources required to do so are considerable. In addition to bringing leadership and content expertise to a guideline panel, developers must now assume responsibility for managing conflicts of interest, and ensure that one or more team members has the necessary methodological expertise required to rate evidence and formulate recommendations. *De novo* synthesis of the evidence and grading of recommendations is also particularly costly and time intensive. High-quality guidelines usually require more than $100,000 and often thousands of person-hours to develop. These figures do not capture the resources required to steward a CPG through its life span, intermittently updating the document as the evidence evolves—what the ATS now calls "living guidelines." To address the high costs of guideline development, developer groups are increasingly motivated to seek funding from multiple parties, including professional societies or other funding agencies. Pooling of resources and expertise across societies strengthens the developed CPG and broadens its target audience, but it also requires developers to successfully navigate differing and potentially conflicting standards for document development between societies. These are only a few of the ways in which the rigorous IOM guideline standards significantly increase the burden of guideline development.

In the face of such challenges, it is anticipated that some groups will elect to adhere incompletely to the IOM standards or settle for less stringent ones (13). Developers that do so run the risk of producing CPGs that consumers view as inferior or potentially not worthy of trust. More importantly, guideline consumers will continue to struggle with heterogeneity in the quality of published CPGs when choosing between existing guidelines because of inconsistent adherence to standards. The IOM therefore suggested that a mechanism is needed to help guideline consumers determine whether a CPG adheres to its standards, possibly including public reporting and/or formal certification (6). Should the guideline community move forward with the IOM suggestions, CPG developer groups, including professional societies such as the ATS, may eventually be audited to determine the extent to which they adhere to the IOM standards. Already, the National Guidelines Clearinghouse applies stringent criteria for posting summaries of CPGs on the website of the Agency for Healthcare Research and Quality (available at www.guideline.gov).

TABLE 1. INSTITUTE OF MEDICINE STANDARDS FOR TRUSTWORTHY GUIDELINES

Domain	Specific Standards	ATS Adherence
Transparency	Funding and development process should be described and made public	Yes
Conflict of interest	All conflicts should be disclosed	Yes
	Chair/cochair should not have COI	At least one
	Majority of panel should not have COI	Yes
	Members with financial conflicts should divest	No
	Funders should not play a role in development	Yes
Panel composition	Panel should be multidisciplinary	Yes
	Panel should include patient or patient advocate	Yes
Literature review	Evidence synthesis should adhere to IOM standards for trustworthy systematic reviews	Pragmatic reviews allowed
	Evidence review and guideline development teams should work separately but interact	No
Grading of recommendations	Systematic approach should be used to summarize benefits and harms, rate the quality of the evidence, grade the strength of recommendations, incorporate values and preferences, and acknowledge differences in opinion	Yes
Articulation of recommendations	Use standardized format, e.g., PICO	Yes
	Strong recommendations should be measureable	Yes
Review process	Review should be confidential	Yes
	Review should be performed by diverse stakeholders	No
	Draft should be available for public comment	No
Assessment of currency and updating	Dates of systematic review and publication should be stated	Yes
	Literature should be monitored and guideline updated when indicated by availability of new evidence	Formal policy under development

Definition of abbreviations: ATS = American Thoracic Society; COI = conflict of interest; IOM = Institute of Medicine; PICO = population, intervention, comparator, outcomes.

ROLE OF THE ATS IN GUIDELINE DEVELOPMENT

Setting Guideline Standards

Anticipating this changing landscape in CPG development, what steps has the ATS taken to move toward producing CPGs of the highest standard? In several respects, the ATS has been a leader among professional societies in establishing rigorous policies for the development of trustworthy CPGs. Almost 10 years ago, ATS established the Document Development and Implementation Committee (DDIC), which was charged with setting strict standards within the ATS, including the use of explicit and transparent methods in document development. In one major step that has posed challenges with implementation, the ATS has adopted the

Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system for rating the quality of evidence and grading the strength of recommendations (14). Although the system adds substantial rigor and transparency to the guideline development process, some guideline panels have found it labor-intensive and difficult to apply, as its execution requires training and experience in clinical epidemiology and evidence-based medicine. At the same time, the ATS adopted a conflict of interest policy mandating that only a minority of guideline chairs and panel members have any conflicts of interest. Together, these two policies ushered in a much more rigorous process through which CPGs are developed within ATS. By the time the IOM standards for trustworthy guidelines were updated in 2011, the ATS fully adhered to four of the IOM's eight recommended standards, and partially adhered with the remaining four.

