VISIONS AND REVISIONS: VIEWPOINTS ON NUCLEAR MEDICINE AND HEALTH CARE REFORM

Part 2: Practice Guidelines

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WHILE THE MOVEMENT FOR practice guidelines hit the medical community with a flourish at the end of the 1980's, promising to buoy health care and contain runaway costs, in the last year health care reform has begun to change the face of the movement. Originally, practice guidelines were viewed as a means for the private medical sector to regulate itself and improve the quality of its services (see *Newsline*, June 1991, p 13n; April 1994, 11N). Between 1980-1991, the number of medical societies formulating guidelines quadrupled. In 1989, the American Medical Association (AMA) established two groups—the Practice Parameters Partnership and the Practice Parameters Forum—to help national specialty societies and state medical societies to develop guidelines. Also in 1989, Congress mandated the Agency for Health Care Policy and Research (AHCPR) to assist the medical community in guideline creation, emphasizing procedures that make up the bulk of Medicare expenditures. But with health care reform altering the entire medical landscape, guidelines are already appearing to hold a different position in the scene.

"Health care planners work on merit, not cost; [but] as we move toward a capitated health care system, merit diminishes and the dollar rules," said Robert E. Henkin, MD, professor of radiology and director of Nuclear Medicine, Loyola University Medical Center (Maywood, IL) and chair of the Practice Guidelines and Communications Committee of SNM's Commission on Health Care Policy. In contrast, originally "if practice guidelines showed you could not do [a procedure] in a given setting, you could not do it." Proponents initially saw guidelines as a way of standardizing practice and unifying it across the nation, or, essentially, as making for practitioners "a cookbook. We're still working on it this way, but it's not clear the way it will end up" under health care reform, Dr. Henkin said. "The insurance industry (which will not be the same) will ask, 'Where can I get the most bang for the bucks?' They will go to practice parameters and ask what [out of, say, three tests] is the single best test to do. This is a very different setting for us.... So practice parameters will not be used as we thought they would be used."

John T. Kelly, MD, PhD, director of the Office of Quality Assurance and Medical Review, AMA (Chicago, IL), who has written extensively on practice parameters and been instrumental in promoting the AMA's role in their development, is more sanguine. He sees the situation as changing with "health system reform," but only in terms of the present relationship between the public and private sectors intensifying and growing stronger. For one thing, health care legislation at different levels of government is beginning to recognize the significance of practice parameters. "Every major [federal] health system reform bill addresses the issue of practice parameters," he said. "A number of states have adopted legislation that addresses the use of practice parameters—Maine, Florida, and Minnesota."

A bill proposed in Maryland, for example, was modeled after a Maine program that permitted practice parameters—if adopted by a majority of members of certain specialty groups—to be introduced as evidence for a defense in a malpractice suit, if proof of adherence to the parameters constituted absolute defense to liability. Such use of practice parameters has been one goal of some health care reform observers interested in tort reform, which has gone to the back burner in recent federal health care reform discussions. This malpractice suit provision of the Maryland bill, offered by the Maryland Society of Emergency Physicians, was eventually defeated under pressure from a plaintiff's defense lobby, leaving a committee that could establish practice parameters which could not be used as evidence in a malpractice suit. (The legislature instead adopted a provision requiring a "similar" community standard of care instead of a national standard in proving malpractice suits, thus preventing use of hired gun experts from large out-of-state medical centers.) Though the bill's practice parameter section was largely defanged, parameters may still come up for utilization review in the future.

But legislation is not just drawing attention to practice parameters; federal agencies like AHCPR and the Health Care Financing Administration (HCFA) are implementing and encouraging the use of practice parameters developed in the private sector. For example, HCFA has helped implement guidelines developed by the American College of

Cardiology and the American Heart Association. As health care reform proceeds, "What we would expect would be considerable cooperation between the public and private sectors, as a majority of practice parameters are developed by the private," said Dr. Kelly. "Given the large number of procedures that could be added, we anticipate the private sector will continue [in this way]. We also anticipate government agencies will be involved at state and local levels and assist in evaluating these [parameters]."

A spokesperson in the National Institutes of Health (NIH) concurred about the federal government's role in guidelines development, but mostly for purely practical reasons. Dr. John Doppman, head of the Department of Radiology at the NIH, pointed out that the private sector is the likely source of guidelines, "because they're trying to protect their own interests. Guidelines have to come primarily from people in day-to-day care. Guidelines won't mean much from those involved in technology," in which the government is primarily involved.

However, Dr. Henkin's concern is not so much with the division of labor between public and private sectors in creating guidelines as it is the forces at work within the private when under a dollar crunch—and how economics will dictate the use of guidelines. Within the private sector, there is the problem of coordinating guidelines from several specialty societies that have their own approaches to a given condition. "If [two] specialties cannot agree on a practice parameter, both are hurt because of the confusion.... Instead of ten practice parameters from ten specialties, we will need one negotiated. If not, we'll have practice parameters as turf protectors."

Furthermore, he draws the picture of a health care manager at a desk, with practice parameters on the one hand and a health care budget on the other, and making decisions on procedures according to a mathematical formula. If for a given condition the nuclear medicine community proposes procedure X at cost Y, yielding 95% accuracy, and another specialty proposes procedure Z at cost W, yielding 85% accuracy, a formula factoring cost with accuracy may tilt the balance toward procedure Z, whether or not that is the best for the patient. "We're not sure our specialty can stand up in this," Dr. Henkin said. "This is where we need other specialties involved in our practice parameters preparation to endorse them."

