

The Guideline Approach to Chronic Obstructive Pulmonary Disease: How Effective?

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Clinical practice guidelines are systematically developed to assist health care decisions in specific clinical circumstances. They first arose to improve quality of care by decreasing unexplained practice variation, controlling health care costs, fostering evidence-based decision-making, and accelerating the application of new advances in medical science to everyday practice. Unfortunately, multiple studies demonstrate incomplete and varied effectiveness of clinical practice guidelines in altering clinician behavior and improving patient outcomes. Efforts to enhance guideline effectiveness have focused on improving the methods for guideline development, diffusion, dissemination, and implementation. Despite evidence of limited effectiveness, more than 40 clinical practice guidelines pertaining to chronic obstructive pulmonary disease have been published since 1985. The present article reviews those guidelines, evidence for their effectiveness, and approaches to improve their implementation. *Key words: chronic obstructive pulmonary disease, COPD, guidelines.* [Respir Care 2003;48(12):1257–1266. © 2003 Daedalus Enterprises]

Introduction

Advances in basic science, pharmacology, outcomes, and population-based research during the last 30 years

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have greatly expanded our knowledge of the pathophysiology, epidemiology, diagnosis, and treatment of chronic obstructive pulmonary disease (COPD). A growing body of “best clinical practices” has emerged from this enlarging evidence base. Unfortunately, barriers remain in translating this knowledge into improved patient care. Multiple studies demonstrate that clinicians are often slow to adopt best clinical practices into their daily patterns of care,¹ and patients do not have the resources to recognize the gaps between available care and the care they receive.² Consequently, there is considerable variability in the delivery of health care between providers, institutions, and geographic regions, and that variability cannot be explained by patient-related risk factors, patients’ values and preferences, or the nature or severity of patients’ health conditions.^{2–4} Extensive observational studies have demonstrated the neg-

ative impact of unexplained practice variation in cardiovascular disease,^{5,6} which is beginning to be demonstrated to have similar negative effects on the management of COPD patients.⁷

The public, payers, government, and regulatory agencies recognize unexplained practice variation as an important public health problem. This recognition has been spurred by rising health care costs and public perceptions that too much of health care is characterized by misuse, underuse, and overuse of available resources. In response, governmental and regulatory agencies have assumed more oversight for clinical decision-making that was previously solely the private domain of physicians. For instance, the United States Department of Health and Human Services has developed a quality-of-care information program that will publicly report the degree to which hospitals adhere to guideline recommendations in the management of acute myocardial infarction, stroke, and several other health conditions.⁸

Although multiple factors contribute to unexplained practice variation, one major cause is the way physicians learn during their training and how they refine their knowledge and skills during practice. Traditional medical education uses an "expert based" model, which relies on experienced teachers, mentors, and consultants to impart their medical knowledge through lectures, textbooks, journal reviews, patient care interactions, and other forms of unstructured communication. These clinical experts in turn gain their knowledge from clinical experience and their own synthesis of various sources of information retrieved by unsystematic techniques.⁹ Because the clinical experiences of experts and the quality of information sources differ, there is unexplained practice variation—different understandings of what constitutes best clinical practice and various interpretations and awareness of the literature.

During the last 15 years, the focus of medical education has shifted from the traditional model toward the new paradigm of evidence-based medicine, which emphasizes empirical evidence over expert knowledge and experience.¹⁰ Evidence-based medicine encourages physicians to conscientiously and judiciously identify and apply the best clinical evidence to the daily care of their patients. This recommendation presents a formidable challenge to individual providers, who have become overwhelmed with the volume of investigative evidence that flows from the literature. No physician or practicing physician group can retrieve, synthesize, and implement the wealth of complex information relevant to their clinical practice that appears in the journals. To assist clinicians in their efforts to identify and adopt best clinical practices, evidence-based medicine promotes the use of clinical practice guidelines (CPGs). Clinical practice guidelines link processes to outcomes and identify the degree to which valid clinical studies support the value of various clinical practices.

As a component of the evidence-based medicine movement, various professional organizations have published over 40 CPGs for the diagnosis and care of COPD patients.¹¹ These guidelines differ considerably in their design, content, and strategies for implementation.¹¹ They have in common, however, an absence of strong evidence that they have altered patient care or improved the health of COPD patients. The present article reviews COPD CPGs, discusses the evidence for their effectiveness, and suggests approaches for promoting their implementation to alter provider behavior and improve patient outcomes.

