



World Ophthalmology Leaders Forum in Education (WOLFE)

Guidelines for Developing Guidelines
Consensus versus Clinical Trials:
Where Is the Future?

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American Academy of Ophthalmology
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World Ophthalmology Leaders Forum in Education

The World Ophthalmology Leaders Forum in Education (WOLFE) was established by the American Academy of Ophthalmology in 2005 to bring together ophthalmic society leaders from around the world to discuss issues in education that are shared around the world.

During the Academy's Annual Meeting these leaders come together to hear a panel discussion of experts from around the world share experiences, solutions and insights. The panel discussion is followed by general discussion with attendees.

Guidelines for Developing Guidelines: Consensus versus Clinical Trials: Where is the Future?, was chosen as this year's topic with the hope that societies could reach a common understanding of guidelines and how they are developed so that there is greater consistency across guidelines and to ensure that ophthalmologists are receiving the best possible information.

We invite you to share this document with leaders in your country or region. This summary is on the Academy's Web site at www.aao.org/international/wolf.cfm.

The Academy is currently working on a *Compendium of Evidence-Based Eye Care*, a collection of clinical practice guidelines based on clinical evidence and expert consensus to assist the clinician in decision-making about treating specific diseases. The successful implementation of such clinical guidelines should improve quality of care by decreasing inappropriate variation and by expediting the application of effective advances into everyday practice. To learn more about the *Compendium*, please visit one.aao.org/CE/PracticeGuidelines/Compendium.aspx.

2007 World Ophthalmology Leaders Forum in Education Panel

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EXECUTIVE SUMMARY

Clinical practice guidelines are being developed around the world by many medical societies, subspecialty groups and even individual countries. The need for these documents is clear: The volume of studies published each year makes it impossible for the busy clinician to keep up with the medical literature. Moreover, physicians often lack the research-analysis training necessary to determine the best course of care from a series of studies with conflicting findings.

Guidelines assimilate and interpret this vast amount of information and translate it into practical recommendations that can improve the quality of medical care. They also help reduce unnecessary and often expensive practice variations.

High-quality systematic reviews are the foundation of clinical practice guidelines. Although well-conducted randomized controlled clinical trials are the gold standard, most medical practice occurs in areas not covered by clinical trials or meta-analyses. In the absence of evidence-based research, expert opinion/consensus can be a reliable and reproducible means of developing practice recommendations.

Guideline implementation requires education to increase physicians' awareness and acceptance of the recommendations. Practice guidelines are more likely to be accepted and used if they are up-to-date; based on high-quality standardized methods that minimize bias; produced by a trusted source with minimal conflicts of interest; and are timely, digestible and readily accessible when a question arises. Guidelines are living documents that must be adapted, or even re-invented, as the knowledge base expands and evolves.

Guidelines for Developing Guidelines

Consensus versus Clinical Trials: Where Is the Future?

H. Dunbar Hoskins Jr., MD, Executive Vice President of the American Academy of Ophthalmology, welcomed participants in the World Ophthalmology Leaders Forum in Education (WOLFE) symposium and began the meeting with some background on how the topic was chosen.

“When we tried to come up with a title for this symposium, we realized that guidelines are being developed everywhere,” Dr. Hoskins said. “Each area of the world is developing guidelines, some countries are developing guidelines, some supranational groups are developing guidelines, subspecialty societies are developing guidelines. We thought it might be useful, with the help of the panel that has been chosen, to begin to examine: **What are the guidelines for developing guidelines?**

“Is it just two people in a room who agree on something? Does it take more than that? Do we need evidence? What is the level of evidence? All of these types of questions....”

Dr. Hoskins then introduced Ronald E. Smith, MD, the American Academy of Ophthalmology’s Secretary, Global Alliances and the symposium’s moderator.

“We thought this would be a good topic for this group to discuss,” Dr. Smith said. “This is the third year for WOLFE—World Ophthalmology Leaders Forum in Education—and this topic is a timely one because many groups are preparing guidelines. We have a good program and will have time for questions and a panel discussion at the end.”

Overview of Clinical Practice Guidelines

Alfred Sommer, MD, MHS, opened the afternoon’s presentations with an overview of the need for clinical practice guidelines as well as the challenges they pose. **The goals of practice guidelines are to reduce unnecessary variation among physicians,**

increase the quality of individual patient care and raise overall standards of care.

