MEDICAL PRACTICE GUIDELINES: IS COOKBOOK MEDICINE HERE?

by WILLIAM J. OETGEN, COL, MC, USAR* and MARY JO WILEY, R.N., J.D.

After a 74 year old woman died in Illinois of breast cancer, her husband and the executor of her estate brought a suit that claimed medical malpractice on the part of one of her doctors.[1] The plaintiffs specifically alleged that the physician had violated the standard of care when he failed to recommend or order a screening mammogram for the patient during the three years prior to the diagnosis of her breast cancer when he served as her general physician. Medical experts for both sides based their testimony regarding whether the standard of care was breached on guidelines established by the American Cancer Society (ACS), the National Cancer Institute, the American Medical Association (AMA) and the American College of Physicians. The defendant argued that the ACS guidelines, as well as recommendations made by other medical organizations, were only "signposts" to assist an internist in practice and were clearly not the "standard of care."

In Illinois, the standard jury instruction states "the only way the jury may decide whether a defendant possessed and applied the knowledge and used the skill and care which the law required of him is from expert testimony (and) (or) evidence of professional standards of conduct."[2] Because the experts disagreed as to the impact of the various guidelines, the trial court exercised its discretion and excluded them as evidence of professional standards. A state appellate court reversed that decision and remanded the case for a new trial. The court declared that the guidelines, although contested, should be admitted as evidence of professional standards. In summary, a jury would have to hear all the arguments and determine the weight to be granted the evidence. In the context of this legal decision, some physicians may view practice guidelines as the self-created noose by which they hang themselves in court.

During the second presidential debate in October 1992, candidate Bill Clinton said, "I've recommended that our doctors be given a set of national practice guidelines and that if they follow those guidelines, that raises the presumption that they didn't do anything wrong." Thus, the concept of medical practice guidelines, or practice parameters, as the AMA prefers, was added to the political porridge.

What are practice guidelines? How are they developed? What are the legal implications of practice guidelines? How will they affect medical practice now and in the future? These are questions posed by physicians with increasing frequency.

Practice guidelines are defined as "systematically developed statements of recommendation for patient management to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[3] The AMA has embraced the concept of practice guidelines, and, in 1989, its Office of Quality Assurance and Medical Review began publishing the *Directory of Practice Parameters: Titles, Sources, and Updates*.[4] This title identified 700 published practice guidelines in all fields of medicine. The 1994 edition of the *Directory* contains over 1500 references, identifies 240 recently published guidelines and another 310 in development. Practice guidelines are not written to last forever, and the 1994 *Directory* also lists 150 guidelines that have been recently withdrawn by their sponsoring organizations. In addition, the names and addresses of 69 sponsoring organizations which have supported the development and publication of the guidelines are also referenced. These organizations span a range of medical specialty societies, from the American Association of Neurological Surgeons through the American Society of Colon and Rectal Surgeons. Further, they include government agencies such as the National Institutes of Health, and the Federal

*Chief of Cardiology, Fort Washington Hospital, Fort Washington, MD; Clinical Associate Professor of Medicine, Georgetown University School of Medicine, Washington, DC. In recent years, Dr. Oetgen has performed reserve duty as a medical consultant, Armed Forces Institute of Pathology, Department of Legal Medicine.

Agency for Health Care Policy and Research, philanthropic organizations such as the National Kidney Foundation, and private research firms such as the RAND Corporation.

Dr. David Eddy of Duke University has noted that practice guidelines are not new phenomena and that many textbooks of medicine are full of them under the "treatment" rubrics.[5] He notes that many have become "grandmotherly" adages; to treat frostbite, for instance, the physician is advised, "freeze in January, operate in July."[6] What is novel is that practice guidelines are being used today not as suggestions to practitioners but as benchmarks for regulatory activities, such as utilization review, quality assurance, credentialing, cost containment, and malpractice litigation.

A driving impetus to formalize and publish officially sanctioned practice guidelines occurred in the mid 1980's and resulted from the confluence of three forces. The predominant force was the rising cost of health care to the federal government. Diagnosis related group payment had been successfully applied to Medicare hospital expenditures. The fastest growing component of the federal health care bill then became physician payments under Medicare. Congress developed a keen interest in scrutinizing physician services for medical necessity and effectiveness and held provider reimbursement in the balance.

