

CLINICAL PRACTICE GUIDELINES: WRITING THE BOOK ON NUCLEAR MEDICINE

HAILED AS A MEANS of buoying the quality of health care and restraining the soaring costs of medicine, practice guidelines are gaining popularity among medical specialty societies. Although The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) have yet to join the growing number of medical societies that have approved clinical practice guidelines, a sense of urgency to do so is mounting.

"There's no question that practice parameters are needed," says James W. Fletcher, MD, professor of internal medicine and radiology and director of nuclear medicine at St. Louis University School of Medicine in Missouri, who chairs SNM's Ad Hoc Committee on Practice Policy. The primary reason for developing practice guidelines, he says, is to improve the quality of medical services. Such is the refrain of everyone from officials of the government and the American Medical Association (AMA) to practitioners and researchers. But other forces, they all acknowledge, such as the demands from without to reduce costs and from within to protect turf, are also driving the widespread emergence of guidelines in medicine.

Expectations and Concerns

The AMA champions the establishment of what officials there call "practice parameters." AMA officials say guidelines will improve the quality of health care, reduce physician liability, and limit inappropriate use of procedures. Despite AMA endorsement, concerns persist that practice guidelines will be used by insurers to cut back on reimbursement for some practices, or that deviation from written guidelines would heighten malpractice liability. How guidelines will be used by government, private insurers, and lawyers is far from

clear. Their eventual introduction in all areas of practice seems certain.

Gary Dillehay, MD, assistant professor of radiology at Loyola University Medical Center in Maywood, Illinois, says, "It isn't so much a question of there being a need for practice guidelines as it is a mandate by the federal government and the AMA." Dr. Dillehay is a member of Dr. Fletcher's committee, and he is chairman of the ACNP committee involved in developing practice policy guidelines.

Mounting Enthusiasm

Practice guidelines are not a new phenomenon. The American Academy of Pediatrics introduced the first practice guidelines over 50 years ago as a tool to assist physicians in making clinical decisions, according to John T. Kelly, MD, PhD, director of the AMA's Office of Quality Assurance. The AMA defines practice guidelines as "recommendations for patient management," which may specify an "appropriate" strategy or range of strategies for treating patients. Practice guidelines may deem what levels of care are adequate and inadequate, and proscribe as well as endorse specific tests and techniques.

What is new is the mounting enthusiasm of medical societies for these guidelines. As of 1980, eight physician organizations were creating guidelines. As of this writing that number has more than quadrupled, and over 1,100 sets of practice guidelines have been written—an "extraordinary commitment," according to Dr. Kelly, who edits the AMA's Quality Assurance Newsletter.

If the goal of practice guidelines is to improve the quality of patient care, then some successes have been achieved. Dr. Kelly cites guidelines written by the American College of Cardiology, which have "contributed significantly" to a rise

in the appropriate implantation of cardiac pacemakers (1), and parameters developed by the American Society of Anesthesiologists, which have reduced the number of hypoxic injuries among surgical patients (2).

Adhering to guidelines enabled anesthesiologists to reduce their liability insurance premiums, according to the study previously cited by Dr. Kelly. Lawyers for the AMA generally conclude that practice guidelines will not expose physicians to new professional liabilities. "In some cases," says Dr. Kelly, "practice parameters will reduce professional liability risks by providing information on what professional organizations deem appropriate care." Such information, the reasoning goes, will increase the fairness and predictability of malpractice suits by leveling standards of care as determined by the courts.

