Letter From The President

Dr. No

Managed Care: Clinical Guidelines

Laxmaiah Manchikanti, M.D.

"...As new discoveries are made, new truths discovered, and manners and opinions changed, with the change of circumstances, institutions must advance also to keep pace with the times. We might as well require a man to wear the coat which fitted him when he was a boy."

— Thomas Jefferson

The world first met Dr. No in the early 1960s, when the fictional character was popularized in a James Bond movie. Now in the managed care medical profession, a new Dr. No has emerged: the medical director of managed care organizations. As viewed by the public, the role of the medical director is to deny medical services for unseen patients. Medical directors, of course, claim that approving or denying services is only one of many tasks they perform. Another new breed of physicians assumes the role of utilization management, once again denying medical services. Medical directors and utilization physicians have many things in common: lack of knowledge of the patient's condition, lack of knowledge of the many modalities of treatment and, conveniently enough, protection from liability. However, the number of differences is also vast. Utilization physician are reimbursed at approximately \$50 to \$100 per case, while the medical director is reimbursed at a much higher level. Both are in contrast to the so-called IME, or the independent medical evaluation, for which physicians are reimbursed at even higher levels, ranging from \$200 to \$2000 per case. Consequently, it is

not surprising that Dr. No, utilization management MD, medical director of managed care, and so-called independent MD, elicit high levels of emotional arousal among clinicians, specifically clinicians in private practices. Tension is created because, for the majority of interventional pain management procedures, arbitrary guidelines are utilized with Teflon coating, to deny approval on the basis of "internal guidelines" and "lack of outcome data."

There is no shortage of general clinical practice guidelines. However, very few specific guidelines for chronic pain management and none specifically for interventional pain management have been developed and none of them have been utilized in clinical practice. Even though the development of clinical practice guidelines has been criticized, there still are no guidelines which are practical, useful, and understandable in interventional pain management. Some have negatively labeled the development of clinical practice guidelines as a growth industry, with various groups attempting to develop guidelines--some with self-serving biases--and with the empirical basis for such guidelines or recommendations often based on expert consensus rather than scientifically valid data (1, 2).

So why another set of guidelines? Members of the Association of Pain Management Anesthesiologists (AOPMA) developed the guidelines published in this issue of *Pain Physician*. The purpose of these clinical practice guidelines of interventional techniques in the management of chronic pain is to:

1. Improve quality of care
2. Increase patient access
3. Improve patient outcomes
4. Improve appropriateness of care
5. Improve efficiency and effectiveness
6. Achieve cost containment by improving cost/benefit ratio

From Pain Management Center of Paducah, Paducah, KY. Dr. Manchikanti is medical director of Pain Management Center of Paducah and President of Association of Pain Management Anesthesiologists. Address correspondence: Laxmaiah Manchikanti, MD, 2831 Lone Oak Road, Paducah, KY 42003

The most compelling reason for the development of clinical practice guidelines for interventional techniques in the management of chronic pain is to improve the quality of pain management and thus the quality of life of pain sufferers. These guidelines also address the issue of systematic evaluation and ongoing care of chronic or persistent pain. They provide information about the scientific basis of recommended procedures, potentially increasing compliance, dispelling misconceptions among the providers and patients, managing patient expectations reasonably, and forming the basis of a therapeutic partnership between the patient, the provider and the payer.

Providers of interventional pain management, though sometimes labeled self-serving, understand that interventional pain medicine is crucial both in the diagnostic and the therapeutic arena of managing pain and providing improvement in the quality of life of the sufferers. Due to lack of conclusive evidence or consensus, pain management as it stands now has been branded with an often unfair negative identity.

Guidelines and recommendations published in the past include those developed by the Quebec Task Force on Spinal Disorders, the Agency for Health Care and Policy Research (3), and Chronic Pain Guidelines by the American Society of Anesthesiologists (4). These groups expended tremendous effort and resources to review the assessment and treatment literature to develop evidence-based guidelines for, in the case of the first two, the treatment of acute low back pain problems in adults and, for the third, the management of chronic pain. Even though the first two sets of guidelines claimed to be evidence based, a serious examination of the guidelines shows that about 85% of the recommendations were not based on any significant evidence. And this phenomenon is not limited to pain management. Evidence and efficacy are major issues with all surgical specialties (3-5). The issues of ethics, feasibility, cost and reliability pose challenges to the "randomized trial," which theoretically represents the "gold standard" in interventional pain management (5-11). Due to the poor methodological quality of a large number of published, randomized clinical trials on the efficacy of interventions in the management of low back pain, whiplash and other painful conditions, there is currently little useful literature. Hence, our approach is to use the best available evidence and blend it with consensus. In fact, Shaneyfeld et al (12), reviewed the methodological quality of clinical guidelines in the peer-reviewed medical literature with evaluation of 279 guidelines developed by 69 different

