Editorial

It Takes a Village to Craft a Clinical Guideline


In this issue of *The Journal* a distinguished and admired group has put forth treatment recommendations for the spondyloarthropathies (SpA)[1]. By the National Guideline Clearinghouse[2], this would be the 2123rd guideline since the beginning of guidelines and the third on SpA since 2003[3,4].

As a genre, these pronouncements are not standards, for fear of litigation, and are meant to be evidence-based (most are not). Originally, "clinical practice guidelines [were intended as] systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances[5,6]." They have also been used as a hedge to maintain quality of care in the face of cost-cutting by managers of healthcare systems, which started in the 1970s. Guidelines continue to proliferate despite sparse evidence that they improve patient outcomes[7,8] or maintain quality care. Judging by our colleagues, we suspect that most guidelines are put in the circular file, unread and unheeded. Many are influenced by the pharmaceutical industry and are therefore, perhaps appropriately, suspect[9-13].

There are guidelines on how guidelines should be developed[6,14], but the evidence suggests they are more often followed in the breach[15,16]. Unfortunately, following guidelines on how to prepare guidelines does not guarantee their correctness; saying that standards were followed does not mean that they were. Consequently, the reader is often reliant on a subjective judgment about whether, or how successfully, the rules of the exercise are followed.

This guideline is an impressive attempt to bring the views of patient stakeholders into the process. It is not the first time[17]. Deliberations for these guidelines sometimes took up to 3 votes, which means that the patients' influence (3 of 20 committee members were consumers) might not have had much influence. Studies indicate that group judgments usually trump the most expert single member, but this is true only if there is conceptual, experiential, and cognitive diversity of the participants; if the judgments are independent and made without a central influence; and if there is a way to aggregate the opinions[18]. The effective input of participants can be undermined without leadership to insure these conditions.

Did the composition of the group matter to the final guideline result? It probably mattered as much as the evidence itself. The recommendations of the group, by their own determination, differ from the Ankylosing Spondylitis Assessment Study/EULAR recommendations in 4 areas. Their rationale is based on opinion in 3 of the areas, but is marginally different from the previous recommendations, in our opinion. In the fourth area, the role of methotrexate treatment in axial spondylitis, the change is based appropriately upon new trials data, but their conclusion, however, is arguable[19]. In our opinion, the most important issue, the disease activity requiring anti-tumor necrosis factor (TNF) therapy, could not be resolved by the group, but it is an honest effort acknowledged.

A novel, interesting feature of this guideline development was involvement of ethicists: but what did the ethicists have to say about the fact that 13 of the 21 authors had received funding from pharmaceutical companies currently offering biologic drugs for spondyloarthritis? Recent high-profile instances of corporate influence show that such relationships at least introduce doubt about the objectivity of the process and have been proscribed[9,12].

Ethics deals with the behavior of the average person with reasonable effort. If it turns toward that to which everyone should aspire, but which only a minority will accomplish, it is a legitimate discussion but not really "ethics." A discussion of what is ethical in a guideline, by this definition, therefore operates from the premise that a guideline is a floor, not a statement of aspirations. In a word, this should be a statement of minimal expectations formulated by the parties most knowledgeable about what's at stake and what

See The CRA/SPARCC treatment recommendations for the management of spondyloarthritis, *page 2273*

works for whom — physicians and their patients. With these expectations openly articulated, deciding what can be done practically takes a village, indeed, and the widest community.

In recent history, the Oregon experiment is the best example of how this approach might work in expanding healthcare coverage in an era of shrinking budgets. In 1989, Oregon started an experiment to add uninsured people to the Medicaid program and to pay for it by reducing its benefits[20]. The plan provoked strong criticism from liberal politicians, the American Academy of Pediatrics, and others and fears of rationing and discrimination against those with no political base. Unlike other states, Oregon created a prioritized list of benefits and increased the number of people receiving Medicaid. The Oregon Health Plan (OHP) went into operation in 1994 and enjoys political support[20]. However, a thoughtful community-based rheumatologist in Eugene, Oregon, Dr. Cody Wasner, has another view (personal communication, 2007):

> "...At the present time we have been able to get biologicals for ankylosing spondylitis with about the same difficulty or ease that we have with the other third-party payers. On a case by case basis I don't think we have noticed more problems...with TNFs but it is always an individual fight..."
>
> "...Opinions on the success of the OHP is a much more complicated problem, however. The original list was really devoid of any rheumatological thought and developed with GP and Internist input only and headed by...[someone who]...didn't realize that RA could be treated. Surgical RA treatment was ranked much higher than medical RA treatment... It was a public relations success but conceptually flawed. Medicaid coverage is no better here than in other states (with some pediatric exceptions).... The Therapeutic Immune Modulator Committee that was formed to advise OHP...has been an extreme headache and used the "evidence based" center to try and say that all biologicals were equivalent and wanted to declare Kineret as the preferred. After many public meetings...that effort failed but it took many man hours.... Things continue to be more complicated because the fundamental motives of the individual stake-holders continue to be at odds."

Finally, these management guidelines for SpA generally met the guidelines for establishing the quality of the evidence, but not in one critical area, we believe. The recommendation that nonsteroidal antiinflammatory drugs be tried no longer than 2 weeks for each of 3 individual agents before anti-TNF are considered implies that a therapeutic window of opportunity exists in the SpA. We believe this window is strongly suggested in rheumatoid arthritis but never studied in the SpA.

