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CLINICAL PRACTICE GUIDELINES AS LEGAL STANDARDS – THE WRONG CURE FOR HEALTH CARE

Summary: Clinical practice guidelines should never be the legal basis for determining whether or not patient harm was the result of negligence, and allowing use of guidelines only by a physician or facility to defend itself against a medical malpractice claim, and not by an injured patient to show negligence, is without any justification and is fundamentally unfair.

Recent discussions about national health care have included suggestions by some political leaders that doctors who practice “evidence-based medicine”¹ or more specifically, follow “clinical practice guidelines”² (that may or may not stem from “evidence-based medicine”³), should be immune, or presumed to be immune, from lawsuits - even though a patient may have been injured or killed.

Both sides in malpractice litigation currently make limited use of clinical practice guidelines in settlement negotiations, or even to help lawyers decide whether or not to file suits.⁴ However, there are two major differences between this practice and recent proposals, *both of which raise serious concerns about fairness and patient safety*:

- Recent proposals suggest that “evidence-based medicine” or its “most common practical embodiment, clinical practice guidelines”⁵ should become the legal standard for deciding liability in a medical malpractice case, and;
- Use of such guidelines would be permitted only by the defense, in order to exculpate a physician. “Inculpatory” use would not be allowed by patients when presenting their cases.

ONE-SIDED CLINICAL GUIDELINES AS LEGAL STANDARDS ARE UNFAIR AND RISK PATIENT SAFETY

- **Patient safety can benefit from clinical practice guidelines.**
 - When triggered by the desire to reduce unwarranted variation in practice and provide patients with benchmark quality care rooted in science, adherence to clinical guidelines can improve patient safety. In 1985, for example, anesthesiologists, motivated by increasing malpractice premiums and studies showing that human error was the most frequent cause of patient harm, undertook a thorough examination of their practices. After reviewing claims from 35 different insurers, the specialty of anesthesiology developed practice guidelines specifically aimed at reducing preventable harm to patients. As a result, “the risk of death from anesthesia dropped from 1 in 5000 to about 1 in 250,000.”⁶

- **When clinical practice guidelines are developed to meet non-safety-related goals, they can actually negatively impact patient safety and lead to unfair results.**
 - **Cost considerations.** Some clinical guideline development has been stimulated because of pressure from managed care and health plans, “pursuing an aggressive agenda of cost containment.” Guidelines developed for the sole purpose of guiding coverage decisions has been criticized as “having no relevance to quality of care debates.”⁷ In fact, guidelines developed in this manner would reflect “what the profession at large currently does not do” instead of being developed through the typical, science-based professional consensus process.⁸ Adopting such guidelines as a legal standard “*would be a substantial departure from existing law.*”⁹
 - **Bias and Immunity.** There is already a general recognition that conflict of interest and specialty bias are ongoing problems in the development of clinical practice guidelines.¹⁰ If medical and specialty societies are allowed to participate in writing guidelines they know will be exculpatory for their members, conflicts of interest and bias will escalate. For example, specialty societies, like the American College of Obstetricians and Gynecologists (ACOG), have been aggressive leaders in the medical lobbies’ push for liability limits in the last few years¹¹ and remain committed to that goal.¹² It would be fundamentally unjust for patients to have their cases judged by liability standards chosen by ACOG for the purpose of exculpating fellow obstetricians.

THE PLETHORA OF OFTEN CONTRADICTIONARY GUIDELINES FOR THE SAME AREA OF MEDICAL PRACTICE RAISES SERIOUS QUESTIONS ABOUT THEIR USE AS LEGAL STANDARDS.