What Are Guidelines? Background and Essential Elements

Clinical practice guidelines first emerged to improve the quality of care by providing information and sound clinical recommendations to clinicians.¹² Early CPGs were expert-based, consensus documents that synthesized the knowledge and experiences of experts in a field. It was soon recognized that more rigorously developed guidelines provided more valid information and a greater probability of altering provider behavior. The Institute of Medicine subsequently defined CPGs as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."¹³ Expert-based guidelines have slowly migrated toward being recognized as "consensus statements," "expert reviews," and "nonsystematic reviews." Evidence-based medicine reserves the term "clinical practice guidelines" for documents that explicitly describe their methods for developing valid and reliable recommendations for care with a systematic retrieval and grading of the quality of the available literature. The evidence grading scales have followed the principles of the 1979 Canadian Task Force on Periodic Health Examination¹⁴ but have evolved toward more simple 3-level evidence schemes (Table 1).

During the 1990s development of practice guidelines for a broad spectrum of conditions became a priority of the Agency for Healthcare Policy and Research (now the Agency for Healthcare Research and Quality) when created by the Omnibus Reconciliation Act of 1989. That agency has promoted methodological standards for developing, implementing, and disseminating practice guidelines. Although the cornerstone of CPGs remains the use of outcomes research with objective and measurable end points, there are multiple standards for the guideline de-

Table 1. Evidence Hierarchy for Grading the Medical Literature

Class I: Prospective, randomized, double-blinded study
Class II: Prospective, randomized, nonblinded study
Class III: Retrospective analysis, uncontrolled studies, or case reports

velopment process that incorporate “essential guideline elements.”^{13,15–20} Rating systems have emerged that allow the grading of CPGs to determine the degree to which their development process incorporated these essential elements.^{21–25}

Because of the diverse health conditions addressed by guidelines, the need to address different target audiences, the unique values and perspectives of the multiple target audiences, and the necessity of considering multiple outcomes domains (eg, quality of life, survival, cost-effectiveness, feasibility) Cook and Giacomini²⁶ observed that “the metric against which clinicians might judge guidelines is complex and multidimensional.” Suffice it to say, however, that sufficient metrics exist to begin judging the quality and impact of COPD CPGs.

Do Clinical Practice Guidelines Work? Evidence of Effectiveness

Despite decades of experience with formal CPGs and millions of dollars of investment into their development and dissemination, much remains unknown about their value and effectiveness.²⁷ Questions exist whether guidelines have a sufficient impact on practice variation, the promotion of best clinical practices, and the improvement of health outcomes to justify their existence. These questions have spawned increasing interest in studying CPGs in a manner similar to how we study other health care interventions, such as new medical devices and drugs.²⁸ Like other health care interventions, CPGs have a potential to cause harm, either by decreasing the probability of a good clinical outcome for individual patients by making invalid recommendations, or by inappropriately directing health care resources for specific purposes to populations of patients and thereby limiting resources for other patient groups.²⁹

Most studies that examine the effectiveness of CPGs have been cross-sectional and observational in design. Some studies examine the degree to which practitioners adhere to guideline recommendations. Many use survey techniques to determine practitioner awareness of the existence of guidelines for a specific condition and the nature of guideline recommendations.³⁰ Others look for evidence that adherence to guideline recommendations improves health outcomes for patients or populations.^{31,32}

Guideline studies commonly use a before-and-after or time-series design to determine the impact of the introduction of a guideline on processes and outcomes of care. These studies may assess provider knowledge of best clinical practices or the outcome of patients before and after guideline development or implementation. They may also assess the clinical outcome of patients stratified by physician knowledge or adoption of guideline recommendations.³³ Some studies examine the impact of different guide-

line development methods on measured outcomes, whereas others assess the effect of different guideline dissemination or implementation methods that promote their adoption. Guideline studies may measure physician perspectives in valuing outcomes to determine benefits of therapy (eg, effects on forced expiratory volume in the first second [FEV₁]), patient perspectives (eg, quality of life, utility of various outcomes), or other perspectives, such as societal (eg, cost-effectiveness of various treatments).

