How Technocrats are Taking Over the Practice of Medicine

A Wake-up Call to the American People

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Citizens' Council on Health Care

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Evidence is said to be the new bright star of health care. A growing chorus of voices is thus calling for physicians and other health care practitioners to follow evidence-based medicine (EBM), or so-called "best practices." To practice EBM, supporters say physicians must follow evidence-based clinical practice guidelines.

Despite being painted as scientifically sound, there are more than a few detractors of EBM, including physicians, patients, and researchers. Even those who support evidence-based medicine and practice guidelines worry about how it may play out in real-life patient care.

This paper will introduce the concepts, note the assertions of supporters, highlight the concerns of critics, question the emphasis on evidence and clinical guidelines for the practice of medicine, identify the costs of guidelines, and show how EBM is making its way into state and federal laws, including medical malpractice reform initiatives. A word about terminology: this report uses "guidelines," "best practices," " algorithms," and "protocols" interchangeably.

Introduction

Clinical practice guidelines are the embodiment of evidence-based medicine.[1] Managed care organizations began developing guidelines in the 1990s to identify inappropriate medical care and reduce unnecessary utilization of services.[2] More recently, state and federal policy makers have incorporated "best practices" or evidence-based guidelines in legislative proposals aimed at health care cost containment and medical malpractice reform.[3]

Practice guidelines "specify the processes of diagnosing and treating particular conditions." [4] Or as defined by the Institute of Medicine (IOM), the federally-funded organization providing the U.S. Congress with health care policy research, "evidence-based guidelines" are:

> Consensus approaches for handling recurring health management problems aimed at reducing practice variability and improving health outcomes. Guideline development emphasizes using clear evidence from the existing literature, rather than expert opinion alone, as the basis for advisory materials.[5]

Proponents of EBM argue that "there are no systems in place for ensuring that best practices are consistently implemented."[6] They claim that physician compliance with guidelines—essentially, practice directives—will reduce "overuse," "underuse," and "misuse" of health care services[7 8 9] (considered by IOM to be the primary quality problems in American health care today[10]).

Moreover, some claim that "although we perceive the U.S. health care system as superior, there are serious and widespread quality problems. There is a gulf between ideal care and what actually takes place."[11] Others point to the 2003 RAND study reported by Elizabeth McGlynn et al., which concludes, "Americans receive about half of recommended medical care processes."[12] However, most EBM advocates do not mention the study's limitations. Earl P. Stinberg, M.D. says the RAND study does not mean adults have only 50 percent chance of getting adequate care. He notes poor documentation in the medical charts used, and a focus on compliance with management recommendations—essentially, guidelines—rather than on how well the patient's medical conditions were actually controlled.[13]

EBM involves a takeover of the clinical consultation by managers and statistical technocrats empowered to define "best practice."

Evidence-based medicine advocates also claim that guideline adherence will protect physicians from malpractice litigation, limit variation in physician practice patterns, and improve quality of care. In addition, advocates believe adherence will cut costs by reducing the practice of "defensive medicine"—which is described by the U.S. Office of Technology Assessment as the ordering by physicians of "tests and procedures, or avoidance of high risk patients or procedures, primarily (but not necessarily solely) to reduce their exposure to malpractice risk."[14]

Compliance with treatment directives, rather than the practitioner's opinion, gut instinct, or clinical experience is preferred by some EBM proponents.[15] [16] Using "evidence" to direct treatment decisions is emphasized, as former U.S. Senator David Durenberger, now CEO and Chair of the National Institute of Health Policy, makes clear when he instructs patients:

> Ask your health care providers about how they make care decisions. Are they using clinical evidence-based guidelines to determine the treatment? Are the clinical outcomes as expected? High-quality clinical decisions come from 'gold standard' evidence—education, training, practice and organizational guidelines built on a culture of quality.[17]

It would be difficult to find a physician opposed to "high-quality clinical decisions," but not all doctors support standardized treatment protocols or so-called "best practices." Thus, although the IOM endorses clinical practice guidelines (CPGs) saying they "aim to change clinical practice to make it more consistent around a definition of best practice,"[18] others view such guidelines as a "cookbook" for patient care.[19]