Current efforts within the committee and the Society are moving to meet as many of the IOM standards as possible, but given the limited resources that many development panels face there may be good reasons to deviate from some. For example, the IOM recommends that evidence review and guideline development teams should work separately but interact extensively (i.e., interactive model) (6). Adherence to this standard requires that a CPG must be developed concurrently with *de novo* systematic reviews, regardless of whether high-quality systematic reviews for the questions of interest already exist. The ATS has adopted a more pragmatic model that allows guideline developers to capitalize on existing systematic reviews provided they meet quality standards. This approach ensures that developers can more efficiently target their limited resources to other aspects of development without significantly compromising the quality of the CPG. While the ATS approach is not officially endorsed by the IOM, the IOM provided some leeway in interpreting this standard, acknowledging that "…the committee is aware that many variants of this [interactive] model may be suitable across differing CPG development contexts" (6). The ATS is also concerned about making documents available for public comment before publication, which may provide opportunities for vested interests to influence the content and introduce bias. Nevertheless, with appropriate safeguards, it is likely that the ATS will seek wider input from diverse stakeholders going forward.

Facilitating Adherence to Standards

Over the last several years the DDIC has also devoted considerable effort to help developers meet the CPG standards (Table 2). At the beginning of and throughout the CPG development process, the DDIC provides outreach to development teams, including a kick-off phone call to newly established document groups, a workshop outlining key steps in document development before the international conference, access to the ATS methodologist who has extensive expertise in the use of GRADE, and oversight from the ATS Documents Editor. Recognizing that a major barrier to the production of high-quality documents is a lack of expertise in evidence synthesis and the use of GRADE, the DDIC is also moving to increase the capacity for methodologists within the ATS. Efforts toward achieving this goal include providing post-graduate courses about GRADE at the international conference, developing an ATS guideline development methodology fellowship that provides a junior member hands-on experience in GRADE methodology and CPG development, and calling for ATS members with experience in performing systematic reviews to participate on guideline development panels. Multiple resources are available for ATS members who want to learn about methods for guideline development. These include a 6-part series in the *British Medical Journal* (15), providing an overview of GRADE; a 20-part series published in *The Journal of Clinical Epidemiology* (16), providing a more in-depth discussion of GRADE; and a 14-part series published in the *Proceedings of the American Thoracic Society* (17), providing instruction on other important aspects of guideline development.

TABLE 2. RECENT ACTIVITIES OF THE AMERICAN THORACIC SOCIETY DOCUMENTS DEVELOPMENT AND IMPLEMENTATION COMMITTEE

Prioritization of Topics
Initiated new leadership-driven RFP mechanism to identify high-priority topics for guideline development
Document Development
Organized kick-off calls with project chairs
Hosted methods workshop before international conference
Hired dedicated methodologist with expertise in systematic review and guideline development
Instituted liaison system to facilitate communication between DDIC and project chairs
Sponsoring fellowship to train ATS members in methods for systematic review and guideline development
Peer Review
Cleared backlog of documents under review
Expedited review process
Implementation and Maintaining
Coordinating sessions at International Conference with Education Committee
Collaborating with Patient and Family Education Committee to develop patient education materials
Working with Quality Improvement Committee to translate selected guideline recommendations into performance measures
Exploring informatics approaches to integrate guidelines within electronic health record systems
Developing a policy for timely assessment of guideline currency, process for updating guidelines, and rapid publication of such updates

Definition of abbreviations: ATS = American Thoracic Society; DDIC = Document Development and Implementation Committee; RFP = request for proposal.

Fostering Multisociety Collaboration

Facilitating cooperation between the ATS and other professional societies during the development of CPGs is an additional focus of the DDIC. The guideline community has increasingly recognized that guidelines are strengthened when the viewpoints, values, and perspectives of multiple groups (e.g., diverse clinicians, methodologists, patients, payers) are represented during the development process (18). Partnering with other professional societies to develop guidelines for diseases of shared interest helps the ATS address this need for panel diversity, but also brings additional benefits. Multisociety collaboration allows participating groups to pool their limited resources, and promotes guideline "ownership" across diverse memberships that facilitates subsequent dissemination and implementation (18). However, partnering with other organizations brings several challenges. At the outset, organizations must agree on the methodology for guideline development, where the guideline will be published, and who owns any derivatives of the guideline (e.g., electronic media, pocket guides). The DDIC is developing policies to overcome such barriers to optimize the opportunities for multisociety documents.