The Impact on Reimbursement

Perhaps of greater concern to physicians is the widely held belief expressed by Dr. Fletcher that "ultimately, there is going to be a linkage between practice policy guidelines and reimbursement." An important undercurrent to the boom in practice policy guidelines, he says, is that medical specialty societies are aware of a push by strapped government agencies and insurance companies to limit the use of costly modalities and want to write their own guidelines before the government or insurers write rules that exclude reimbursement for nuclear medicine imaging modalities like PET. As Dr. Fletcher puts it: "HCFA is saying we don't have the budget to pay this kind of money. If the Society doesn't establish guidelines that delineate the importance of say, radionuclide lung scans, then HCFA or some other entity is likely to say, 'we don't need radionuclide lung scans anymore, we'll rely on Doppler

Patient Outcomes Research Team (PORT) Projects Funded by AHCPR

Title	Principal Investigator	Affiliations	Period
Back Pain Outcome Assessment Team	Richard A. Deyo, MD	University of Washington, Seattle, WA	9/89-8/94
Outcome Assessment of Patients with Biliary Tract Disease	J. Sanford Schwartz, MD	University of Pennsylvania, Philadelphia, PA	8/90-7/95
Assessing and Improving Outcomes: Total Knee Replacements	Deborah A. Freund, PhD, MPH	Indiana University, Indianapolis, IN	4/90-3/94
Analysis of Practices: Hip Fracture Repair and Osteoarthritis	James I. Hudson, MD	University of Maryland, Baltimore, MD	9/90-9/95
The Consequences of Variation in Treatment for Acute Myocardial Infarction	Barbara J. McNeil, MD, PhD	Harvard Medical School, Boston, MA	9/89-8/94
Outcome Assessment Program in Ischemic Heart Disease	David B. Pryor, MD	Duke University Medical Center, Chapel Hill, NC	7/90-6/95
Variations in the Management and Outcomes of Diabetes	Sheldon M. Greenfield, MD	New England Medical Center, Boston, MA	9/90-9/95
Variations in Cataract Management: Patient and Economic Outcomes	Earl P. Steinberg, MD	Johns Hopkins University, Baltimore, MD	9/89-8/94
Assessment of the Variation and Outcomes of Pneumonia	Wishwa M. Kapoor, MD, MPH	University of Pittsburgh, Pittsburgh, PA	9/90-9/95
Variations in Obstetric Practice and Patient Outcomes	Emmett Keeler, PhD	RAND Corporation, Santa Monica, CA	9/90-9/95
Assessing Therapies for Benign Prostatic Hypertrophy and Localized Prostate Cancer	John E. Wennberg, MD, MPH	Dartmouth Medical School, Hanover, NH	9/89-8/94

Nuclear medicine is important in these areas of outcome assessment. The myocardial infarction study at Harvard is the only PORT headed by a nuclear medicine physician or radiologist.

ultrasound instead.’”

Spiraling health-care costs give adequate cause for alarm. In 1960, Americans spent about 5% of the gross national product (GNP) on health care. By 1989 the amount had swollen to nearly 12% of the GNP. Guidelines could help control costs by discouraging inappropriate and unnecessary medical services. So far, the Federal Government, through the Agency for Health Care Policy and Research (AHCPR), has a direct hand in the creation of only ten of the hundreds of practice policy guidelines being written. Congress created AHCPR in 1989 and gave it a mandate to develop clinical guidelines and, according to AHCPR officials, those guidelines are designed “to enhance the quality, appropriateness, and effectiveness” of medicine. Congress put priority on guidelines for the conditions that account for the bulk of Medicare expenditures. The guidelines

are intended for use by practitioners, consumers, and educators, as well as utilization review organizations.

Utilization review is sorely in need of reform, according to the AMA’s Dr. Kelly. He acknowledges that one reason his organization is pushing “practice parameters” is the desire to standardize the review criteria used by Medicare and private insurers. “The primary importance is to improve quality of patient care, but an additional benefit will be to provide a foundation for improved review criteria,” Dr. Kelly says. “Many private insurers and review organizations are already second guessing the judgment of physicians . . . and many of these entities are using secret review criteria.” Dr. Kelly published a study in March that evaluates the variability of the review criteria used by the Medicare Peer Review Organization, which are public, for the three procedures most frequently

reviewed by PROs: carotid endarterectomy, cataract removal, and cardiac pacemaker implants (3). “We found tremendous variability in different reviews of the same procedure,” he says. “Physicians are subjected to reviews based on weak and secret criteria and they are properly concerned.”