Another key assumption that the recommendations apply to the entire spectrum of SpA, which also leads toward early biologic use, is at least acknowledged as opinion.

These Canadian guidelines are a courageous attempt to deal with provincial health financing decisions in a more transparent and inclusive process. The input of ethicists seems like a good idea, but it failed to prevent the potential perception of bias. It is our opinion that guidelines should not confuse their primary job (which is to state the minimum expectations for care that is attainable with reasonable effort, a "floor" for acceptable care) with the purpose of outlining ideal care in an aspirational policy statement. The latter is a societal judgment and should include all those affected by the resource allocation decision.

In this one guideline, the entire challenge of contemporary healthcare financing is played out. The tension between what could be (aspirational) and what is possible is palpable (and one might add unbearable) and unsatisfactory. As the expensive technological possibilities of modern medicine increase and the public's demand for them seemingly outpaces our collective ability to pay for them, things are likely to get worse. We might all ask ourselves whether the time and effort and results of more than 30 years of practice guidelines have shed more light than heat. Ethics and politics are as often about competing goods as about right versus wrong.

Because the guideline process, however broad, cannot guarantee an affordable recommendation, it cannot properly supplant and may not even greatly influence the political process. The physician, nevertheless, must not abrogate his duty to do the best he/she can for the patient; the patient should not accept less; and the agents of a benevolent society must try to balance their aspirations with those of everyone else. The last, a political process, imperfect, sullied by interest groups, or by the art of the possible — depending on whether one is the winner or the loser — must be eminently fair and transparent, in good faith, and involve as many competing interests of the village as possible.

W. NEAL ROBERTS, MD;
MATTHEW H. LIANG, MD, MPH,
Medical College of Virginia Hospital,
Virginia Commonwealth University,
Richmond, Virginia; and
Section of Clinical Sciences,
Robert B. Brigham Arthritis and Musculoskeletal Diseases Clinical Research Center, Brigham and Women's Hospital; and
Section of Rheumatology,
Boston VA Healthcare System,
Boston, Massachusetts, USA

We acknowledge the expert assistance of G. Bagnato of the University of Messina in preparing this editorial.
Address reprint requests to Dr. M. Liang, Brigham and Women's Hospital, 75 Francis Street PBB-3, Boston, MA 02115.
E-mail: mliang@partners.org

REFERENCES

1. Maksymowych WP, Gladman D, Rahman P, et al. The Canadian Rheumatology Association/Spondyloarthritis Research Consortium of Canada treatment recommendations for the management of spondyloarthritis: A national multidisciplinary stakeholder project. J Rheumatol 2007:34:2273-84.
2. Agency for Healthcare Research and Quality. National Guideline Clearinghouse. [Internet. Guidelines] Accessed September 11, 2007. Available from: http://www.guideline.gov
3. Braun J, Pham T, Sieper J, et al. International ASAS consensus statement for the use of anti-tumour necrosis factor agents in patients with ankylosing spondylitis. Ann Rheum Dis 2003; 62:817-24.
4. Zochling Z, van der Heijde D, Burgos-Vargas R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2006;65:442-52.
5. Field MJ, Lohr KN, editors. Committee to Advise the Public Health Service on Clinical Practice Guidelines, Institute of Medicine. Clinical practice guidelines: directions for a new program. Washington, DC: National Academy Press; 1990.
6. Field MJ, Lohr KN, editors. Committee on Clinical Practice Guidelines. Institute of Medicine. Guidelines for clinical practice: from development to use. Washington, DC: National Academy Press; 1992.
7. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. Lancet 1993;342:1317-22.
8. Worrall G, Chaulk P, Freake D. The effects of clinical practice guidelines on patient outcomes in primary care: a systematic review. CMAJ 1997;156:1705-12.
9. Choudhry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. JAMA 2002;287:612-7.
10. Eichacker PQ, Natanson C, Danner RL. Surviving sepsis — practice guidelines, marketing campaigns, and Eli Lilly. N Engl J Med 2006;355:1640-2.
11. Sheldon T. Dutch health minister orders probe into influence of industry on medical guidelines. BMJ 2006;332:1472.
12. Clinical practice guidelines and conflict of interest. CMAJ 2005;173:1297-9.
13. Taylor R, Giles J. Cash interests taint drug advice. Nature 2005;437:1070-1.
14. Steinbrook R. Guidance for guidelines. N Engl J Med 2007;356:331-3.
15. Shaneyfelt TM, Mayo-Smith MF, Rothwangl J. Are guidelines following guidelines? The methodological quality of clinical practice guidelines in the peer-reviewed medical literature. JAMA 1999;281:1900-5.
16. Graham ID, Beardall S, Carter AO, et al. What is the quality of drug therapy clinical practice guidelines in Canada? CMAJ 2001;165:157-63.
17. Bigos S, Bowyer O, Braen G, et al. Acute low back problems in adults. Clinical Practice Guideline No. 14. [monograph]. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, 1994: AHCPR publication no. 950642.
18. Surowiecki J. The wisdom of crowds: why the many are smarter than the few and how collective wisdom shapes business, economies, societies, and nations. 1st ed. New York: Doubleday; 2004.
19. Chen J. Is methotrexate effective for the treatment of ankylosing spondylitis? Nat Clin Pract Rheumatol 2007;3:490-1.
20. Bodenheimer T. The Oregon Health Plan — lessons for the nation. First of two parts. N Engl J Med 1997;337:651-5.