Whose Guideline Is It, Anyway?

If, as Tip O'Neill said, "All politics are local politics," must all guidelines be local guidelines? This is one of the key questions raised by Fang and colleagues[1] in their article in this issue of the ARCHIVES, in which 87% of responding provider groups affiliated with a large California health maintenance organization stated that they were planning, developing, or had completed work on at least 1 clinical guideline. The costs to develop a guideline incurred by the few organizations providing estimates were quite modest, $100 to $5000. Given that the evidence-based guidelines produced by the Agency for Health Care Policy and Research (AHCPR) each cost hundreds of thousands of dollars to produce, is the private sector being vastly more efficient than the public sector, or are these organizations doing something else? Local expert opinion, the medical and scientific literature, and externally developed guidelines were rated as the 3 most important factors influencing the development of guidelines. This suggests that many of these organizations are not independently developing their own guidelines and following the evidence-based, explicit approach advocated by Eddy[2] and used by AHCPR in developing its guidelines. It seems more likely that they are doing a combination of codifying local expert opinion and modifying guidelines developed elsewhere for local consumption.

Why should it be necessary to modify credible, explicit, evidence-based guidelines to fit local situations? There are several possible reasons why this might be. First, if the local population does not reflect the population(s) used in the studies analyzed for the national guideline, modifying the guideline or ignoring it might be necessary. For example, a guideline intended for primary care physicians might need adaptation for the selected referral population seen by specialists, or vice versa, and local patterns of antibiotic resistance might dictate choice of treatment for infectious diseases. Second, it may be that local adaptation is believed to be necessary to obtain local "ownership" of a guideline. Whether this is necessarily true is unknown, but it is widely believed to be true[3]; a review of guideline evaluations concluded that internally developed guidelines had the greatest likelihood of being effective, while externally developed, national guidelines had the least likelihood.[4] Third, even guidelines developed with an explicit, evidence-based approach are not immune to bias, as different readers might interpret the same studies differently, and recommendations based on expert opinion for areas in which there is little or no good evidence are subject to the prejudices and preferences of the experts involved. For example, when the AHCPR depression guideline was first released, I heard an interview on National Public Radio with a psychiatrist who served on the guideline panel. He said,"Now that this guideline is out, there's no excuse for family doctors not going out and doing what they're supposed to do." This did not make me want to run out and get the guideline to see what I was doing wrong; rather it suggested that the guideline would be biased by the attitude that psychiatrists knew and were doing what was right all along, and it was just those primary care physicians who needed to be sent to reeducation camps.

See also pages 528

Part of the perceived need for local adaptation may come from an irrational reaction against guidelines explicitly presented as such, especially if the guidelines come from "somewhere else." The "don't tell me how to do my job" reaction is not apparently provoked by traditional, less explicit means of presenting guidelines. The Washington University *Manual of Medical Therapeutics*,[5] for example, contains what are essentially many treatment guidelines, yet we do not see a University of Washington *Manual of Medical Therapeutics* or a *Community Hospital Manual*. One does not hear complaints that "Seattle patients are different from St Louis patients and their hyponatremia needs to be treated differently," or "We have a different case-mix here than in St Louis."

The experience of Kaiser Permanente Northwest in adapting the AHCPR depression guideline is instructive. Local adaptation was believed necessary for many reasons, including the perception ". . . that the AHCPR guideline, although addressed to primary care clinicians, was actually written from a psychiatric perspective and based on a psychiatric literature not relevant to primary care,"[6(p6)] a belief that the guideline documents needed to be adapted in format, organization, and emphasis, and the need to provide local information about available resources. The adapted guideline focused on actions and decisions to be made by primary care providers and contained relatively few references. Its recommendations were not believed to differ appreciably from the recommendations of the original AHCPR guideline,[6] although the alteration of the order of preference of use of some antidepressant drugs, apparently based on cost, was noted when the adaptation was presented at the AHCPR-Supported Guidelines: A Mid-Course Review conference (my materials titled "Implementation and Evaluation of the AHCPR Depression Guideline in a Managed Care Setting," given to participants [Rockville, Md;

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November 7, 1994]). The adaptation did not reference any of the tables and figures taken from the AHCPR guideline documents and included the guideline only as 1 of 27 citations in a bibliography. Local, nontechnical authority was believed to lend much more credibility than the extensive, evidence-based national effort.[6]

What are the disadvantages of local development or adaptation of guidelines? As Fang et al[1] note, local guidelines may differ in content and quality from national ones and they may merely serve to codify local practices that are not based on good evidence.[7] Standardization for its own sake is not necessarily good; given the phenomenon of large regional variations in medical practices that do not seem to be driven by patient-related factors,[8,9] standardizing on local practices rather than moving toward a more evidence-based approach could well be bad.