Staking Turf

Physicians are also concerned that guidelines might be adopted nationally that unfairly limit or preclude the use of nuclear medicine modalities—to the detriment of patients. Says Dr. Dillehay of clinical guidelines: “If we don’t write them, then somebody else will and we probably won’t like the results.” SNM President Naomi Alazraki, MD, co-director of nuclear medicine at Emory University Hospital and chief of nuclear medicine at Veterans Hospital, both in

(continued on page 16N)

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Guidelines

(continued from page 14N)

Atlanta, Georgia, acknowledges the potential impact of practice guidelines on delineating turf, but “the bottom line is quality of care,” she says. If nuclear procedures are not written into the emerging practice parameters, then primary care physicians might fail to use advanced radionuclide diagnostic imaging procedures that otherwise could have benefitted patients. “The issue is not who will perform nuclear medicine procedures,” she elaborates. “If nuclear medicine specialists don’t add their input, then some nuclear procedures could unintentionally be overlooked—the data may not appear prominently in the literature of other specialty societies, so we have to call it to their attention.”

Wanted: Outcome Data

There are three ways to come up with the needed data: scouring the published literature to derive a consensus, convening expert panels, and conducting costly prospective studies. Nuclear medicine is “missing the boat” for funding of prospective studies, according to Dr. Barbara McNeil, MD, head of the department of health care policy and Ridley Watts Professor of Radiology, Harvard Medical School, Boston, Massachusetts, in her address to SNM trustees in February. She was talking about government funding for prospective studies that could support the use of diagnostic nuclear imaging. The AHCPR is funding at least 11 studies, called Patient Outcome Research Team (PORT) projects, to assess the performance and cost-effectiveness of alternative diagnostic procedures, as well as other aspects of

clinical management. Funding for each PORT study averages around \$1 million for a period of five years, according to AHCPR officials. Dr. McNeil points out that diagnostic medicine is an important component of many of the PORT projects, but her study of the variation in treatment for acute myocardial infarction is the only one headed by a nuclear medicine physician or radiologist (see table on p. 14N).

Dr. Alazraki believes that SNM should support studies to collect data on the effectiveness of nuclear medicine procedures. She advocates the formation of a national office of quality standards and practice policy to organize and develop practice guidelines, not only by convening expert panels, but also by applying for federal grants to support prospective data collection. SNM’s Executive Committee authorized the formation of this office in April and is putting funding together as it seeks a director. Malinckrodt Medical Inc., has already granted \$25,000 to help support the work of the practice policy office. Dr. Fletcher adds that the office could work in cooperation with the ACNP. “Right now our efforts are unstructured,” he says.

“We’re not really pulling in the same direction.”

Consensus on Dementia

Dr. Alazraki points to the efforts of the Society’s Functional Brain Imaging Dementia Consensus Panel as a “good first step” in creating practice policy guidelines. The panel, comprising specialists in neurology, gerontology, and nuclear imaging of the brain, met in February to assess the state of nuclear imaging of dementias. The international panel set out to determine if the scientific literature contains enough data to support the writing of parameters for clinical imaging of dementias and to identify priority areas where further research is needed.

Panel leader Michael D. Devous, Sr., PhD, associate director of the Nuclear Medicine Center, and associate professor of radiology, University of Texas Southwestern Medical Center, Dallas, says, “We will be able to clearly establish the sensitivity and specificity of PET and SPECT for diagnosing dementia due to Alzheimer’s disease, and we should be able to establish the difference between PET and SPECT in specificity and sensitivity. Enough data already exist.” As to how capable the field is in differential diagnoses, say, distinguishing pseudodementia due to depression from multi-infarct dementia, Dr. Devous says, “it’s not as clear whether we have enough data.