organizations and published from 1985 to 1997 concluding that these guidelines do not adhere to established methodological standards. They added that while all areas of guideline development need improvement, the most work is needed in the identification, evaluation and synthesis of scientific evidence. Responding to the increased interest in the development of guidelines, several major medical organizations, including the American Medical Association, the Institute of Medicine and the Canadian Medical Association, formulated methodology for developing scientifically sound guidelines (13-17). Shaneyfeld et al (12) identified important aspects of the guidelines as follows:

- Identification of the purpose of the guidelines
- Identification of rationale and importance of the guidelines
- Specification of the participants and their expertise in the guideline development
- Definition of the targeted health problem or technology
- Specification of the targeted patient population
- Specification of intended audience or users of the guidelines
- Specification of the principle preventive, diagnostic or therapeutic options available to clinicians and patients
- Specification of health outcomes
- Specification of the method by which the guidelines underwent external review
- Specification of expiration date or date of scheduled review
- Specification of method of identification of scientific evidence
- Specification of time period from which evidence is reviewed
- Identification of evidence used with appropriate citations and references
- Specification of method of data extraction
- Specification of method for grading or classifying the scientific evidence
- Description of formal methods of combining evidence or expert opinion
- Specification of benefits and harms of specific health practices.
- Quantification of benefits and harms
- Specification of the effect on health care costs from specific health practices
- Quantification of costs
- Discussion of the role of the value judgments used by the guideline developers in making recommen-

- datations
- Discussion of the role of patient preferences
- Specification of recommendations to apply to the stated goals of the guidelines
- Grading of the recommendations according to the strength of the evidence
- Specification of flexibility in the recommendations

The first ten standards relate to methodological standards on guideline development and format. The second ten standards relate to methodological standards on evidence identification and summary. The final five standards relate to methodological standards on the formulation of recommendations.

Needless to say, we have attempted to adhere to all the standards and met at least 20 of the 25. In addition, a major shortcoming in guideline development is that all guidelines do not account for differences in patient views regarding the desirability of specific health outcomes, such as low back pain (18). Because differences in patients' preferences may lead to differences in the therapy, a clinical practice guideline that does not consider patients' preferences may provide recommendations that are not optimal. Owen (18) summarized guideline development methods to four categories:

1. Global subjective judgment
2. Evidence-based
3. Outcome-based
4. Preference based, which should be accurate, accountable, predictable, defensible, and usable.

Global subjective judgement is used by many physicians and may be accurate and usable; however, it is not accountable, predictable, and defensible.

As Thomas Jefferson, speaking about the evolution of institutions in a letter to Samuel Kercheval in 1816, said, "... As new discoveries are made, new truths discovered, and manners and opinions changed, with the change of circumstances, institutions must advance also to keep pace with the times. We might as well, require a man to wear the coat which fitted him when he was a boy (19)." The

problems in the development of guidelines are more complex today than ever before.

When a patient is denied a medical service, one of two reasons are given for the denial. One reason is that the service is not covered by the patient's insurance plan. The other reason is that the medical director or another reviewing physician does not consider the service appropriate for the patient's medical condition. These denials are supposed to prevent the provision of unnecessary and potentially harmful services to patients (20). In congressional testimony critical of HMOs, Linda Peeno, a former medical director of a large HMO, said, "When all else fails in trying to justify the denial of a health care benefit, use medical necessity – the smart bomb of managed care" (20 21). In the 1960s, insurers adapted the term "medical necessity," a legal mechanism to limit the services for which they would pay. Over time, by adding the requirement of medical necessity to insurance contracts, insurers gave themselves the right to determine whether a service was medically necessary (22). Quinn (23) has offered a common sense formulation of how the matter of medical necessity should be handled in individual cases. Ideally, medical necessity encompasses as the shortest, least expensive, or least intense level of treatment, care, or service rendered, or supply provided, as determined to the extent required to diagnose or treat an injury or sickness. Further, the service or supply must be consistent with the insured person's medical condition, is known to be safe and effective at the time the service is rendered, and is not provided primarily for the convenience of the insured person, physician or insurance company. According to Black's Dictionary of Law, medical necessity is defined as: "an absolute physical necessity, an inevitability, or convenient, useful, appropriate, suitable, proper or conducive to the end sought"(23). But the lack of consistency among health plans remains a major problem (20). Patients with the same condition may receive or be denied new treatments or even established treatments depending on which company provides them with health insurance (24-26).