The diverse nature, purpose, and quality of guidelines, differences in study design, and the variable quality of the studies that evaluate guideline effectiveness have presented challenges in understanding the impact of CPGs on medical care. Systematic reviews have synthesized existing guideline effectiveness studies to provide a more comprehensive evaluation of guideline effectiveness.^{27,34–37} These reviews report that guidelines do improve clinical practice, but the degree of improvement differs considerably.^{35,37}

These systematic reviews are limited, however, because most of the CPGs evaluated by the primary studies for effectiveness are older and less evidence-based than more recent guidelines being introduced.²⁷ Also, older evaluation studies used assessment methods that lacked sensitivity to detect small changes in patient outcomes.²⁷ Moreover, most studies that examine the effectiveness of guideline implementation strategies have focused on altering the behavior of individual clinicians as the primary outcome.³⁴ Few studies have evaluated the effect of guidelines on improving practice systems or organizational support of clinician behavior, the mechanisms for producing change, or the interaction of the practice environment with the behavior or process the guideline is attempting to change.³⁴

A central limitation in assessing the impact of CPGs relates to the design of the primary evaluative investigations. Most guideline effectiveness studies attempt to examine the impact of CPGs as generic medical interventions and do not analyze specific types of guidelines in specific settings for specific target conditions. If such study designs were applied to other health care interventions, we would be attempting to investigate the benefit of “drugs” or “surgery” for “patients” without regard to the specific drug, method of prescribing, target condition, or desired outcome. More recent evaluative studies have begun to examine specific guidelines with greater precision. Malone and Shaban, for instance, demonstrated improved outcomes for patients with community-acquired pneumonia treated in a manner consistent with American Thoracic Society guidelines.³⁸

Effectiveness of COPD Guidelines

As reviewed above, effectiveness studies demonstrate that guidelines in general can improve patient care and

clinical outcomes, although the degree of improvement varies. Studies are now emerging of the effectiveness of published COPD guidelines. These studies have focused on the impact of COPD guidelines on physician knowledge, processes of care, and patient outcomes.

Impact on Physician Knowledge

Several studies performed in Denmark examined physician awareness and knowledge of COPD guidelines and physician practice patterns relative to guideline recommendations. Phanareth et al performed a telephone survey of in-patient physicians at all 70 hospitals in Denmark that have emergency facilities, to assess self-reported practice patterns in caring for COPD exacerbations.³⁹ They repeated the survey 3 years later, after the publication of Danish COPD guidelines that contained detailed recommendations for therapy. The authors observed wide practice variability in the baseline survey results. This variability showed only moderate improvement after publication of the national guidelines, with overall poor adherence to guideline recommendations.

In Greece, Trakada and Spiropoulos evaluated with a questionnaire survey the dissemination of COPD management guidelines among primary care physicians.⁴⁰ They found a low rate of adherence of physician-stated management decisions in caring for COPD patients with guideline recommendations.

Impact on Processes of Care and Patient Outcomes

In France, Roche et al studied whether respiratory physicians' drug-prescribing patterns for 631 COPD patients conformed with guideline recommendations.⁴¹ They found that 78% of patients were treated with β_2 agonists, 56% with inhaled anticholinergic agents, and 76% with inhaled corticosteroids. These "real world" practices did not adhere to existing guidelines, which recommended anticholinergic agents for persistent exertional dyspnea and on-demand β_2 agonists for symptomatic patients. Based on disease severity, inhaled corticosteroids were overprescribed, relative to guideline recommendations, in that 54% of patients with $FEV_1 > 70\%$ of predicted received inhaled corticosteroids. The authors suggested that poor adherence to guideline recommendations may have resulted from the structure of the published guidelines, which did not provide grading of the evidence or explicitly describe the support for therapeutic recommendations. Also, guidelines did not incorporate newer data that suggested a primary role for long-acting β_2 agonists in the care of COPD patients. They suggested that many COPD guideline recommendations are vague, overly complex, and inapplicable, which promote nonadherence.⁴¹

Roberts et al performed an audit of 1,400 acute admissions of COPD patients to United Kingdom hospitals.⁴² They compared actual practices with those recommended by the British Thoracic Society guidelines and found large differences in clinical practices between hospitals for many of the treatment standards assessed. Also, treatment standards fell below those recommended by the British Thoracic Society guidelines. Lack of conformance with guidelines was noted for patients cared for by either pulmonary or nonpulmonary physicians.

In Denmark, lack of adherence to guidelines for long-term oxygen therapy was found among 1,354 COPD patients registered in a nationwide database.⁴³ Overall adherence with guidelines recommendations was 34% (range 14–63% in different regions). Pulmonary physicians were more likely to comply with guidelines than general practitioners, but overall compliance for both physician groups was poor.

In the Netherlands, Jans et al evaluated with a randomized, controlled trial a comprehensive implementation project to encourage primary care physicians to follow asthma and COPD guidelines.⁴⁴ One year after starting the project, they found that processes of care were better aligned with guideline recommendations. They also noted improved lung function and symptoms scores among the intervention group patients. The effect on lung function, however, was small.