According to Professor Arnold Rosoff, J.D., at the University of Pennsylvania,

> Some decry the spread of CPGs as the advent of "cookbook medicine," having the potential to turn doctors into automatons and lower the quality of health care by subordinating and subverting professional skill and judgment. [20]

Some physicians view EBM—and its associated treatment directives—as a fancy term for imposing rigid standards of care, cutting costs, and restricting professional freedom and judgment.[21] As written in *QJMed*, "Evidence-based medicine involves a takeover of the clinical consultation by an alliance of managers and their statistical technocrats who are empowered to define 'best practice,'" yet retain no responsibility for the clinical consequences.[22]

Moreover, physicians may disagree on what constitutes "best practice."[23] According to Woolf et al., the view of practice guidelines depends on who is doing the evaluation:

> [A]ttitudes about whether clinical guidelines are good or bad for medicine vary from one group to another. Guidelines produced by governments or payers to control spiraling costs may constitute responsible public policy but may be resented by clinicians and patients as an invasion of personal autonomy. Guidelines developed by specialists may seem self-serving, biased, and threatening to generalists. To specialists, guidelines developed without their input do not contain adequate expertise. Inflexible guidelines with rigid rules about what is appropriate are popular with managers, quality auditors, and lawyers but are decried as 'cookbook medicine' by doctors faced with non-uniform clinical problems and as invalid by those who cite the lack of supporting data.[24]

Practice Guidelines – HMOs

In the private sector, HMOs and other health plans strongly support the development and use of clinical practice guidelines. For example, six managed care organizations fund the Institute for Clinical Systems Improvement, a major guideline development organization.[25]

Alan Muney, M.D., from Oxford Health Plans, clarified the importance of clinical guidelines to managed care plans. At a 1999 medical education conference, he said the "second generation of managed care" will focus on using evidence-based medicine as a method

"It is not stretching things too far to say that whoever controls practice policies controls medicine."

to identify and control clinical practice outliers[26] — those physicians who practice outside prescribed guidelines. In fact, some managed care organizations may prefer that physicians be trained early to follow these treatment protocols. As Dr. Muney explained,

> The purpose of such a program [evidence-based education] is to drive lifelong adherence to clinical practice guidelines resulting in improvement in the value of healthcare expenditures. The target audience is medical students, interns, and residents.[27]

Most physicians, but likely few patients, know that practice guidelines are already a prominent feature of HMOs and managed care. In fact, managed care organizations often claim a strong evidence base for the practice guidelines and treatment algorithms they give physcians to follow. As Uwe Reinhardt, Ph.D., a noted economist and professor at Princeton University, says:

> EBM is the sine qua non of managed care, the whole foundation of it.[28]

Guidelines – A Public Sector Example

The push to require physician adherence to treatment protocols has advanced across the country as state budgets are increasingly squeezed by the high cost of public health care programs. Some administrators and government officials claim treatment guidelines can not only cut costs in Medicaid, but improve care.[29] For example, Minnesota Governor Tim Pawlenty, in his 2004 State of the State address, said his administration's approach to health care will include,

> …leveraging the purchasing power of the state and other partners to force health care providers to use best practices and deliver higher quality results.[30]

Although Governor Pawlenty's plan did not sit well with the public—a stack of citizen and physician petitions more than 12-inches high was delivered to his office—the Governor signed the "best practices" bill into law on May 29, 2004.[31] The new law authorizes government-issued "best practices" guidelines, government data collection, and public reporting of physician adherence to government-defined "best practices." It also permits contractually-based financial penalties for health plans whose physician-employees and physician networks do not adhere to "best practices" guidelines in the treatment of state employees and recipients of government health care programs, such as Medicaid.

Shortly after the bill was signed, *Minnesota Physician* published an interview with the governor. Although Governor Pawlenty stated his opposition to government micromanagement of treatment decisions, his comments seem to advocate an implicit version of it:

> I don't think we want government micromanaging health care or presenting the government-sanctioned cookbook on how physicians should practice. I'm not interested in that. What I am interested in is using higher rates of reimbursement or premium reimbursement rates if providers achieve certain outcomes, better outcomes.[32]

No details were provided regarding how the terms "certain outcomes" or "better outcomes" would be defined—or payment decisions made. But the intent appears to include financial rewards for health plans who can coax or coerce physician performance matching a yet undefined list of government treatment stipulations which may or may not coincide with patient needs or preferences.