Secondly, an increasing awareness of medical outcomes research had begun to influence health care policy debates. In the early 1970's Dr. John Wennberg from Dartmouth Medical School documented substantial geographic variations in the rates of surgical procedures, which occurred in spite of the presence of nearly homogeneous populations. In one of the earliest studies, the rate of tonsillectomy varied from 13 per 10,000 residents in one Vermont community to 151 per 10,000 in another.[7]

Subsequently, researches began to construe statistically significant elevations in surgical rates as potential indicia of inappropriate surgery, and studies were designed to test clinical appropriateness of treatments. In a 1987 RAND Corporation study of Medicare patients, 17% of coronary angiography, 17% of upper gastrointestinal tract endoscopies, and 32% of carotid endarterectomies, adjudged by predetermined selection criteria, were considered inappropriate treatment.[8] The issue of inappropriate care became the third force driving governmental interest in clinical practice guidelines.

With potential reimbursement and public determination of appropriate clinical care at stake, many medical specialty organizations quickly realized an interest in publishing clinical practice guidelines. This was a new endeavor for some, but for others, such as the American College of Cardiology, this was a continuation of activities commenced years earlier.

Congress formalized the process on the federal level in 1989 when it established the Agency for Health Care Policy and Research (AHCPR). The stated purpose of the agency is to enhance the quality, appropriateness and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing and delivery of health services.[9] The AHCPR is part of the United States Public Health Service and functions at the same administrative level as the Center for Disease Control and the National Institutes of Health. A component of its mission is the development and promotion of clinical practice guidelines.

The AHCPR has published several practice guidelines. The first was published in March 1992 and dealt with postoperative pain management. It was published in three forms: a definitive scientific paper, a reference summary for physicians, and a patient pamphlet. Reaction by providers and the public appeared quite favorable, as with the next two federal guidelines, devoted to urinary incontinence and decubitus ulcers. The

following two guidelines, regarding the evaluation and treatment of cataracts and mental depression, however, stimulated some controversy. For instance, optometrists complained about the conclusion of the cataract panel that postoperative care be performed only by operating ophthalmic surgeons, and psychologists strongly objected to medication-oriented therapies favored by the depression guideline.[10]

State legislatures have also passed laws dealing with practice guidelines and their implementation.[11] Minnesota and Washington have enacted health care reform legislation that created commissions to develop and promulgate practice guidelines to minimize unnecessary and ineffective care. Florida's statute specifically addresses the issue of cost effectiveness as well as the quality of care.[12] Maryland's new health care reform package establishes a multidisciplinary commission, including three physicians, to research and develop practice guidelines.[13]

The medical community has often voiced strong reservations about the publication of practice guidelines, especially with regard to their legal implications. Physicians' greatest fear is that a technical deviation from a guideline will be construed as negligence *per se*, conclusive evidence alone, or "by itself", of legally substandard care.

No jurisdiction has permitted a deviation from a practice guideline to be equated with conclusive evidence of malpractice. Some jurisdictions, such as Illinois, will permit the admission of a relevant guideline as one piece of evidence but not as the definitive evidence of applicable standards of care.

Most often, those jurisdictions also insist that the published guidelines cannot be introduced in the form of documented evidence alone. They compel the presence of an expert witness to introduce the guidelines to the judge or jury, to substantiate their authenticity and their relevance, to explain their contents, and to be subjected to potential cross examination. Further, defendants retain their rights to present evidence that the proffered guidelines were irrelevant to the clinical circumstances, that any deviation whatsoever had occurred, or that the reasonable practice of medicine embraced the care as rendered, regardless of the guidelines or any technical deviation.

The idea that adhering to practice guidelines could provide a shield against liability in malpractice cases has helped overcome some physicians' antipathy toward their publication.

Maine, in its Medical Liability Demonstration Project (the Project), is currently experimenting with giving conclusive effect to practice guidelines for the defense of malpractice claims.[14] The Project initially funded the development of practice parameters or guidelines in four medical specialties: obstetrics and gynecology, radiology, emergency medicine and anesthesiology. State legislation gives those guidelines the force and effect of law. The rationale of the Project is that "practice guidelines provide a means of using health care resources more efficiently, discouraging the practice of defensive medicine, improving the quality of medical care, reducing the incidence of iatrogenic harm, and rationalizing medical malpractice litigation."[15] The guidelines published to date are literally checklists, almost like recipes for appropriate medical care. They have been in effect since 1991. What would have once been abhorrent to some physicians has become tolerable, even desirable, in Maine, because the legislature has created a nearly irresistible incentive for physicians-malpractice immunity.

In a medical malpractice action against a physician participating in the Project, only the physician may introduce the practice guidelines into evidence. As an affirmative defense, the physician must then prove compliance with the guideline. Once the guideline is introduced, the plaintiff may offer rebuttal evidence to

support noncompliance. If the jury concludes that the practice rendered complied with the published guideline, the physician cannot be found liable for malpractice. While some physicians remain dissatisfied with the cookbook nature of Maine's guidelines, few quarrel about the obvious benefit of liability protection.

