SPECIAL COMMUNICATION

Clinical Practice Guideline Panels: Personal Experience

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Few family physicians can have escaped clinical practice guidelines. Physician groups, hospitals, practice organizations, insurers, and even actuaries are developing and implementing clinical practice guidelines in hopes that clinical care will become more predictable and achieve higher quality and that costs will be restrained. That these outcomes are unproved has not dissuaded the enthusiasts, because there are no available alternatives: the current environment of wide practice variation, little information on outcomes, and disregard for the costs of care is not sustainable, and no other single strategy so squarely addresses these problems.

The clinical practice guideline movement poses extraordinary opportunities and extraordinary risks for all physicians, but especially for family physicians. Further, it forces us to confront some unpleasant realities about medicine's scientific base. In this essay I narrate my own experience with four national clinical practice guideline panels, drawing on that experience to pose issues that we must solve if we are to avoid becoming overwhelmed by the worst of what this movement has to offer us.

In the last 5 years I have been chair or member on four national expert panels developing clinical practice guidelines: member, Guidelines for Adolescent Preventive Services (Centers for Disease Control and Prevention [CDC] and American Medical Association [AMA]); chair and moderator, 1993 Sexually Transmitted Disease Treatment Guidelines (CDC); cochair, Otitis Media with Effusion in Young Children (Agency for Health Care Policy and Research [AHCPR]); and member, United States Preventive Services Task Force (USPSTF). These experiences have given me an unusual perspective on what works and what does not, with particular relevance to family practice.

Guidelines for Adolescent Preventive Services

The Panel

The Guidelines for Adolescent Preventive Services (GAPS) panel was convened to address the perceived gaps in recommendations for preventive health services for adolescents. Although not explicit in the official reports, part of the impetus for the GAPS project emerged after publication of the first USPSTF report in 1989,[1] which did not include many of the issues thought to be important by specialists in adolescent medicine. The CDC supported a 3-year project to develop appropriate guidelines, with the AMA Department of Adolescent Health serving as the contractor. Background materials were prepared by staff. A scientific advisory panel of 19 members met to review materials and make recommendations. The final report was published and widely disseminated in late 1993 and early 1994.[2] The report comprises 24 recommendations directed at 14 health topics. If fully implemented, the recommendations would be a major departure from current practice by increasing the frequency and intensity of routine health visits: annual visits between the ages of 11 and 21 years to include counseling and examinations for general health, injury, diet, exercise, sexually transmitted diseases (STDs), substance abuse, hypertension, eating disorders, physical and sexual abuse, learning problems, and immunizations. The recommendations were critically reviewed by Stevens and Lyle in 1994.[3]

The Experience

I was the only family physician on the panel, officially representing the American Academy of Family Physicians, and also one of a small minority who were experienced in producing evidence-

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based recommendations. Most panelists, inexperienced in and unfamiliar with evidence-based methods to develop clinical practice guidelines, were much more accustomed to (and preferred) the standard method of global subjective judgment. Many of the specialists in adolescent medicine viewed the process as primarily applying to nonspecialists; that is, the specialists were not the ones who needed help. Staff were familiar with evidence-based methods in theory but inexperienced in practice. Although the background literature reviews were thorough, there was a consistent disjunction between the evidence and the recommendations. The quality of scientific information upon which many common practices (and panel recommendations) were based was inadequate. There were many examples where the evidence was equivocal or nonexistent, with nonetheless strong recommendations made based on the strongly held opinions of panel members. The reports are replete with statements unsupported by evidence, such as "health professionals generally agree," "justification comes from the widely-held belief," and so on. The few panelists who would have preferred sticking to the evidence were politely tolerated but ultimately were overruled, outvoted, and ineffective.

1993 Sexually Transmitted Diseases Treatment Guidelines

The Panel

Among the publications most requested from the CDC is the regularly updated STD treatment guidelines. The usual process has been to have staff prepare background papers and convene a panel of experts (mostly researchers in STDs) for a 2- or 3-day meeting to craft recommendations. The CDC wanted to attempt a more evidence-based process for the 1993 revision. Staff prepared background papers and evidence tables, and the conduct of the panel sessions was modified to be more explicit and accountable. Panelists who participated in the 3-day session were, as before, almost exclusively specialists in STD research and practice. Final drafts were prepared by staff, with many stages of expert review before publication in late 1993.[4] Since publication the treatment recommendations have retained their authoritative position in the field with a worldwide audience; the CDC receives as many as 3000 requests each month for reprints.