Attack on Autonomy

Practice guidelines can be "a mechanism for nonclinicians to use in controlling clinicians."[33] David M. Eddy, M.D., Ph.D., notes that the use of practice guidelines as management tools "puts a mechanism designed for internal use in the hands of 'outsiders,' such as utilization reviewers, the government, and insurers. Not only does this expose internal thoughts to external scrutiny, it opens those thoughts to manipulation."[34] He further cautions,

> It is not stretching things too far to say that whoever controls practice policies controls medicine.[35]

Total population management will ensure physician use of evidence-based medicine and reward doctors for adherence to guidelines.

Control over practice policies does not appear to be headed in the direction of physicians or patients. David Plocher, vice president of health consulting for Cap Gemini Ernst & Young, predicts that the future of total population management (TPM) will include ensuring physician use of evidence-based medicine, financial incentives for patient compliance, developing methods to measure outcomes, and rewarding doctors for adherence to guidelines.[36]

Another suggested use of guidelines could eventually lead to reduced patient access to physician care. At a roundtable discussion on diabetes, Gary Rice, M.S., Director of Pharmacy and Retail Services at Texas-based Kelsey-Seybold Clinic, discussed his company's plan:

> With this data warehouse [of 7,000 patients], our goal is to get the physicians to allow the pharmacist to gain access to that data and to allow the pharmacist, through clinical protocols and pathways, to be able to dose escalate, dose change, and therapy change based on those protocols.[37]

Convincing physicians to leave their professional autonomy and responsibilities behind requires a certain array of tools, including financial incentives. A project by the American College of Cardiology (ACC) sought to "better understand what factors led to more rapid and complete alignment of practice with the recommendations in the guideline."[38] The ACC project found that adherence to guidelines was improved when "critical recommendations are embedded in the practice environment," including reminders on key performance goals for clinicians.[39] The study's authors note,

> [A]pplying those guidelines in practice requires systems to structure the environment in which care is delivered so that 'doing the right thing' becomes automatic. This requires tools that simplify and provide focus by embedding the recommendations for evidence-based care into the care itself…Achieving this—that is, changing and aligning the behavior of clinicians and managers—is no small accomplishment… Clearly, appropriate financial incentives and regulatory stimuli can play a role. Doing what is 'right' is more likely to occur when knowledge, systems, and incentives are aligned.[40]

Payment for doing what is dubbed "right" does not sit well with some physicians who take umbrage with the very idea of such "pay for performance" proposals. Roy B. Verdery, Ph.D., M.D., responded to an article published in *The New England Journal of Medicine* titled "Paying Physicians for High-Quality Care." He wrote,

> Epstein et al. would have us conform to static norms and care for uniform patients, with money as our primary reward. We would prescribe only the "right" drugs, use only the "best" techniques, and implant only the "best" devices, as determined by formularies, pundits, and industry-sponsored studies…Economic incentives are always subject to "gaming," inappropriate manipulation of data, and "cherry-picking" of patients by physicians and groups more interested in making money than in providing good care. Most physicians (and other professionals) work for rewards that are more important than money, including the respect of their patients and peers and the personal satisfaction of a job well done.[41]

Dr. Verdery has legitimate cause for concern. It appears that the treatment of patients outside guideline specifications is already considered a "violation" —in other words, wrong—by one consortium of large employers, The Leapfrog Group. In November of 2003, members of the American Medical Association received a presentation from a representative of the group. Their proposals for physician offices included, "Generation of periodic reports of guideline-adherence rates for the physician office's patient population as a whole," and "Flagging (and documented override) of clinical guideline violations." [42]

That practice guidelines may restrict patient care and physician autonomy does not bother one physician researcher. Dr. Marshall de Graffenried Ruffin, Jr. in *The Physician Executive,* writes, "Evidence-based medicine can be seen as an acceptable, even necessary, limita-

EBM is about the destructive industrialization of medicine by those who want to control it.

tion of clinical freedom, because it leads to practice guidelines meant to standardize and reduce the variation in clinical care." [43]