Dr. Sommer illustrated the degree of variation that can exist even within a geographically limited area like Rhode Island. For example, in 1981, the rate at which Rhode Island surgeons performed some procedures, such as radical mastectomy, varied by 30-fold or more. He also noted the far-reaching consequences of adopting new technology without evidence of benefit. With fetal monitoring, for instance, Caesarean births rose from about 5 percent in 1970 to nearly 25 percent in 1985. Today, the Caesarian rate is about 21 percent, despite 11 randomized controlled clinical trials now showing that fetal outcomes are no better with monitoring than with intermittent auscultation.

Dr. Sommer **defined a clinical guideline as the “thoughtful interpretation of the best available evidence translated into practical clinical guidance.”** **Interpretation is a key component** because study findings vary by entry criteria, and safety, efficacy and cost-benefit are dependent upon the clinical status of patients.

“Evidence” and, in turn, conclusions and guidance vary with time and circumstances—and the truth of a clinical guideline is short-lived. Dr. Sommer noted that only about 50 percent of conclusions from systematic reviews are still valid five to six years later. As a result, clinical practice guidelines must be living documents.

A Practical Approach to Clinical Guideline Development and Implementation

Richard L. Abbott, MD, presented a practical approach to clinical practice guideline development and implementation, with real-world examples from a U.S. – China collaboration.

The challenges of clinical guideline development include making the evidence readily available to physicians and encouraging them to accept and

comply with the guidelines in conjunction with their own experience. He noted that patients currently receive evidence-based care only half the time and that it takes about 12 years for the results of randomized clinical trials to be incorporated into practice.

Guideline development involves choosing a group of respected and experienced colleagues, headed by a knowledgeable and respected expert. The group identifies the most relevant diseases to be included, makes a template for organizing the guidelines, evaluates the literature using the principles of systematic review, extracts evidence-based process-of-care recommendations; and establishes a method for using consensus opinion in the absence of evidence.

Guideline implementation requires education to increase physician awareness and encourage guideline acceptance. **Physicians' willingness to adopt practice guidelines depends on variables such as the ease of incorporation; degree of change required; the cost and time commitment; consideration of patient desires, demands, and acceptance; staff and administrative support; and willingness to change practice.**

Dr. Abbott said encouraging compliance with the guidelines is a significant challenge because most physicians believe they already provide excellent care. **Successful implementation of clinical guidelines requires solid evidence when available (or, if not, the consensus of a diverse team of respected experts); peer review and comment from the constituency before dissemination; and guidelines that are defined in terms of their potential to improve clinical outcomes.**

Consensus vs. Evidence: What is Most Helpful to the Practitioner? A Debate

Kay Dickersin, PhD, and Anne L. Coleman, MD, PhD, discussed the value of guidelines derived from research evidence versus those that rely on consensus or expert opinion.

Dr. Dickersin, who presented the case for evidence-based guidelines, examined the factors that promote physician acceptance and use of clinical recommendations. The **guidelines must be transparent**, she said, **and based on up-to-date systematic reviews that rely on high-quality, standardized methods that minimize bias**. Guideline users must be informed if good-quality evidence was not identified or available.

Guideline users must also be able to trust the source. This means **minimizing real or perceived conflicts of interest**—not just conflicts related to gifts and funding but also to potential intellectual or other conflicts in which guideline panel members stand to gain from the recommendations. To minimize conflicts of interest, clinicians from multiple specialties should be involved in the creation of guidelines, as well as generalists, nurses, methodologists and other health professionals. The guidelines also must be timely, digestible and accessible—ideally, obtainable with one click when a clinical question arises.

Dr. Dickersin pointed out that evidence-based guidelines are necessary because the average doctor cannot be expected to go to the literature, summarize it systematically and determine the best course of clinical care. In addition to having considerable time constraints, physicians often turn to unreliable online sources for information, including Medline/PubMed and Google. Dr. Dickersin also noted that doctors are rarely in a position to interpret the literature themselves, as research suggests they have knowledge gaps in statistics and interpretation of research findings.

Dr. Dickersin cautioned the audience not to assume that evidence-based medicine is focused solely on randomized trials. Different types of research questions require different forms of "best evidence." **Randomized trials are best for questions about intervention effectiveness** (therapy, prevention, screening), but **observational studies are probably best for questions of etiology and are necessary for determining harm**.