The latter study highlights the difficulties faced by health services researchers in establishing that improvements in the quality of care improve patient outcomes. Studies that examined mortality related to hip fracture,⁴⁵ stroke,⁴⁶ and coronary artery bypass grafting surgery⁴⁷ demonstrate little to no effect on survival after new programs were implemented to improve the quality of care. Patient outcomes are relatively insensitive indicators of quality of care, because multiple patient, physician, and institutional-related factors contribute to patient outcomes. It is not surprising, therefore, that little data exist that COPD guidelines improve outcomes for COPD patients. As recommended for most quality improvement efforts,⁴⁸ the effectiveness of COPD guidelines should be measured by their effects on improving processes of care rather than by patient outcomes.

Barriers to Guideline Success

Existing studies demonstrate limited effectiveness of COPD guidelines in meeting their stated goals—providing information, altering practice, and improving patient outcomes. Although several studies of COPD guidelines speculate on reasons for this limited effectiveness, none has investigated the relative importance of various barriers. Other studies, however, have examined obstacles that have

interfered with the implementation of guidelines for health conditions other than COPD. Identified barriers include factors related to the guideline development process, diffusion and dissemination methods, and implementation strategies.

Guideline Development

Well-constructed guidelines with reasonable and practical recommendations developed with an explicit evidence-based approach are more likely to alter processes of care and physician behavior and improve patient outcomes than are loosely constructed consensus statements.^{35,49–51} Guidelines should be clearly written in unambiguous language with precise terms and definitions. Vague and nonspecific recommendations have a low rate of adherence. Guidelines should also be acceptable to clinicians. Grol et al demonstrated that controversial guideline recommendations are only 50% as likely as noncontroversial recommendations to be followed by physicians.⁵¹ It is ironic that CPGs emerged to address the unsystematic and highly variable delivery of health care, yet professional organizations have developed—and continue to develop—guidelines in an unsystematic manner and with different content and formats. This unsystematic development process has persisted despite the availability of multiple resources for assisting guideline developers in adopting standard methods that produce evidence-based documents.^{18,19,21–24}

Recent reviews demonstrate that guidelines developed for respiratory conditions in general remain largely non-evidence-based, despite rapid growth in the number of guidelines published in pulmonary medicine during the last 20 years. Hackner et al reviewed pulmonary-related guidelines published before 1999 and found that most were based on informal consensus methods or expert opinion.⁵² Fabbri et al reviewed COPD guidelines published by the

British Thoracic Society, American Thoracic Society, and the Thoracic Society of Australia and New Zealand before 1998 and found that most were based on limited evidence and had unsystematic development processes.¹¹

Recently, more systematic critical appraisals of COPD guidelines have been published. Lacasse et al⁵³ performed a systematic appraisal of COPD guidelines before the publication of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guideline.⁵⁴ These investigators identified 15 guidelines that met study inclusion criteria and found that none was based on systematic review of the literature. Only two were peer-reviewed before publication, only one included plans for dissemination and implementation, and only one considered the financial and economic implications of its recommendations. The reviewers found guideline recommendations difficult to understand because of the nonexplicit nature of the written document (reviewers' concordance on recommendations median kappa 0.41). Lacasse et al⁵³ concluded that COPD guidelines were limited by their methodological quality and by discrepancies between the guidelines published by various professional groups.

Iqbal et al systematically appraised COPD guidelines published before GOLD and noted an absence of evidence-based methods and publication formats, and over-reliance on expert consensus.⁵⁵ The explicitness of guideline recommendations differed, as did the definitions of COPD.

Publication of the GOLD guidelines addressed many of the deficiencies of previous COPD guidelines. The GOLD participants came together as a collaboration of the World Health Organization and the United States National Heart, Lung, and Blood Institute to unify international efforts for the management of COPD.^{54,56} They recognized the consensus-nature of previous COPD guidelines and wrote the "Global Strategy for the Diagnosis, Management, and Prevention of COPD" as an evidence-based document, with grading of the supporting literature.⁵⁴

Table 2. Quality Criteria for Evaluating Clinical Practice Guidelines

Applicability: Describes the target condition, patient population, interventions, and clinical providers to allow appropriate application of guideline recommendations
Validity: Describes development methodology, comparisons with existing guidelines, strength of the evidence, and health outcomes
Reproducibility: Lists the literature and other sources of information used and the process for synthesis of the evidence
Clinical flexibility: Discusses the uniqueness of patients and how to apply recommendations in a manner that maintains clinical judgment
Clarity: Simplification of clinical recommendations with the use of flow charts, unambiguous descriptors, and tools to assist retrieval of information
Multidisciplinary: Includes relevant disciplines in the development process and lists participants
Documentation: Documents date of publication and edition or version of the guideline
Schedule review: Specifies the date for review and update
Medico-legal: Discussion of medico-legal implications
Ethical: Statement of conflicts of interest. Transparent presentation of sponsorship and source of funding for the development and distribution of the guideline

(Adapted from Reference 57.)