However, variation in care does not necessarily equate with bad medical practice. Gary Belkin, M.D., Ph.D., writing from Harvard University, asserts, "Very respectable and productive medical traditions found variations natural and expected." He also notes that variation was "not a problem discovered," but instead came to be considered a problem when cost control through standardization became a goal of researchers and HMOs.[44]

Shifting Control through "Science"

Dr. Belkin is author of one of the most comprehensive papers on the motivation and philosophy behind the new focus on scientific evidence in medicine. He says EBM is not purely about so-called "good science," but about the destructive industrialization of medicine by those who want to control it.[45]

In "The Technocratic Wish: Making Sense and Finding Power in the 'Managed' Medical Marketplace," Belkin writes, "we need to explain how a given version of scientific credibility is embraced to sustain influence and power in society." [46]

Dr. Belkin argues that analyzing patient data, measuring physician performance, and calling the process "scientific" is the mechanism being used today to shift power and control away from physicians—and undermine the doctor's longstanding role as medical expert:

> By offering a scientific solution, [managed care] can finally crack the nut plaguing health policy for the past decades: reconciling global budgeting decisions with individual physician behavior.[47]

Arnold Rosoff, speaking at a workshop sponsored by the Agency for Healthcare Research and Quality (AHRQ) and the Institution of Medicine in April 2000, says the following in reference to Belkin's paper:

> In the arena of managed care, the technocratic wish takes the form of a search for a (seemingly, at least) objective and verifiable rationale to justify the shift of control from an entrenched medical elite to a new cadre of health services researchers, MCO [managed care organization] executives, and government policy makers. This latter group views the country's health care needs, and thus leans toward allocating its health care resources, using a systems approach, looking at issues on a macro rather than micro level, and employing population-based rather than individual-based measures to assess the utility and cost-effectiveness of health care inputs.
>
> To put it another way, the technocrats tend to measure the success of health care activities by looking at their aggregate effect on populations rather than on individual patients, contrary to the clinician's natural tendency to focus on the individual patient she or he is currently treating.
>
> To implement their health care philosophy, those who share the technocratic wish collect data from entire populations, crunch the numbers, and express their conclusions as to what works best in terms of population-wide statistics.
>
> …In Belkin's view, managed care has embraced the technocratic wish in its desire to find a rationale and a mechanism for standardizing medical practice and reining in physicians' natural inclination to treat each patient as a special case.[48]

Physician Response

Although it has been reported that physician groups support "best practices" and practice guidelines,[49] the American Medical Association (AMA) is said to endorse guideline flexibility that avoids "cookbook medicine."[50] Deborah Cook, M.D., MSc. and Mita Giacomini, Ph.D. concur, writing,

> [C]linicians should heed the universal caveat that "guidelines are only guidelines," intended

Physicians subject to profiling linked to financial incentives report difficulties making appropriate medical decisions.

> to inform, rather than to tell what to do with pious certitude.[51]

Nevertheless, physicians are under pressure to comply with guidelines. Health plans, government agencies, employer groups and the U.S. Congress are developing payment models that focus on physician performance.[52] The Institute of Medicine advises that payment methods should:

> align financial incentives with the implementation of care processes based on best practices and the achievement of better patient outcomes."[53]

Doctors who provide this type of "quality care" are often eligible to receive bonuses from health plans.[54] Yet, physicians express frustration over the format of 'best practice compliance reports,' which allow only a 'yes' or 'no' response and no opportunity for an explanation.[55]

Debra Stone, from Brandeis University, warns that when payment is based on behavior, the physician's criterion for decision making can be "changed from *medically necessary* to *medically necessary for the patient and financially tolerable for the primary care doctor*." [56]

Linda Peeno, M.D., former HMO medical director, and now a consultant on managed care and health care ethics, believes that monitoring physician behavior can lead to conflicts of interest between patients and doctors—effectively severing the patient-doctor relationship:

> Studies show that physicians who have been subject to profiling linked to financial incentives—meaning that managed care organizations have detailed reports on the physicians' hospital admissions, test orders, and referrals to specialists, and they link payment to those numbers, giving higher payments and bonuses to physicians who stay within those numbers and penalizing those who exceed them—reported difficulties with making appropriate medical decisions for their patients. These physicians said they were often torn about doing what is best for the patient while working under a health plan that rewards physicians who control costs by limiting treatment.[57] *[em-dashes added for clarity]*

The Institute of Medicine similarly reports that a "cycle of fear" may result from applying practice guidelines and reporting physician compliance. Practitioners who react negatively may "try to block access to data that could contribute to similar criticism in the future."[58] One study has already found 39 percent of physicians falsifying insurance records to secure needed health care services for patients.[59]

Some physicians flatly refuse to follow certain treatment protocols. In 1996, physicians in one clinic sent their patients a letter stating that a certain health plan's insurance would no longer be accepted because the plan "insists that we follow their version of 'practice guidelines' in the treatment of each [health plan] enrollee, without any safeguards against 'undertreatment,' or withholding of optimum care."[60]

One network of independent physicians, clinics, and hospitals has put in writing their concerns about guidelines. A multi-topic document focused on informing patients has been distributed to all network physicians. The section on "best practices" explains:

> Health plans are promoting best practice guidelines as a "one-size-fits-all" concept, as if there is only one answer to a particular condition. It would be nice if there were just one way to solve every health problem. But, achieving good health is usually much more complicated. The truth is that "one-size" often doesn't fit most. The truth is patients often do not respond as predicted. The truth is that "best practice guidelines" change all the time. They change because they do not work as promised.
>
> Let's work together to determine your specific, individual needs and treat accordingly, mindful of the guidelines, but never limited by them.[61]

Even physicians who typically follow practice guide-

There are inconsistencies in medical literature supporting one practice versus another, as well as biases based on the author's perspective.

lines sometimes refuse to follow those very same guidelines—to the patient's benefit. In one study, 24 percent of doctors treating Type 2 diabetic patients did not comply with guidelines. The researchers explain: "Our data suggest that failure to follow guidelines is not necessarily explained by 'bad doctors,' or forgetfulness; rather, noncompliance may reflect valid questions about the usefulness and applicability of a best practice to an individual patient." [62]

Underscoring the myriad concerns about practice guidelines, researcher Eric Wall asks a critical question in *The Journal of Family Practice*:

> Whether guidelines fulfill their promise or merely become a tool for cost-containment, rationed care, specialty self-interest, and privilege may not be the most important question…The real question for family physicians is: who will have such control? [63]

The answer is clear, according to George E. Thibault, M.D. Control over the practice of medicine must remain in the hands of a physician at the bedside of an individual patient:

> We…need to decide which approach in our large therapeutic armamentarium will be most appropriate in a particular patient, with a particular stage of disease and particular coexisting conditions, and at a particular age. Even when randomized clinical trials have been performed (which is true for only a small number of clinical problems), they will often not answer this question specifically for the patient sitting in front of us in the office or lying in the hospital bed.[64]

The "Evidence" Problem

Much of the leadership in evidence-based medicine—the purported foundation of "best practices" guidelines—has come from Canada and England, two countries with government-run health care systems.[65]

EBM has been defined as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." [66] EBM advocates say that best evidence should be derived from the findings of (a)"randomized controlled trials" (RCTs)[67]—the so-called gold standard in research—and (b) meta-analysis,[68]—a systematic review of research studies.

However, as the Institute of Medicine notes in *Patient Safety: Achieving a New Standard for Care*, determining what classifies as authoritative evidence is not clear cut:

> There are gaps and inconsistencies in the medical literature supporting one practice versus another, as well as biases based on the perspective of the authors, who may be specialists, general practitioners, payers, marketers, or public health officials (Maviglia et al, 2003).[69]

In fact, research results can be quite contradictory. In July 2002, scientists were alarmed to learn that hormone replacement therapy using Prempro had risks, including heart attacks. These new results, coming from the large federal RCT study called the Women's Health Initiative (WHI) directly contradicted earlier and ongoing studies, in particular the longstanding Nurses' Health Study (NHS). While the NHS shows reduced risk of heart disease from hormone replacement therapy, the WHI found that women taking hormones had 40 percent more heart attacks.[70]

At issue is the reliability of all medical research. As Isaac Schiff, M.D. chairman of obstetrics and gynecology at Massachusetts General Hospital in Boston, asks,

> If there are such discrepancies, how many other medical facts do we believe based on one type of study or another type of study because we don't have the luxury of having both? [71]

Location of research and selection of subjects can also significantly impact study findings, later classified as "evidence." John Swales, Director of Research and Development at the Department of Health in London, gives the following instructive example:

"My fear is that medicine will slide into the same intellectual morass in which economists now wallow, often with politics practiced in the guise of science."