- It is estimated that more than 1400 sets of clinical practice guidelines exist today.¹³ While some standards, such as those in anesthesia, are “simple and clearly defined” and easily complied with, others, such as on obstetrical cases, are complicated and can be contradictory.¹⁴ Moreover, as they are written for “average patients” and cannot encompass the huge variation in how patients present, there may be good reason to vary from a guideline’s recommendation for a patient. Even experts firmly committed to evidence based medical practice recognize that there may be benefit to avoiding a “one size fits all” approach.
- As one commentator wrote, “Knowledgeable, respected professional groups can, and often do, come down on opposite sides on a particular treatment issue.... Accepting that there will almost certainly be multiple guidelines for many conditions, courts will have to engage in a process of deciding, when guidelines conflict on a material point, which one to treat as authoritative, or more authoritative. This promises to be a daunting task.”¹⁵
- Attempting to establish a single authoritative guideline for every medical condition would result in a loss of “public, professional, and judicial confidence” in the guideline itself. As one commentator wrote, “achieving such unanimity would require designating some entity, presumably a governmental agency, as the sole arbiter of what is acceptable medical practice. That is practically and politically inconceivable; the commitment to pluralism and

competition is too deeply ingrained in the American spirit, to say nothing of pervasive distrust of government processes.”¹⁶

THE MEDICAL PROFESSION ITSELF HAS NOT ACCEPTED CLINICAL PRACTICE GUIDELINES AS APPROPRIATE LEGAL STANDARDS, EVEN FOR EXCULPATORY PURPOSES.

- **AMA.** Because of questions about confidence in guidelines in the past, the American Medical Association has opposed use of guidelines as a legal standard even when they are only allowed for exculpatory purposes, urging instead “that they be used only as evidence of the customarily observed professional standard of practice and that their degree of authority be dependent upon the degree of their acceptance among medical practitioners.”¹⁷
- **State Experiments.** Only a few states have ever attempted to develop and use certain guidelines as legal standards. These limited state experiments, which began and ended in the 1990s, provide little support for adoption of guidelines as national policy.
 - **Maine.** In the 1990s, Maine established a program that allowed doctors in four specialties—anesthesiology, emergency medicine, obstetrics and gynecology, and radiology—to participate in a program allowing use of guidelines as exculpatory evidence in lawsuits. Other specialties were encouraged to take advantage of this program but did not. The program expired, and the Maine Bureau of Insurance concluded, “the medical demonstration project had no measurable effect on medical professional liability claims, claims settlement costs, or malpractice premiums.”¹⁸
 - **Other states.** In 1996, Florida also began a demonstration project for cesarean deliveries, but reportedly “garnered relatively little support among physicians—only 20% of physicians eligible to participate chose to do so and the project ended in 1998.... Three other states (Kentucky, Maryland, and Minnesota) adopted test projects in the 1990s, though none of the projects is fully operational today (the Maryland and Minnesota projects have fully expired).”¹⁹

ONE-WAY USE OF GUIDELINES RAISES FUNDAMENTAL ISSUES OF FAIRNESS AND CONSTITUTIONALITY.

“[A]llowing such one-sided use of evidence in a court of law raises disturbing questions of fairness and of validity under the U.S. Constitution's Fifth and Fourteenth Amendments’ due process and equal protection mandates, and under state constitutional principles as well.”²⁰

NOTES

¹ Evidence-based medicine is “defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” *Journal of Health Politics, Policy and Law*, Vol. 26, No. 2, April 2001.

² As defined by the Institute of Medicine, clinical practice guidelines are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” Andrew L. Hyams;

Jennifer A. Brandenburg; Stuart R. Lipsitz; David W. Shapiro; and Troyen A. Brennan; “Practice Guidelines and Malpractice Litigation: A Two-Way Street, *Annals of Internal Medicine*, 15 March 1995 | Volume 122 Issue 6 | Pages 450-455.