Dr. Dickersin told the group about the Evidence Gap Project being carried out by the Cochrane Eyes and Vision Group (CEVG). This project is examining practice guidelines to determine the clinical problems that are important to clinicians and will then develop answerable clinical questions from the guidelines and identify existing evidence for each question. CEVG will take this information to the clinical community and ask clinicians to determine priorities for systematic reviews and new research.

Dr. Coleman presented the counterpoint view. She noted that **in a perfect world, every clinician would practice only evidence-based medicine, but most real-world medicine is practiced in areas not covered by clinical trials or meta-analyses**. Expert opinion/consensus is needed because evidence or randomized clinical trials will never be available for every clinical situation. Randomized clinical trials, she said, apply to only 15 percent of patients.

Dr. Coleman maintained that **expert opinion/consensus can be as reliable and reproducible as commonly used diagnostic methods**. The RAND/UCLA Appropriateness Method is a consensus process that uses a modified Delphi approach. In this method, a wide range of experts conducts systematic reviews of the literature, creates patient scenarios to ensure relevance to real patients, reviews a round of entries before the panel meets and during the meeting and arrives at a consensus by averaging the panel members' responses. Using this method, **RAND/UCLA panels have produced consensus recommendations that were confirmed years later through randomized clinical trials, including recommendations concerning carotid endarterectomy and the appropriateness of cataract surgery**.

Use of Guidelines in the Philippines: The Benefits and Challenges

Romulo N. Aguilar, MD, PhD, shared the Philippine experience with clinical practice guidelines. **Practice guidelines in the Philippines are promoted as a means of**

reducing health care utilization and costs, improving health care quality, providing a means of assessing accountability and encouraging effectiveness and consistency in medical practice.

The Philippine Health Insurance Corporation identifies areas deemed problematic, such as conditions associated with high costs, and asks national specialty societies to develop guidelines.

The challenges of guideline development include physicians' ignorance of—or resistance to—the proper process; expense and access to needed resources; and health equity issues. Dr. Aguilar noted that publishing practice guidelines and even high physician awareness of their existence are not enough to influence medical practice. Broader dissemination is necessary but difficult because guideline development depletes most of the funding.

Adoption and utilization of clinical practice guidelines are major hurdles. Barriers to guideline adoption include lack of physician “opinion leaders” in primary care, physician focus on symptom control and inability to overcome the inertia of current practice.

In addition, survey results indicate that 66 percent of Philippine physicians believe guideline recommendations may be outdated or wrong; 64 percent view them as stereotyping patient care; 52 percent believe guidelines can hurt clinicians through unfair judgments or comparisons; 37 percent believe they are not updated regularly; and 25 percent think guidelines might be used against them in malpractice litigation.

The primary challenge in the Philippines, Dr. Aguilar said, is to refocus guideline activities from development to adaptation and from publication to more active methods of dissemination and implementation.

Is There a Role for Guidelines as an Educational Tool?

Enrique L. Graue, MD, addressed the importance of clinical guidelines, including their use as an educational tool for practitioners and residents. He noted that clinical guidelines are necessary because keeping up with the volume of medical literature is impossible. **Guidelines attempt to improve the quality and efficiency of health care and foster a greater awareness of the patient in medical decisions.**

However, the value of clinical evidence is often “lost in translation.” Dr. Graue cited several examples of slow translation of widely publicized and potentially life-saving findings. For example, the benefits of beta-blockers after a heart attack were confirmed in a 1981 report in the *Journal of the American Medical Association*, but 15 years later, only 62 percent of eligible patients were receiving beta-blocker treatment. Similarly slow translation occurred with findings on the benefits of rapid reperfusion during a heart attack and with evidence of the cardioprotective effects of aspirin.

Dr. Graue noted that the essence of clinical guidelines is to enable research to be translated into clinical practice as quickly as possible. Professional organizations play an important role in ensuring that timely translation takes place.

Some physicians are more likely to be “early adopters” of clinical practice guidelines, Dr. Graue said. The vast majority, however, like to “play it safe.”

Identifying the early adopters—who typically are leaders, program directors and respected practicing physicians—and making their activity observable through venues like congresses and courses promotes earlier acceptance of guideline recommendations.

Dr. Graue added that guidelines must be both adopted and adapted, noting that “reinvention is an act of creativity and courage.”

Can We Develop Guidelines that Would Be Applicable Around the World?