Similar to Maine, legislation in Minnesota cites adherence to approved practice guidelines as an absolute defense to malpractice charges, allowing physicians to employ them to support a defense of care rendered within standards but prohibiting their use by plaintiffs to evince substandard care.[16,17] Florida included liability protection in its clinical guideline statute as an effort to reduce the expense of defensive medical practices.[18] Maryland specifically prohibits either plaintiff or defendant from citing practice guidelines in malpractice cases, while the state of Washington specifically encourages the use of guidelines as evidence in medical liability cases. At the national level, no legislation exists that links practice guideline adherence to protection against claims of negligence.

Empirical evidence that clinicians are applying practice guidelines to patient care is sparse. Despite the growing interest in practice guidelines at the policy level, it appears that only half of physicians use the guidelines available with any regularity. In 1994, the *American Medical Association News* reported that hospital-based specialists were more likely to use guidelines than office-based generalists.[19] The *AMA News* also reported that an American College of Physicians survey, scheduled for publication in January 1996, has found a generally favorable reaction by physicians to guidelines. Two-thirds of the internists surveyed considered guidelines convenient sources of advice and good educational tools. A similar proportion agreed that guidelines could improve the quality of care. Only one-fourth objected to guidelines because they represented "cookbook" medicine, and a slightly smaller proportion objected to them on the grounds of their reducing physician autonomy. Less than one-fifth of those surveyed thought that guidelines would reduce malpractice suits.

Practice guidelines are now a familiar fixture on the American medical scene. Their theoretical ability to improve quality of care, reduce inappropriate care, minimize differences in geographic usage, and limit malpractice exposure has captured the imaginations of candidates, legislators, policy makers and quality reviewers. Clinicians expected to apply them have been cautiously slower with their embrace.

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Presentation on theme: "Clinical Practice Guidelines â€¦.cookbook medicine? Mike Starr Chair, Statewide CPG Steering Group."â€” Presentation transcript: 1 Clinical Practice Guidelines â€¦.cookbook medicine? Mike Starr Chair, Statewide CPG Steering Group.Â 5 â€œGuidelines are a constructive response to the reality that practicing physicians require assistance to assimilate and apply the exponentially expanding, and often contradictory, body of medical knowledgeâ€ Allan Sniderman, Curt Furberg, JAMA Research â†’ Clinical Practice 5-10 years. 6 What could be useful to an resident or nurse in ED? 10pm Friday Night 15 patients in cubicles 35 more in waiting room Mild Asthma Septic young infant. Guidelines for selected areas of practice in obstetrics/gynecology, emer-gency medicine, radiology, and anesthesia were developed by four medical specialty advisory committees appointed by the Maine Board of Registration in Medicine (see box H-l). Guide-lines were developed in areas of practice where defensive medicine was believed to be extensive. The statute permits physicians electing to par-ticipate in the demonstration to use these guide-lines as an affirmative defense in medical mal-practice proceedings. Under the affirmative defense provision, use of guidelines as evidence is no longer ... This is not cookbook medicine â€“ instead, it allows us for the first time to effectively collect data about adherence to guidelines, appropriate deviations from guidelines, and eventual correlation of process measures and the effects of those measures on clinical outcomes. There is no better way to document the significance of process measures of all classification levels than to do so at the point of care and correlate that information with clinical outcome in thousands of patients. Practice guidelines are being introduced throughout medicine, but expectations about their impact on patient care depend on whether one is a clinician, patient, payer, administrator, or politician. Proponents hope that guidelines will enhance the knowledge, attitudes, and behavior of practitioners and will optimize health outcomes, costs, and malpractice decisions, but scientific evidence of these effects is limited. There are also concerns that guidelines could harm patient care. Clinicians worry that guidelines will promote "cookbook medicine," decrease their autonomy and income, and increase medicolegal liability. A particular concern relates to the expansion of enforcement programs that require clinicians to follow guidelines or face financial or other penalties. Current Hospital Medicine: Quick guide for management of common medical conditions in acute care setting. by Amil Rafiq MD Paperback. $22.89. In Stock. Ships from and sold by Amazon.com. FREE Shipping on orders over $25.00. Critical Care and Hospitalist Medicine Made Ridiculously Simple. by Michael Donahoe Paperback.Â Love love love this book. I use it daily when doing admissions to capture guidelines requirements for different conditions. Read more. Helpful. Report abuse. Amazon Customer. 3.0 out of 5 stars good but not great. Reviewed in the United States on November 28, 2018.