³ “EBM[evidence-based medicine] can show up in forms other than CPG[clinical practice guidelines]—for example, in journal articles, unpublished studies, and expert testimony. Conversely, CPGs are not necessarily based upon EBM—although the vast majority of the CPGs being generated nowadays are, or at least purport to be. Cynthia Mulrow and Kathleen Lohr’s essay recognizes that guidelines generated primarily through a professional consensus process—the traditional approach—may differ from those based more directly on hard, empirical evidence—the EBM approach.” Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” *Journal of Health Politics, Policy and Law*, Vol. 26, No. 2, April 2001.

⁴ Andrew L. Hyams; Jennifer A. Brandenburg; Stuart R. Lipsitz; David W. Shapiro; and Troyen A. Brennan; “Practice Guidelines and Malpractice Litigation: A Two-Way Street, *Annals of Internal Medicine*, 15 March 1995 | Volume 122 Issue 6 | Pages 450-455.

⁵ Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” *Journal of Health Politics, Policy and Law*, Vol. 26, No. 2, April 2001.

⁶ George J. Annas, J.D., M.P.H., “The Patient’s Right to Safety – Improving the Quality of Care through Litigation against Hospitals,” *New England Journal of Medicine*, May 11, 2006.

⁷ Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” *Journal of Health Politics, Policy and Law*, Vol. 26, No. 2, April 2001.

⁸ *Ibid.*

⁹ *Ibid.*

¹⁰ “Developing Trusted Clinical Practice Guidelines, Selected Findings from Knowing What Works in Health Care: A Roadmap for the Nation,” Institute of Medicine, January 2008.

¹¹ See, e.g., ACOG News Release, Mark 25, 2005 http://www.acog.org/from_home/publications/press_releases/nr03-15-05.cfm; Help Your Patients Push for Medical Liability Reform, http://www.acog.org/departments/dept_notice.cfm?recno=11&bulletin=3933

¹² “A new and rapidly growing specialty society coalition called Doctors for Medical Liability Reform is poised to wrest the helm of the tort reform campaign from the American Medical Association. With \$10 million in its coffers so far, Doctors for Medical Liability Reform (DMLR) plans an aggressive television campaign during the 2004 election season with one goal in mind: to change the balance of power in the U.S. Senate to guarantee passage of a federal medical liability reform bill. Other \$1-million donors are the American Association of Neurological Surgeons/Congress of Neurological Surgeons, the American College of Emergency Physicians, the American College of Surgeons, and the American Academy of Orthopaedic Surgeons. The American College of Cardiology pledged \$500,000, and the North American Spine Society pledged \$100,000, according to Dr. Dunsker....[T]he American College of Obstetricians and Gynecologists and the American Academy of Dermatology had also joined the new coalition and agreed to donate undisclosed amounts. Peggy Peck, “Coalition includes ACOG: specialty societies push tort reform, *OB/GYN News*, March 1, 2004.

¹³ Andrew L. Hyams; Jennifer A. Brandenburg; Stuart R. Lipsitz; David W. Shapiro; and Troyen A. Brennan; “Practice Guidelines and Malpractice Litigation: A Two-Way Street, *Annals of Internal Medicine*, 15 March 1995 | Volume 122 Issue 6 | Pages 450-455.

¹⁴ Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” *Journal of Health Politics, Policy and Law*, Vol. 26, No. 2, April 2001.

¹⁵ *Ibid.*

¹⁶ *Ibid.*

¹⁷ *Ibid.*, citing (American Medical Association 1993: 58; Hirshfeld 1993: 323) (“As Richard F. Corlin, M.D., testified on behalf of the AMA (1993: 58): ‘At the present time, insufficient evidence exists to show that clinical practice guidelines can be developed in a manner specific enough to be introduced as an affirmative defense in medical liability litigation.’ It is notable that the AMA’s reservation about CPGs was stated even in the context of their defensive use.”

¹⁸ Linda L. LeCraw, Esq., “Use of Clinical Practice Guidelines in Medical Malpractice Litigation,” *Journal of Oncology Practice*, Vol 3, No 5 (September), 2007.

¹⁹ *Ibid.*

²⁰ *Ibid.*