> The European Carotid Surgery Trial demonstrated a reduction in disabling or fatal stroke as a result of surgery in patients with a tight carotid stenosis [9]. Postoperative complications in the form of disabling stroke or death were low at 3.7% in a trial which was carried out largely by surgeons in specialist centres. In a community-based study carried out at approximately the same time in Medicare patients this complication rate was 9.8%, a value which would have eliminated the benefits of surgery in the European trial [10]. The 'real world' may not reflect conditions in clinical trials used in guidance for clinicians.[72]
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> [9] European Carotid Surgery Trialists Collaborative Group. MRC European Carotid Surgery Trial; interim results for symptomatic patients with severe (70 – 90%) or with mild (0 – 29%) carotid stenosis. Lancet 1991; 337:1235-43.
> [10] Winslow CM, Solomon DH, Chassin MR, Kosecoff J, Merrick NJ, Brook RH. The appropriateness of carotid endarterectomy. N Eng J Med 1988; 318: 721-7.

Furthermore, the production of "evidence" is not straightforward. As such, Dr. Uwe Reinhardt hopes the "whole evidence-based enterprise doesn't become cumbersome, ethically compromised, and ultimately useless."[73] He further cautions,

> My fear is that medicine will slide into the same intellectual morass in which economists now wallow, often with politics practiced in the guise of science. In medicine, it might be profit-maximizing in the guise of science.[74]

Canadian physician R. Brian Haynes, M.D., says evidence is not authoritative in medical decision-making. Invited to travel from McMaster University in Canada to present at a federally-funded U.S. conference on medicine and law, Dr. Haynes told the audience,

> Evidence-based medicine in practice defines the likelihood of something happening. It is never 100%. It is not absolute truth. Evidence never tells you what to do. The same evidence applied in one case may not apply in another. The circumstances of the individual may be different, or the circumstances may be the same, but patients may refuse one treatment in favor of another. What evidence-based medicine does is inform one about what the best options are—but it doesn't make the decision.[75]

Other well-recognized problems with the "evidence" used to develop practice guidelines deserve careful consideration:

- **Researcher Bias.** Values and biases of researchers determine "which research to pursue, which articles to read, and which patient-oriented outcomes are most important." [76]
- **Discordant Views.** "What counts as best evidence" varies by interpreter.[77] As a former director of the U.S. Agency for Healthcare Research and Quality writes, "Who will determine what evidence should be followed?" [78]
- **Levels of evidence.** Evidence exists in a hierarchy of importance, and several different evidence hierarchies exist, introducing confusion.[79] [80]
- **Conflicting evidence.** Evidence can be "murky, dubious, narrow, conflicting, or irrelevant." [81]
- **Source of data.** Evidence is often based on the results of clinical trials reported in peer reviewed research journals, but not all editors are qualified to distinguish between sound or flawed research protocols.[82]
- **Insufficient reporting.** Not all results of studies, particularly negative ones, are reported or available.[83] [84] [85]
- **Flawed research.** Guideline developers often fail to notice that many clinical studies have poor methodology and should not be used to draw conclusions.[86] [87] [88]
- **Selection bias.** Assembly and critique of evidence is not necessarily neutral, objective, comprehensive or rooted in science. [89]
- **Possibilities of fraud.** The principle investigator of the sole positive trial of autologous bone marrow transplant in stage II breast cancer confessed to falsifying the data.[90]
- **Loss of compassion.** Efforts to quantify the qual-

"There is great variability within scientific communities as to what evidence, techniques, assumptions, and so on, count as scientific."

ity of care may threaten, rather than strengthen, the physician's commitment to sick people.[91]

The Question of Research

Evidence problems notwithstanding, few gold standard clinical trials exist for much of what is practiced in clinics and hospitals every day.[92] [93] There is, in fact, a paucity of evidence-generating research. According to Steven Woolf, M.D., speaking at the Evidence-Based Practice of Oncology, 3rd Annual Symposium, "There just aren't enough studies to really do evidence-based guidelines on most of what we do in medicine." [94] Science itself is a limiting factor, he said.