Christopher Kai Shun Leung, MBChB, MD, addressed the challenges of creating guidelines that can be applied internationally. Even when the best clinical guidelines are available, he said, translating the guidelines into best clinical practices is not a simple task. **Those who develop practice guidelines must identify barriers to implementation and devise appropriate strategies to overcome these obstacles.**

The advent of electronic information sources has made the delivery of guidelines more timely and efficient. **The AAO, Royal College of Ophthalmologists (RCOphth) and International Council of Ophthalmology (ICO) all offer clinical guidelines online.** Dr. Leung noted that ICO's international guidelines encourage ophthalmologists to examine new evidence from different parts of the world, and they support and educate clinicians worldwide. The ICO Web site offers 20 international guidelines that can be downloaded in PDF form.

Guideline implementation involves making a common body of knowledge available and then enabling or reinforcing changes in clinical practice. **Enabling and reinforcing changes is a cyclic, active process that involves continuous innovation with new ideas and interventions and recognition of new obstacles,** Dr. Leung said. Some of the barriers to guideline implementation include patient preferences and expectations; clinicians' skill, knowledge, attitudes, and sense of competence; organizational constraints; and social norms and standards of practice.

Organizations can maximize their resources by identifying what resources are available; defining the role of economic evaluation in clinical guidelines; examining the costs and benefits of various strategies; and setting priorities based on the local disease burden, availability of effective and efficient medical interventions and local evidence of current suboptimal performance.

PANEL DISCUSSION

How to Create, Use and Measure the Impact of Clinical Guidelines

In a panel discussion following the presentations, speakers and audience members shared their experiences with practice guidelines. Some of the topics discussed included:

Awareness and adherence: Dr. Abbott said that he, Paul Lee, MD, JD, and others have examined the use of AAO's Preferred Practice Patterns (PPPs), which have been in existence for 20 years. After more than 10 years of effort, 90 percent of physicians are aware of the guidelines. Physicians who incorporate guidelines into their practice tend to use parts of the guidelines while ignoring others.

A carrot-and-stick approach, Dr. Abbott added, has increased guideline adherence in other countries and is likely to be the most successful way to improve compliance in the U.S. The government's pay-for-performance program, which uses practice recommendations based on the PPPs, takes a carrot-and-stick approach by paying physicians more if they follow the guidelines.

Chart review, as now occurs in the HMO environment, may extend into regular practice as electronic medical records become readily available, Dr. Abbott said. This will likely focus more attention on adherence.

Sometimes physicians are simply unaware of a problem, such as low childhood immunization rates in their geographic area or how seldom they and other ophthalmologists examine the optic disc. Compliance rates often soar when clinicians are made aware of the shortcoming or when they realize how their practice differs from that of other physicians. Dr. Mills noted that the chart review implemented by the American Board of Ophthalmology as part of their recertification process may increase this type of awareness as physicians receive feedback.

Allocation of resources: Dr. Hoskins raised the issue of allocation of resources in guideline development. Dr. Sommer said that in developing the PPPs, they chose the

conditions that are most often encountered by ophthalmologists as well as those that have the greatest impact on patients in terms of visual outcome.

Keeping guidelines up-to-date: Because AAO's PPPs are mostly electronic, they can be altered quickly if an important research finding requires that a guideline be updated. The change is then announced on the AAO Web site.

Adapting guidelines for international use: Dr. Leung said that they do not have their own general guidelines in Hong Kong. Instead they rely on guidelines from organizations like AAO, ICO and the RCOphth. However, because the spectrum of glaucoma in the Chinese population differs from that in Caucasian populations, they have developed specific guidelines that address these different manifestations of glaucoma. AAO's new Ophthalmic News & Education (O.N.E.) Network has a compendium of guidelines available for review by physicians around the world and that can be adapted to the specific needs of ophthalmologists in other countries.

Resources: The Cochrane group is a good resource for people who are developing clinical practice guidelines. Dr. Coleman said they have methodologists who will help formulate a hypothesis and people who will assist with the scientific literature review and in rating and grading the evidence. The group also provides support for writing the manuscripts.

Mark Your Calendars!

Joint Meeting of the American Academy of Ophthalmology (AAO) and the European Society of Ophthalmology (SOE)

November 8 – 11, 2008
Atlanta, Georgia

World Ophthalmology Leaders Forum in Education (WOLFE)

Monday, November 10, 2008
3 to 5:30 p.m.
Atlanta, Georgia