The Experience

Although I had participated in a few research studies in STDs in the past, I was by no means an expert. Thus my serving as chair and moderator (a family physician) received a mixed reaction from staff and panelists. Although some were probably never convinced, most were eventually persuaded that the evidence-based approach was better than the old method, that I knew what I was doing, and that I was not out to derail what had been during the years one of the most consistently successful products of the CDC.

Nonetheless, the process was challenging. Insisting that disagreements be resolved by data disrupted usual patterns of resolving them by seniority or position. Insisting on statements based on evidence led to discomfort in writing recommendations for areas where evidence does not exist (for example, almost anything to do with syphilis). Raising the possibility of financial conflict of interest discomfited some around the table whose research depended on substantial support from the diagnostics and pharmaceutical industries whose products were being considered for inclusion in guideline recommendations. Questioning the scope of the document (eg, why is yeast vaginitis included?) irritated those who saw the recommendations as a handbook for primary care practiced in STD clinics, rather than what the title would otherwise imply.

Once again I was shocked to discover the poor quality of scientific information that supports common practice. For example, the efficacy and effectiveness of physician counseling in typical primary care practices about sexual behavior are almost unknown, yet a strong recommendation for practitioners to provide counseling is one of the cornerstones of US Public Health Service policy on STD prevention.

Otitis Media with Effusion in Young Children

The Panel

The AHCPR panel on Otitis Media with Effusion in Young Children was a unique collaboration among three professional organizations: the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics, and the American Academy of Otolaryngology—Head and Neck Surgery. A 19-member panel of representatives nominated by the organizations and others and approved by the AHCPR worked more

than 3 years to produce the clinical practice guideline, the 12th in the series from the AHCPR.[5] I was nominated by the AAFP and served as co-chair. The panel met four times during 14 months.

The process was explicit and evidence based, closely modeled on the methods of David Eddy.[6] Dr. Hanan Bell, clinical policies analyst from the AAFP and well versed in evidence-based methods, served as the panel's methodologist. Because most members of the panel were unfamiliar with evidence-based methods, Dr. Bell conducted a 2-day introduction to the methodology before the process formally began. The process included focusing the question, determining the target population, performing an exhaustive literature review (more than 3500 citations), constructing evidence tables, performing meta-analyses, and crafting recommendations using explicit criteria. The final guideline made 21 statements (recommendations, options, and no recommendations) based on the quality of scientific evidence and opinions of the panel.

The Experience

The process was complete to the point of being cumbersome both because the methodology was rigorous and because the panel was mostly inexperienced. Selecting more than 3500 articles, evaluating 1300 abstracts, extracting critical data from nearly 400 articles, and preparing evidence tables and meta-analyses requires an astonishing effort, regardless of how efficient the staff might become. Further, decisions that should have been straightforward extended to occupy hours of the panel's time, principally because most panelists were unfamiliar with the methodology.

A serious allegation of conflict of interest with respect to data on antibiotics was raised, necessitating special and time-consuming interventions. The quality of data on many important issues was once again inadequate, especially on the absolutely central issues of long-term outcomes of otitis media with effusion and the effectiveness of treatment. Some specialists who found it difficult to step back and view the data objectively maneuvered to circumvent the process to achieve recommendations more favorable to their point of view. A cost analysis predicting considerable cost savings if the guideline were to be implemented (especially by reducing the frequency of tympanostomy and tube placement) was vigorously challenged, leading to minority statements in the technical report.

The final recommendation and option statements, while cleverly crafted to accommodate panelists' divergent views, proved almost impossible to convert into useful medical review criteria because the clever compromises could not be reversed (for example, for a medical review criterion does "may" in the parent recommendation mean that something should or should not be done, or does it matter?).

United States Preventive Services Task Force

The Panel

The first USPSTF was convened in 1984 and spent 4 years to produce the first edition of the *Guide to Clinical Preventive Services*,[1] an influential document widely used in government and by professional organizations. The second task force convened in 1990, a smaller group with just 10 generalists (family physicians, internists, pediatricians, obstetrician-gynecologists, and epidemiologists). I was 1 of 2 family physicians on the panel (the other, Paul Frame, MD). The task force was supported by staff at the Office of Disease Prevention and Health Promotion (with many functions now moved to AHCPR) and maintained a close collaborative relationship with the Canadian Task Force on the Periodic Health Examination.