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(continued on page 27N)

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Commentary

(continued from page 24N)

ing costs of health benefits for employees, large corporations have negotiated managed care plans with HMOs and contracted with consultant firms to monitor quality in those plans.

These actions are designed to contain cost without sacrificing quality. Recent studies published in the *Journal of the American Medical Association* indicate that quality of care generally has not declined after seven years of DRGs, the government initiated pre-payment care plan for hospitalized medicare patients. Despite these cost-containment measures, however, health care costs to government continue to rise, in large part because of increasing volumes of medical services. To discourage physicians from increasing volumes of services, the Health Care Financing Administration (HCFA) is implementing formulae that reimburse specialties less for volumes of services exceeding the prior year's volumes.

These trends reflect what we all know: To maintain income, we're all working harder, delivering more services, and having less time for everything else. We seem to have less time for SNM work during this critical period when SNM's need for our talents and attention have increased.

To respond effectively to these demands, SNM needs structural reorganization. We need medical and scientific leaders who can dedicate the additional time necessary to meet the challenges of today. A president alone, or with a handful of others, all of whom have the demands of other full-time jobs, won't be as effective in the 1990s as such a cohort might have been ten years ago. In addition to our officers, we need professional leadership dedicated to SNM, and capable of representing nuclear medicine before the government, other medical specialty groups, and the scientific community.

Naomi P. Alazraki, MD

President, The Society of Nuclear Medicine

Guidelines

(continued from page 16N)

the radiologist and president of SNM's Brain Imaging Council says. "We want to be able to hand people percentile numbers—this pattern gives you an 80% chance of Alzheimer's disease, this gives you a 60% chance of multi-infarct dementia." The findings of the dementia consensus panel will be published in a number of journals, according to one of the panel's co-writers, Ronald S. Tikofsky, PhD, research associate professor and director of brain imaging research, department of radiology, Med-

ical College of Wisconsin, Milwaukee.

Regardless of the procedures used to establish practice policy guidelines, Dr. Alazraki and others say that nuclear medicine specialists should work together with radiologists who carry out nuclear medicine procedures. The American College of Radiology approved several sets of clinical practice guidelines late last year that touch upon nuclear medicine. "We have to work with all of the other specialties," says Dr. Fletcher. As important, says Dr. Dillehay, "is to write these guidelines so they reflect the way we want nuclear medicine to be

practiced." Gathering sufficient data to determine how nuclear medicine should be practiced, and hammering out a consensus with radiologists and other specialists—that is the delicate task ahead.

J. Rojas-Burke

References

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2. Liability premiums reduced for anesthesiologists. *QA Review* 1989; 1-6.
3. Kellie, SE, Kelly, JT, Medicare peer review organization preprocedure review criteria. *JAMA* 1991; 265:1265-1270.

Xenografts

(continued from page 17N)

"It is possible that not all tumors will grow in the immunosuppressed dog, but the melanomas Dr. Wiseman tried grew very well," says Dr. Nelp. "This is real ingenious work and should provide a model that has certain advantages for work on solid tumors." Solid tumors of the liver, lung, ovaries, and other organs have proven more formidable in resistance to treatment with radioactive antibodies than radiosensitive tumors such as lymphomas (see *Newsline*, December

1990, p. 15A). Among the problems blocking the advancement of radioimmunotherapy is the low rate of incorporation of antibody into tumor. Dr. Wiseman is comparing tumor blood flow to tumor size, and specific antibody binding of tumor to tumor blood flow, looking for relationships. He suspects this might lead to a way to increase the rate of uptake of radioactive antibodies into malignant tumors for improved detection and treatment of cancers.

Dr. Wiseman is completing the second

year of his special three year combined fellowship at the University of Washington Medical Center and conducting his research at the Fred Hutchinson Cancer Research Center. Dr. Wiseman graduated from the University of Wyoming, Laramie in 1978. Awarded his medical degree from the University of Utah Medical Center, Salt Lake City, in 1983, he worked at the Mayo Clinic in Rochester, Minnesota until 1989.

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