Implementing and Maintaining Guidelines

Recognizing that CPGs are useful only to the extent that they are implemented, the DDIC is working with other committees to ensure that guidelines generated by the ATS have the greatest possible footprint. Through collaboration with the Education and International Conference Committees, the DDIC is working to ensure that existing CPGs in the development pipeline can be used

to program CPG-themed symposia during the International Conference. Not only will such content aid in dissemination of the guideline, it provides continuing medical education (CME) credits for participants, and moves the ATS closer to implementing performance-based CME. A similar model could be applied to graduate medical education. To facilitate use at the point-of-care, the DDIC is seeking to partner with organizations that specialize in translating CPGs into a machine-readable format such that they can be integrated into the electronic health record. In addition, CPG developers will be working in parallel with the Patient and Family Education Committee to generate CPG-related content for lay audiences. Last, the ATS hopes to influence how third parties interpret the guidelines that it produces. In particular, the DDIC recently partnered with the Quality Improvement Committee to create a framework for translating strong recommendations based on high- or moderate-quality evidence into performance measures. This framework will be published in an upcoming issue of the *Annals of the American Thoracic Society* (formerly *Proceedings of the American Thoracic Society*) and lays the groundwork for the ATS to develop evidence-based measures that reflect the priorities of the pulmonary, critical care, and sleep medicine communities and the patients that they serve.

An additional way for the ATS to enhance the value of its guidelines is to ensure that they remain relevant by reflecting the most recent evidence. Although there are few studies discussing how often and by what process guideline currency should be maintained (19), virtually all stakeholders, including the IOM, believe that updating is an integral part of a guideline's validity (6, 13). Professional societies and other guideline developers have struggled to develop efficient policies to maintain their guidelines and the ATS is no exception (20). At present, ATS guidelines are updated on an *ad hoc* basis, a process driven not by the need for an update, but rather by the interest and available time of panel members involved in the initial guideline. This informal process has resulted in long delays between the initial development and subsequent updating of guidelines to reflect the most current evidence. To move toward a "living guidelines" model for CPGs, the DDIC is actively developing a process that outlines how CPGs should be assessed for currency, the frequency of such assessments, and procedures for integrating novel evidence into an existing guideline and subsequent dissemination of the changes.

Prioritizing Areas with Greatest Need

Last, the DDIC has spearheaded an initiative to identify, prioritize, and select topics of high importance to the ATS and to society at large. Although the process continues to evolve, at present the ATS Planning and Evaluation Committee is charged with soliciting nominations for topics, and subsequently makes recommendations to the ATS Executive Committee for their approval. These "top down" guidelines are intended to fill a gap in the portfolio of official Society documents for conditions of public health importance that are of interest to not only ATS members, but also patients, policymakers, regulators, payers, and other societal representatives. In 2012, "Mechanical Ventilation in Adults with the Acute Respiratory Distress Syndrome" was chosen as the inaugural topic, and the DDIC announced a "Request for Proposals" for a state-of-the-science CPG on this topic. Provided ATS members were represented on the proposed guideline panel, proposals from ATS members and nonmembers were accepted. An ad hoc committee that included representatives from multiple standing committees subsequently reviewed the submissions, and a highly meritorious proposal was selected for funding. Going forward, the ATS plans to select at least one "top down" guideline per year for funding via this mechanism.

Although this pulmonary perspective has focused exclusively on CPGs, it is important to note that the ATS continues to strongly support the publication of Workshop Reports, Research Statements, and Policy Statements. Within these documents, authors review pertinent literature, provide context, explore controversies, and offer suggestions for policies and/or future research. The ATS also continues to support the development of Technical Standards (previously referred to as Health Technology Assessments), which address questions regarding "how to" perform a test or procedure. However, recommendations about "in whom" and/or "under what circumstances" a test, procedure, or treatment should be applied can be addressed only in a CPG, using appropriately rigorous methodology to minimize the introduction of bias.

Along with the three Society journals and the International Conference, official ATS documents are jewels in the Society's crown. Because of their growing importance not only to clinical practice, but also to CME and quality improvement, and because their development is so resource-intensive, CPGs warrant special attention and continued support. The ATS has made great strides toward producing trustworthy guidelines, but methods for guideline development and implementation continue to evolve, and the ATS must continue to keep abreast of developments in the field and remain at the forefront of methodology. To do any less would be a disservice to our members and the patients and families that we serve.

Author disclosures are available with the text of this article at www.atsjournals.org.

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