Table 3. Strategies for Promoting the Implementation of Clinical Practice Guidelines

<ul style="list-style-type: none"> • Systems approach through Total Quality Management projects within local institutions • Obtain guideline support from leadership at national, regional, or local level • Force field analysis with a systematic planning process to generate and analyze forces that facilitate or hinder adoption of a proposed change • Identify and strengthen driving forces for guideline adoption • Identify and remove barriers to change and constraining forces • Small-group education for clinicians and patients • Workshops to assist clinicians in adopting new interventions • Role playing programs to assist learning of complex tasks, such as communication approaches • Academic detailing with clinicians • Physician opinion leaders in national, regional, or local settings • Concurrent feedback of performance relative to guideline recommendations • Contracting with providers to implement guideline recommendations • Incentives for adopting guideline recommendations • Presentation of supporting evidence to promote clinician acceptance of the validity of a guideline • Specialty society sponsorship • Reminder systems and alerts at the point of care • Computerized decision support at the point of care • Patient education for promoting consumerism • On-line availability • Embed guideline recommendations into processes of care • Monitor outcomes and feedback • Embed guidelines into electronic medical record and audit use • Promote guidelines through continuous quality improvement programs • Administrative fiat • Accreditation and regulatory review of processes of care, with public disclosure
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After the publication of the GOLD guideline, Smith et al⁵⁷ performed a systematic critical appraisal of COPD guidelines to determine their adherence to strict quality criteria consolidated from several sources (Table 2).^{21–24} Of the guidelines retrieved with a literature search, seven met study inclusion criteria. Smith et al concluded that COPD guidelines differed markedly in their methodological quality.⁵⁷ Most of the guidelines used informal consensus methods. There was little evidence of a structured literature search, appraisal, rating, and presentation. None of the guidelines presented pilot data on their impact on clinical practice. The GOLD guideline was developed with the most valid, evidence-based methods and conformed to standards for grading evidence. However, none of the guidelines incorporated patient priorities and values, which is an important element of guideline development.^{57–61} None of the guidelines used techniques to weight evidence that used outcomes of interest to patients, such as quality of life

or functional status, as opposed to outcomes of more interest to physicians, such as FEV₁ or disease progression.^{56,62}

A primary limitation of all COPD guidelines relates to the limited nature of primary evidence that various treatment modalities improve patient outcome. Multiple studies clearly demonstrate that interventions prevent morbidity and improve survival for patients with cardiovascular disease. For instance, aspirin, β blockers, and statins improve survival after myocardial infarction; angiotensin-converting enzyme inhibitors benefit patients with congestive heart failure; and warfarin decreases the incidence of stroke among patients suffering atrial fibrillation.^{63,64} Less data support the benefits of interventions to improve outcome in COPD patients.

Diffusion and Dissemination

Guideline diffusion refers to a passive process by which guidelines are made available to clinicians, usually by publication in professional journals, and it is up to the clinicians to seek out the guidelines. Guideline dissemination refers to an active process by which the guideline developers or other interested parties distribute guidelines to the target audience, often in multiple media and formats.⁶⁵ Dissemination methods that use multiple formats, media, and forums in a repeated and ongoing manner have the highest probability of making physicians aware of the guidelines and their recommendations. Regardless of the sophistication of dissemination efforts, however, guideline effectiveness is limited without a comprehensive and well-organized implementation strategy. No data exist regarding the relative effectiveness of the various dissemination methods for COPD guidelines.

Implementation

Guideline implementation refers to a persistent process of communicating guideline recommendations by multiple and overlapping avenues and media that clinicians find hard to ignore as they perform their daily clinical tasks.⁶⁵ In the absence of an effective and well-coordinated implementation effort, CPGs have minimal impact on clinician behavior.^{66,67} Most guideline developers have neglected to design implementation strategies as they developed their guidelines. Of existing COPD guidelines, only the GOLD guideline developers organized an implementation group as they began their guideline development efforts. Multiple resources and strategies exist to provide guideline developers with models for implementation strategies (Table 3).^{36,67–69} Some organizations that adapt published guidelines to their local use devise an implementation and monitoring plan as they revise the guideline to alter patient care in their practice setting (Table 4).