Dealing with other specialty societies involves a combination of scientific and political process, but this easy-to-say combination requires developing negotiating skills in entirely new areas. For example, Dr. Henkin related how Dr. James W. Fletcher, chair of the SNM Committee on Competence and Certification, approached the neurology community about developing guidelines in conjunction with the Society, "and they said, 'We know what we want, we don't need you to tell us.' It was naive of them—and of us to think we can go in there without enough data and convince them. It's not as easy as we thought at first."

The AHCPR could be a helpful tool in resolving some of this conflict, as it "will be a clearinghouse" for practice parameters, he said. The agency has set up several PORT (Patient Outcome Research Team) studies, examining what does and does not work, and the result may lead to practice parameters. "They find the scientific methodology to back what we do clinically," he said. And though "they are a political group... they are the only group out there without a vested interest. They may end up as arbiter. So they have a potentially [great] role."

Dr. Kelly does not perceive quite so much conflict arising from the dollar crunch and how this will effect inter-specialty relations—because of the AMA recommendations on practice parameters, with the emphasis on physician judgment. "The real benefit of practice parameters is that they assert decision-making and do not replace clinical judgment: they are a tool. Many practice parameters attempt to manage rather than identify conditions; we see this as helpful for clinicians. Others attempt to address the utilization of resources, incorporating cost decisions into recommendations. We recommend that if cost information is taken into account that it be identifiable so the physician will know... We feel the physician will have flexibility in treating the patient."

As for the problem of specialty turf, "we've encouraged specialties to develop good information that is beneficial [to all]," Dr. Kelly said. "There are also some choices to be made, and more information will be best for physician and patient. I would emphasize there is more interest in organizations in developing these [choices]. Although there are some proponents for one set of practice parameters, we [the AMA] feel there is a role for those who do the care to develop practice parameters."

To this end, he sees that local review and local modification of practice parameters will help break up national monopolies on procedures and give the physician more flexibility in decision-making. "Thus we think it's important that so many organizations develop [practice parameters]. If there's more than one practice parameter on a given subject, it's up to individual physicians to decide what to use."

Michael Goris, MD, PhD, at the Division of

"Although there are proponents for one set of practice parameters, we feel there is a role for those who do the care to develop the parameters," said Dr. Kelly.

Nuclear Medicine, Stanford University, who will be speaking on "Efficacy and Cost-Effectiveness" at the Quality Guidelines in Nuclear Medicine Symposium this September, sees that the problem of interspecialty conflict can be solved another way. "Guidelines should not be made in a specialty group. It should do the background work," he said. "You have to split the labor and have specialty societies concentrate on operating characteristics of a test or treatment" and define the technical standards to be used, then have a general group like the AHCPR compile the guidelines. "It would be suspect for specialties to do this," he added, not only because they cannot avoid even an unintentional bias, but outsiders would consider them motivated by self-interest.

Whatever the final plan for generating practice parameters, it appears that health care reform will have some effect on how they are developed and implemented and that the AHCPR could play a crucial role. And apparently general and specialty societies will have to work out some kinks if the development and implementation process is going to run smoothly through the health care reform gantlet.

Lantz Miller

Annual SNM Fellowship Awardees Focus on Enhancing Clinical Applications

Medi Physics, Du Pont, and Mallinckrodt Fellowships boost young researchers

Kenneth T. Cheng, Ph.D.

THE SECOND ANNUAL SOCIETY OF Nuclear MEDicine/Medi-Physics Award for Innovation in Therapy in Unsealed Sources goes to an investigator seeking to improve radiopharmaceutical therapy by making target cells more sensitive to the radiopharmaceutical with taxol. The recipient, Kenneth T. Cheng, PhD, BCNP, —in the Division of Nuclear Medicine, Medical University of South Carolina, will apply the $30,000 grant to study clinical applications of taxol as a radiosensitizer for three particular therapeutic modalities.

Sponsored by the Amersham company, Medi-Physics, Inc., this award was first given last year to encourage advances in therapeutic applications of nuclear medicine.

Monoclonal antibodies as radioisotope carriers have recently been widely researched as potential nuclear medicine therapies. A molecular designer can make a "monoclonal" highly specific for a tumor cell recognition site and ideally bring an attached radioisotope directly to a tumor and to nowhere else. But immunological, physiological, pharmacological factors influence the antibody's tumor localization, and the radioisotope damages normal tissue. But making the tumor cells more sensitive to radioactivity may counteract some of these problems. Dr. Cheng is going to further the investigations he has already begun (using a 1993 SNM Research and Education Foundation grant) on taxol's role as a sensitizer. He will also test two other nuclear medicine therapies for taxol radiosensitization: ^{131}I-metaiodobezylguanadine (MIBG) and ^{89}Sr. This information on taxol's effectiveness as a radiosensitizer may improve these modalities' opportunities for clinical application.

Thomas Chen, MD

Habib Dakik, MD

David A. Mankoff, MD, PhD

DuPont Fellowship Studies Involve ^{99m}Tc Sestamibi

This year's DuPont Pharma Cardiovascular Nuclear Medicine Research Grants will go to an investigator studying the use of ^{99m}Tc sestamibi myocardial perfusion imaging to risk-stratify patients, and to another researcher also using ^{99m}Tc sestamibi imaging, along with rest-redistribution