What can be done to minimize a perceived need for local adaptation? First, making guidelines as free from the perception of bias as possible is critical. The US Preventive Services Task Force took the approach of having methodologists, not content experts, direct the guideline development process. Potentially biased content experts were used as consultants but could not control the outcome of the guideline development process. This is in marked contrast with, eg, the American Cancer Society's mammography guideline, which recommends mammography for women aged 40 through 49 years despite considerable evidence that there is no benefit in this age group,[10] and the National Cholesterol Education Program, which has provoked continuing debate[11] (see also *The Atlantic Monthly*. September 1989:37-70). One suggestion for improvement in the development process of AHCPR guidelines might be to adopt this approach so that future guidelines do not seem to be subject to the biases of a particular specialty or person. Second, having a committee composed primarily of members of the intended audience for the guideline produce a brief, clinically oriented guideline summary, like the "Quick Reference Guide for Clinicians" AHCPR produces, could meet physicians' needs for an accessible, easily interpretable source of information that would not be perceived either as biased or clinically useless. For multiple audiences, separate committees and summaries might be needed. However, some members of the guideline committee should have veto power over materials produced to ensure that unpopular recommendations are not eviscerated. How the recently announced changes in the AHCPR guideline program affect the quality and credibility of the guidelines produced remains to be seen. Some of these recommendations could be adapted to this new process, but leaving the development of the guidelines in the hands of potentially partisan organizations after the meta-analytic work has been performed will leave guidelines developed under this process even more vulnerable to potential bias. The content of the back pain guideline[12] might have been very different had it been sponsored by a society of surgeons. Third, medicine needs to continue its transition from an apprenticeship-based trade to a profession based on the best available science. In particular, medical schools need to place greater emphasis on teaching critical evaluation skills and the practice of evidence-based medicine. Students should be inoculated with a healthy dose of skepticism about traditional dogma and expert opinion that cannot be buttressed by solid science.

Whatever their flaws, the guidelines developed by the AHCPR are among the best and most credible guidelines available. Thus, it is surprising that only 45% of the respondents indicated that they had heard of the AHCPR guidelines; it is likely that a significant proportion of those reporting they had heard of these guidelines did not accurately know their contents.[13] The AHCPR guidelines have been released with significant national publicity and materials in several forms, including brief provider reference pamphlets, complete guideline documents with extensive references and detailed evidence summaries and discussions, and patient-oriented pamphlets. Nevertheless, dissemination of these materials to leaders in the surveyed organizations seems to have been quite limited.

The authors suggest that less effort has gone into guideline implementation and evaluation than guideline development in these organizations, and this would fit with much of the existing literature on guideline dissemination.[14] Sanctions were reported to be used by 19% of the organizations and they may well be effective in improving compliance, but it is critical that the concepts of standards, guidelines, and options[15] be distinguished and physicians not be sanctioned for reasonable differences of opinion rather than lapses in standards of care. Information feedback was reported as the most commonly utilized means of improving compliance; feedback alone does not necessarily produce an effect,[16] although patient-specific feedback seems more likely to change behavior than general feedback.[4,17] Changing physician behavior seems to require ongoing effort using multiple modalities,[3,4,16,18-21] which tends to be expensive and time consuming.

Evaluating the outcomes of guideline implementation may require data that often are unavailable without considerable expense, such as chart audits and patient surveys. The modest total expenditures reported for "guideline development," if they include implementation and evaluation costs, suggest that the outcomes measured were most likely simple ones, available from administrative data, such as charges and resource utilization, and not patient-centered outcomes. However, as administrative data systems improve and the use of electronic medical records spreads, the potential to rapidly and inexpensively evaluate guideline implementation grows. Such systems, in fact, allow for not only evaluation but also improved implementation, eg, through presenting information at the time of decision or providing feedback about one's patients.[22] It is discouraging, but probably reflective of the state of computers in medicine in 1993, that only 1 organization reported using "computer programs" in their implementation efforts. Implementation and evaluation must be local, but given the number of credible, evidence-based guidelines extant, it is hard to justify efforts at local guideline development beyond, for now, judicious local adaptation.

The reasons the organizations surveyed and most other health care organizations are interested in clinical guidelines are obvious and fit the data presented by Fang et al. Documenting the implementation and evaluation

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of guidelines is required for accreditation of health maintenance organizations by the National Committee for Quality Assurance. This requirement would probably move meeting accreditation criteria and responding to employer groups higher on the list of motivations than was the case in 1993. Guidelines offer the possibility of reaching the Holy Grail of American medicine: higher quality at lower cost. Guidelines, however, must be based on the best available evidence, be credible, be effectively implemented, and be meaningfully evaluated before these benefits can be achieved. Otherwise, the name has gone on, but the quality has not gone in.

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Clinical Pearls

A nicotine patch, as compared with a placebo patch, was associated with increased acid reflux into the esophagus. The authors conclude that patients may wish to remove their nicotine patches at night. (*Am J Gastroenterol.* 1995;90:919-921.)

Men who come from violent families are less likely to be violent as adults if they develop strong personal attachments and if they perceive negative consequences of violent behavior from significant others. (*J Marriage Fam.* 1995;57:295-305.)

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