Table 4. Four Steps in the Southern California Permanente Medical Group's Approach to Guideline Development and Implementation

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- Develop the clinical practice guideline
 - Develop an implementation plan
 - Develop a monitoring plan
 - Select physician leaders or champions from each medical center to educate their colleagues and enhance the potential for acceptance of guidelines. Physician involvement is an essential part of the process at each step.
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Implementation strategies can be passive or active. Passive strategies present information near or at the point of care when patient care needs would make providers most receptive to access guideline recommendations. As opposed to guideline dissemination, passive implementation efforts attempt to link the time and place of need for guideline information with the time that the information is presented. Increasingly, computer prompts and reminders are being used as passive implementation strategies.

Active implementation strategies are coercive or facilitative¹⁵ and guide caregivers in their practice settings to decisions or actions that adhere to guideline recommendations. These strategies include audit-feedback-benchmarking,⁷⁰ use of opinion leaders,⁷¹ continuous quality improvement teams, academic detailing,⁷² computer-based decision-support or decision-constraining tools,⁷³⁻⁷⁷ administrative fiat, and financial rewards (see Table 3). Different implementation strategies may be more or less effective, depending on the guideline topic, practice setting, realities of the external environment, and other yet to be defined factors. Development of an effective implementation strategy requires consideration of these factors in the context of a local practice site.

Existing COPD guidelines have depended largely on diffusion and dissemination of their recommendations. Only the GOLD guidelines designed an implementation strategy concurrently with developing the guidelines. No data exist regarding the relative effectiveness of various implementation strategies employed in various practice settings to promote the adoption of COPD guideline recommendations.

Regardless of the implementation strategy used, guidelines fail if they meet a nonreceptive clinician audience. A decade ago Tunis et al found that general internists had a negative attitude toward CPGs.⁷⁸ These clinicians preferred an "expert-based model" of health care and did not believe that guidelines would enhance their clinical practice. A more recent study in the United Kingdom found a favorable attitude toward guidelines: approximately 99% of physicians surveyed stated that

CPGs represented value to their practice and benefits to patient care.⁷⁹

Because physician attitudes toward guidelines differ regionally and by the nature of the specific guideline being implemented, some guideline developers recommend physician focus groups to evaluate the relative value of various implementation strategies.^{78,80,81} These efforts attempt to determine the characteristics of both the guideline and the target audience that affect the likelihood of successful guideline implementation.⁸² These studies also study the physician, patient, and expert values implicit in CPGs, to seek a common ground that can assist the implementation of effective guidelines.⁸³ There are no data from physician focus groups about physician attitudes toward the published COPD guidelines or the features of COPD guidelines that might promote or hinder their adoption.

Few data exist regarding attitudes toward existing COPD guidelines among physicians who care for patients with respiratory disease. In the Netherlands, Jans et al began a guideline implementation project that first assessed barriers to acceptance of COPD and asthma guideline recommendations among general practitioners.⁴⁴ They then designed an implementation strategy to overcome these barriers and promote guideline adherence in a randomized, controlled trial. One year after the project started, they found greater adherence to guideline recommendations and improved patient outcomes, as measured by lung function and symptom scores.

Despite focused efforts to identify and overcome physician-related barriers to guideline acceptance, physicians frequently prove resistant to adopting guideline recommendations that require large changes in their practice patterns. Recent research in altering complex systems of care based on best clinical practices has focused on overcoming physician barriers by introducing systems approaches. Ely et al, for instance, developed protocols, algorithms, and clinical pathways for weaning patients from mechanical ventilation.^{84,85} Nonphysician caregivers implemented the protocol-directed care recommendations. The researchers found better outcomes with the protocol-directed care than with weaning directed by traditional, physician-initiated, nonprotocol care. No data exist regarding the effects of protocols and pathways on implementation of COPD guideline recommendations.

Implementation strategies directed by nonphysician clinicians offer opportunities to provide patient care that adheres more closely with guideline recommendations. COPD guidelines and clinical practice guidelines in general, however, largely ignore the nonphysician audience.⁸⁶ The GOLD guideline developers have commented on that deficiency in their guidelines.⁵⁶ Table 5 summarizes barriers to guideline implementation.