Topics were chosen based on burden of suffering in the population. Scope and mandate were explicit. Literature reviews were conducted according to causal pathways developed early in the process and checked for completeness by outside consultants and reviewers. Drafts were prepared by staff, members, and members' associates (junior faculty and fellows). Linkages between evidence and final recommendations are explicit and accountable. Meetings were held quarterly from 1990 through the first part of 1994. The second edition of the *Guide to Clinical Preventive Services* was released in December 1995.[7]

The Experience

In my 4 years on the task force, we reviewed a large number of topics—nearly 200. That we were able to do so owes much to the streamlining of the process, all members being familiar with the evidence-based approach at the outset, and almost no instances where members had any-

thing at stake professionally in whichever way the final recommendation came out. Further, the panel's focus tended to narrow on the issue of efficacy, so that the individual recommendations read more like mini-technology assessments rather than fully formed clinical practice guidelines. In other words, we considered it an honorable outcome if the panel failed to find compelling evidence one way or the other, not feeling obligated to go beyond the evidence to make a recommendation for clinical practice. Finally, clarity on the question at hand allowed the panel to perform limited literature reviews on the particular aspect(s) of the critical pathway that must be met to make a recommendation, most of the time avoiding the immense, comprehensive, and expensive literature reviews that must be performed for a general clinical topic. By focusing on evidence and injecting as little expert opinion into the process as possible, the time that might have been spent dealing with divergent expert opinions could be productively put to use reviewing more clinical topics.

Lessons

Evidence

The lack of high-quality evidence to inform clinical practice has always troubled me, but my experience with these four panels (addressing scores of topics) has turned concern into alarm. Without exception these experiences show that the layer of scientific evidence upon which much of medical care is based is very thin indeed. That there can be more than 3000 articles on otitis media with effusion yet none on many important clinical questions (that have been known about for decades) demonstrates a profound flaw in the way research is designed and supported. Without denying the potential importance of basic research, that we know more about the physiology of eustachian tubes than we know about the medical outcomes of antibiotic treatment tells me something fundamental is amiss. Experience on these four panels has made me a much stronger advocate for clinical research with direct patient applicability.

Panels

These four experiences have given me strong views on panel size and composition. Panels should be modest in size, and members should have experience in evidence-based methods, be able to take a broad perspective, and be free of financial and disciplinary conflicts of interest.[8] Panelists should be able to make decisions based on agreed-upon rules of evidence, not upon the effects the decision might have on their (or their colleagues') reputation or pocketbook. Although in my experience these criteria were most likely to be met by generalist physicians with training in clinical epidemiology, there is no reason why any physician, whether generalist or specialist, could not be trained to apply the new methods. Specialists are especially helpful in clarifying the clinical problem, determining critical steps, assuring a complete literature review, and critically reviewing products for completeness and accuracy. But whether generalist or specialist, no one should be making decisions where a major financial or disciplinary conflict of interest exists.

Process

The process should be explicit, evidence based, and publicly accountable. A process that focuses on critical decisions in a clinical pathway is more likely to be efficient than one that attempts to review everything about a clinical topic. At minimum the process should provide a straightforward assessment of the question, does it work? If resources are adequate, the panel might pursue questions of economics, medicolegal considerations, and physician and patient preferences, although one might argue (persuasively, I think), that a single panel is unlikely to have the expertise necessary to complete a clinical guideline covering all potentially relevant considerations. In any event, I see no need to make recommendations based on poor-quality evidence or expert opinion alone. In such cases it is preferable to simply summarize why the scientific evidence is inadequate, laying out the principal research questions that might be addressed with further study.

Conclusions

My experience with clinical practice guidelines leads me to the following messages for family physicians:

Be wary of clinical practice guidelines. Judge a practice guideline by the quality of its process, not by the reputation of its panelists or sponsoring organization. Look for policies that use evidence-based methods applied by experts who

have no financial or disciplinary conflicts of interest. Resist guidelines developed using the older method of global subjective judgment.

Advocate for research in primary care. Many important clinical questions cannot be answered from current research. Most will be answered only in actual clinical settings where patients with the problem are seen. Family practice has an enormous stake in assuring that research on important clinical topics is conducted in settings similar to those in which we practice.

Become a therapeutic skeptic. We are a gullible lot when it comes to expert advice and opinion. In the past I optimistically assumed that if I did not have the answer to a clinical question, an expert or textbook or journal article surely did. Now my default is to greet almost any clinical recommendation with the question: On what basis is the recommendation made? Family physicians are well-known for demanding clinical relevance in things they read; no journal or textbook failing to provide "what to do" advice survives long in the family practice market. Family practice, as a discipline, needs to recognize that for some clinical questions, however, there are no answers. Pretending otherwise will do neither us nor our patients any good.

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