In summary, these guidelines are guidelines only. It is the hope of the AOPMA that these guidelines will be the best currently available in the market and that they will be used extensively. These guidelines will not only be useful for

practitioners but also for patients and provider care organizations. As such, the best interests of everyone will be served.

REFERENCES

1. Turk DC. Here we go again. Outcomes, outcomes, outcomes. *Clin J Pain* 1999; 15:241-243.
2. Turk DC, Okifuji A. Treatment of chronic pain patients. Clinical outcomes, cost-effectiveness, and cost-benefits of multidisciplinary pain centers. *Crit Rev Phys Rehabil Med* 1998; 10:181-208.
3. Bigos SJ, Boyer OR, Braen GR et al. *Acute low back problems in adults*. Clinical Practice Guideline Number 4. AHCPR Publication No. 95-0642. Rockville, MD. Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services, December, 1994.
4. Task Force on Pain Management. *Practice guidelines for chronic pain management*. A report by the American Society of Anesthesiologists Task Force on Pain Management, Chronic Pain Section. *Anesthesiology* 1997; 86:995-1004.
5. Van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute chronic nonspecific low back pain. A systematic review of randomized controlled trials of the most common interventions. *Spine* 1997; 22:2128-2156.
6. Turner JA, Loeser JD, Bell KG. Spinal cord stimulation for chronic low back pain. A systematic literature synthesis. *Neurosurgery* 1995; 37:1088-1098.
7. Weinstein JN. The tortoise and the hare. Is there a place in spine surgery for randomized trials? *Spine* 1999; 23:2548-2549.
8. Winter RB. The prospective, randomized, controlled clinical trial in spine surgery. Fact or fiction? *Spine* 1999; 23:2550-2552.
9. Carey TS. Randomized controlled trials in surgery. An essential component of scientific progress. *Spine* 1999; 23:2553-2555.
10. Fairbank J. Randomized controlled trials in the surgical management of spinal problems. *Spine* 1999; 23:2556-2563.
11. Tosteson TD. Point of view. *Spine* 1999; 24:2562-2563.
12. Shancylfelt 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; 281:1900-1905.
13. Committee to Advise the Public Health Service on Clinical Practice Guidelines. Institute of Medicine. Field MJ, Lohr KN. *Clinical practice guidelines. Directions of a new program*. Washington, DC. National Academy Press, 1990.
14. Eddy DM. A manual for assessing health practices and designing practice policies: The explicit approach. Philadelphia, PA, American College of Physicians, 1992.
15. *Attributes to guide the development and evaluation of practice parameter*. Chicago. American Medical Association, Office of Quality Assistance, 1990.
16. *Quality of care program. The guidelines for Canadian clinical practice guidelines*. Ottawa, Ontario, Canadian Medical Association, 1993.
17. Woolf SH. *Manual for clinical practice guideline development*. Rockville. Agency for Health Care Policy and Research; 1991. AHCPR publication 91-0007.
18. Owen DK. Spine update. Patient preferences and the development of practice guidelines. *Spine* 1998; 23:1073-1079.
19. Jefferson T. Letter to Samuel Kercheval. July 12, 1816.
20. Bodenheimer T, Casalino L. Executives with white coats. The work and world view of managed-care medical directors. Health Policy Report JAMA 1999; 341:1945-1948.
21. Pecno L. Testimony before the US House of Representatives. Committee on Commerce, Subcommittee on Health and Environment. May 30, 1996.
22. Jacobson PD, Asch S, Glassman PA, et al. Defining and implementing medical necessity in Washington State and Oregon. *Inquiry* 1997; 34:143-154.
23. Quinn C. Issues of medical necessity. A medical director's guide to good faith adjudication. *Am J Managed Care* 1997; 3:883-888.
24. Light DW. Life, death, and the insurance companies. *N Engl J Med* 1994; 330:498-500.
25. Peter WP, Rogers MC. Variation in approval by insurance companies of coverage for autologous blood marrow transplantation for breast cancer. *N Engl J Med* 1994; 330:473-477.
26. Steiner CA, Powe NR, Anderson GF et al. Technology coverage decisions by health care plans and considerations by medical directors. *Med Care* 1997; 35:472-489.