Table 5. Factors That Limit the Adoption of Clinical Practice Guidelines

• Impractical recommendations for a specific patient care environment
• Recommendations appear potentially obsolete because guideline does not state plan for updating
• Absence of guideline implementation plan
• Absence of statement regarding cost implications
• Absence of legal discussion
• Recommendations are complex, lengthy, and difficult to read
• Developer group not credible without multidisciplinary members who have appropriate expertise
• Invalid methods of literature retrieval and analysis
• Poor clarity of guideline recommendations
• No appropriate measures for success
• Evidence that assessed only a narrow range of health care outcomes
• No involvement of target patient population
• Provider lack of awareness of guideline existence
• Lack of involvement of practitioners with guideline development process
• Lack of confidence in level of evidence supporting guideline recommendations
• Clinician awareness of more recent data
• Different opinions regarding treatability of the underlying condition
• Recommendations require a drastic change in existing practices
• Clinician habituation to existing practice patterns
• Environmental disincentives to change

Summary and Future Directions for COPD Guidelines

COPD clinical practice guidelines have matured during the last 2 decades, with the physician audience now expecting that guideline developers will use rigorous, evidence-based methods that grade the medical literature. The GOLD guidelines represent an important advance, having used a systematic approach to retrieving, grading, and synthesizing the primary evidence. The British Thoracic Society and the Thoracic Society of Australia and New Zealand are adopting evidence-based methods for their next COPD guidelines.⁵⁷

Additional efforts are needed to further advance COPD guideline development methods. Guideline developers need to incorporate the patient's perspective, cost-effectiveness analyses, and more patient-centered functional outcomes in making treatment recommendations. The inclusion of functional outcomes will require more primary studies that assess the impact of treatment on outcomes such as quality of life, rather than spirometry values.⁵⁶ Physician readers would benefit from greater collaboration with guideline developers. It remains a paradox that the treatment variability that CPGs were originally designed to address has been approached with multiple, independently developed COPD guidelines that

have considerable differences in their treatment recommendations. The GOLD participants have developed a database of evidence, with consultation by a multidisciplinary panel of experts, and that will be shared with other guideline developers.

Also, COPD guidelines in some practice settings have progressed from passively diffused documents published in professional journals to more active implementation. Despite these efforts, physician and organizational practice patterns continue to resist change and are reluctant to rapidly adopt guideline recommendations, because of multiple barriers that are only beginning to be understood.^{18,82,87}

It is clear, however, that well-constructed CPGs have gained recognition by the medical profession and society at large as summarizing the best clinical evidence for patient care. In the future, governmental, regulatory, and accreditation bodies will become increasingly involved with ensuring that valid guideline recommendations find their way into clinical practice. We are already experiencing this engagement of external groups in guideline implementation. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has focused an enlarging commitment to the improvement of safety and quality of patient care. Current JCAHO standards recommend but do not require the use of CPGs in hospital settings.⁸⁸ In July 2002, however, core measures of patient care processes and outcomes derived from published guidelines were, for the first time, evaluated during JCAHO hospital inspections.

We are also experiencing more collaboration between JCAHO, the Center for Medicare/Medicaid Services, and the Agency for Healthcare Research and Quality, and they are assessing the quality of patient care processes that derive from published guidelines.⁸ We anticipate that COPD guideline recommendations will soon be incorporated into quality measures for hospitals and ambulatory practice settings and that those measures will be reported directly to the public. As such, regulatory agencies will represent another implementation strategy among the multiple interventions required to overcome physician barriers to change and will ensure that COPD patients receive care consonant with best clinical practices.

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Discussion

Gay: In my role as a physician advocate for quality respiratory care, I've had an opportunity to deal with guidelines from the Center for Medicaid/Medicare Services. It's quite clear to me that the efforts to use guidelines are not only for the advantage of boilerplate recognition or getting the big picture for them to organize policy; they're also for punitive use when there are violations for standard-of-care or coverage criteria for treatment plans. You pointed that out very nicely, but unfortunately, the physician is not the victim of the problem: the physician is the *problem*, and the patient is the *victim*. How do you deal with that in the interim, and, also, knowing our rather abysmal rate of compliance with guidelines, how can we improve?

Heffner: Yes, that is a challenge, and I think part of the solution is through better consumerism. The content of valid guidelines needs to be made available to patients in an accessible form so as to raise their expectations of the therapy they should receive. HMOs [health-maintenance organizations] have tried to do this in the past, with variable success. Regulatory and governmental bodies are now doing the same by reporting, in local newspapers, hospital adherence to best clinical practices. The patient safety movement is based on partnering with patients for shared decision-making through providing information on best clinical practices.

Hansen-Flaschen: At another meeting recently, I challenged you a little bit on the North American/Western European elitism of several of the guidelines we're most familiar with. We make guidelines focus on best practice. We put a great deal of energy into our guidelines and the science that backs them up to find the one therapeutic alternative with the 6 or 7% best advantage over all the others.

We've put much less energy into alternative approaches that might be much less expensive. People outside of a few developed countries don't have access to the things we recommend in our guidelines, and even in the United States there is a huge number of individuals who are shut out of the top-rated recommendations in our guidelines.

I wonder if you have thoughts about modifying the structure of guidelines? Can we write one integrated guideline that would at the same time address those with unlimited health care access and those with more limited access?

Heffner: John Hansen-Flaschen speaks with experience in that area, in that he provides leadership to the American Thoracic Society in their effort to develop a strategic plan for promoting international health. In regard to guideline implementation, an international strategy is both important and challenging. Guideline developers face a charge to look at the evidence and make evidence-based recommendations, but those recommendations may be more or less relevant and feasible in various health care settings. How do we implement North American or European guidelines in a small African country that has problems with COPD? Clearly that is not the solution.

I believe that large professional groups who develop guidelines should partner with local physician groups in specific practice regions who can adapt the guidelines for local use. The more partnerships we have with the international groups, the more likely it is that we will get that done. All guidelines are local, which means that strategies are required to implement national guidelines in the local setting, whether that setting is in Peoria or Uganda.

Stoller: You alluded to the basic premise that guidelines should ideally eliminate geographic variation, and

I'd liken guidelines, perhaps, to protocols, though there are some differences. You also alluded to the dissemination of COPD guidelines, some fourteen of them, I think you showed.

One thing that concerns me is the dissemination of guidelines; there is now the opportunity for discordance among guidelines from leading groups, creating the need for a "meta-guideline", if you will—an overarching look at discordance between guidelines so as to eliminate their geographic variation. I wonder what your thoughts are about a broad, systems approach that will eliminate the possibility for *sanctioned* geographic variations from that discordance.

Heffner: Clearly, unexplained and unwarranted practice variation should be eliminated, but not all practice variation is bad. Readers of guidelines should recognize that each patient is unique, and guidelines should be implemented in a flexible and individualized manner. GOLD attempted to narrow the range of acceptable clinical decisions rather than to eliminate various options entirely. I believe their approaches for doing so are valid. Newer guidelines such as GOLD focus on generating the body of knowledge in terms of the evidence review. This evidence review is then made available to diverse guideline developers, who, hopefully, then read from the "same page" in developing their guidelines. Local developers lay their unique values and practice styles over the evidence so as to adapt the evidence to their local practice. This promotes *explained* practice variation and avoids mindless standardization of care.

Hill: I think one of the barriers to some guidelines among primary care physicians and our colleagues practicing out in the field is the perception that guidelines represent arrogant statements by self-appointed experts, and so there's an attitude of "what the hell do they know?" To a certain extent I think there

may be some validity in that, because we put these guidelines together and we think they represent the best science and that we have a finished product.

However, and I think you alluded to this, we need to be humble, because guideline development should be seen as a dynamic process. We should compose a guideline as a "first draft" and then re-evaluate it periodically. We should not just look at physician adherence to our guidelines as the outcome, but rather ask, are we favorably impacting something meaningful to patients? It seems that very few guidelines really have subjected themselves to that kind of rigorous post-development evaluation. Even with the GOLD guidelines I don't think there's been much in the way of evaluation. Don't you think that kind of evaluation process should be undertaken? What kind of steps are we taking in that direction?

Heffner: Those are very good points. One of the reasons I like systematic development of guidelines and the move away from expert-based reviews is that a good guideline is *transparent*. The final document should be explicit and transparent as to how the evidence was incorporated into clinical recommendations. Readers can then see which recommendations are strong, being based on level 1 data, and which are less robust, being based on expert consensus. Greater degrees of practice variation are allowable for the recommendations that are based on weaker evidence. Readers can decide how much faith to put in the various recommendations on the basis of the nature of the supporting evidence.

Second, guideline developers are beginning to examine implementation strategies as they develop the primary guidelines. During this early

process, they should consider what outcomes studies would be required to determine the guideline's effectiveness. They should at least, through the grading of the evidence, stimulate investigators to perform the needed studies after publication of the guideline.

For instance, a grade C recommendation should stimulate investigations of the validity of that recommendation. We experienced this process with the American Thoracic Society's community-acquired pneumonia guidelines. The recommendations based on weaker supporting data generated new research that has advanced our understanding and improved subsequent pneumonia guidelines. Well-constructed guidelines stimulate research by transparently defining the limits of the evidence base.