Ian Kerridge et al. therefore caution against making treatment decisions according to practice protocols that are said to be based on evidence:

> [T]he large quantities of trial data required to meet the standards of evidence based medicine are available for relatively few interventions. Evidence based medicine may therefore introduce a systematic bias, resulting in allocation of resources to those treatments for which there is rigorous evidence of effectiveness, or toward those for which there are funds available to show effectiveness (such as new pharmaceutical agents). This may be at the expense of other areas where rigorous evidence does not currently exist or is not attainable (such as palliative care services). Allocating resources on the basis of evidence may therefore involve implicit value judgements, and it may only be a short step from the notion that a therapy is "without substantial evidence" to it being thought to be "without substantial value."[8][95]
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> [8] Evidence-Based Care Resource Group. Evidence-based care. 1. Setting priorities: how important is this problem? Canadian Medical Association Journal 1994; 150:1249-54.

Dr. Belkin critiques the evidence-based scientific focus of medicine today. "There is great variability within scientific communities as to what evidence, techniques, assumptions, and so on, count as scientific," he writes. [96] "Social roles, needs and political agendas often determine what scientific claims and methods (outcomes studies vs. individual physician judgement) gain authority such that, *what was once anathema becomes gold standard*."[97] [my emphasis]

Belkin further questions the scientific claims purported by managed care:

> [T]echniques that people see as objective proof, when more carefully examined, are easily seen to be the result of a multitude of subjective choices (my subjectivity of objectivity). Health services research and the foundational practices of managed care that...appear to offer new scientific rigor to medicine are a perfect example of this. Measuring outcomes of medical interventions and paying for, approving, and rewarding those treatments with desirable outcomes seems obvious, straightforward, and long-delayed. But the value-laden nature of what is "desirable," the innumerable choices and disagreements as to outcome variables, interventions, and observed population definition, make the measuring of outcomes anything but straightforward.[98]

Validity of Guidelines Questioned

The question of research and scientific evidence aside, practice guidelines have their own problems.

Guidelines rapidly become outdated. In 2000, a group of researchers determined that more than 75 percent of the guidelines developed between 1990 and 1996 needed updating. In addition, they discovered that half the guidelines were outdated in 5.8 years. Of the 17 clinical practice guidelines they assessed—the entire output of a high-profile program developing practice guidelines with the assistance of the U.S. Agency for Healthcare Research and Quality (AHRQ)—13 were in need of an update. Seven needed a major update, 6 needed a minor update, 3 were judged to still be valid, and no conclusion was made about the last one.[99]

Guidelines fail to make explicit how recommendations are devised, leaving practitioners to follow in blind faith. Dr. Shaneyfelt and colleagues took the guideline

"Guidelines allow narrow interest groups to impose their priorities on the health service."

development industry to task in one study of 279 guidelines.[100] Only 7.5 percent of the guidelines described how the developers combined evidence and expert opinion, and only 6.1 percent described the values that were used to make recommendations.

Many guidelines are of dubious quality.[101] In one study, researchers found that only 14.7 percent of 217 drug therapy guidelines developed or endorsed by Canadian organizations over a 5-year period met half or more of their criteria for rigor in the development process.[102 103] Independent reviewers rated only 9.2 percent of the guidelines as sound without modification.[104] They noted, "The quality of the guidelines assessed varied significantly by developer, publication status and drug company sponsorship."[105]

Other concerns surround the content and use of practice guidelines:

- **Conflicting guidelines.** One guideline conflicts with another guideline.[106]
- **Individual vs. population.** What is best for patients overall, as recommended in guidelines, may be inappropriate for individuals.[107 108 109 110]
- **Poor research.** "[G]uideline developers must often reckon with research that is modest in rigor, discordant, or nonexistent."[111 112]
- **Poor medical skills.** "[E]arly exposure to practice parameters in medical school or residency training could hinder inexperienced physicians in the honing of clinical reasoning and decision-making skills basic to the practice of medicine."[113]
- **Comorbidities.** Many patients have more than one disease process, while guidelines focus on a single disease.[114]
- **Special interests.** "Guidelines allow narrow interest groups to impose their priorities on the health service."[115]
- **Researcher opposition.** Researchers in evidence-based medicine are not comfortable with prescriptive use of guidelines.[116]
- **Selective interpretation.** Utilization managers can interpret guidelines according to their own "biases, assumptions, history, mood, distractions, and personalities."[117]
- **Values-based.** Recommendations can be based not only on someone's personal determination of what constitutes "evidence" but also on economic considerations, values of the guideline developers and presumed values of society.[118 119 120 121 122]
- **Not reality-based.** Guidelines are often based on ideal research situations. But day-to-day clinical practice is not a controlled environment. There are fewer resources, less patient compliance and the practice is not limited to a narrow group of patients.[123]
- **Narrow focus on science.** Medical decisions involve not only matters of the head, but matters of the heart.[124]
- **Reduction in care.** Eliminating variation in practice can reduce individualized care, particularly for those who have special needs.[125 126]
- **Impact not studied.** Despite publishing criteria for guideline development, federal agencies provide little information or guidance on assessing the clinical impact of guidelines.[127]
- **Hinder medical advances.** Rigid guidelines could impede adoption of new medical technologies.[128 129 130]

Guideline Development—One Rationale

According to guideline proponents, physicians need treatment protocols to stay abreast of the latest research.[131 132] Between 1990 and 1999, more than 2 million research articles were published per year in over 20,000 biomedical journals, and more than 250,000 controlled medical research trials were conducted.[133]

With new studies being reported every week,[134] David L. Sackett and others estimate that general practice physicians would need to read 19 articles a day, 365 days a year to keep up with the mushrooming information.[135] With some physicians reading only 2 hours per week,[136] the task is said to be overwhelming.

Yet, as reported above, study results conflict, there are problems with relying on research findings and reported results, and some researchers claim that many scientific studies printed in journals are of poor quality or little value.[137 138]

"If a policy is wrong, the harm can be huge."

Potential for Harm

One of the great concerns surrounding practice guidelines is that they do not concentrate on individual patients. They "attempt to make decisions for a collection of patients," writes David M. Eddy, M.D., Ph.D., at Duke University. In doing so, the injury can be substantial. He warns,

> If an individual physician and a patient make a wrong decision, that patient will be harmed, but the damage will stop there. In contrast, practice policies are intended to influence thousands, even millions, of decisions. If a policy is wrong, the harm can be huge.[139]

Patient satisfaction is another concern. In a yet-to-be-released study, patients whose physicians follow "best practice" guidelines are less satisfied with the care they receive.[140]

Finally, critics warn that guidelines can be used to ration health care services—to withhold treatment options and sanction denial of care. In 1999, the British government created the National Institute for Clinical Excellence (NICE) to analyze evidence, assess new technologies, and provide "reliable guidance on current 'best practice'"[141]—including treatment protocols for physicians to follow.

As Keith Syrett at the University of Bristol in England writes, this "technocratic approach" offers "a means of scientifically depoliticizing the rationing debate."[142] Decision making by guideline, including guidelines that exclude innovative or costly treatments, allows the government to "avoid direct responsibility for making uncomfortable and politically sensitive rationing decisions."[143] Sabine Kleinert, an executive editor at *The Lancet* in Oxford, England, asserts,

> In the search for objectivity and firm guidelines the field of evidence-based medicine has quickly advanced to evidence-based decision-making and evidence-based rationing.[144]

In America, the Institute of Medicine appears to support rationing. In its oft-referenced 2001 report, *Crossing the Quality Chasm*, the IOM discusses a need for commitment to evidence-based practice, and writes,

> When a patient seeks inappropriate health care services…if a conflict cannot be resolved through counseling, the clinician should refuse to provide nonbeneficial services.[145]

Who defines "non-beneficial" is a key question. Debates over access to advanced technology are already emerging. The new heart scanner has spurred disagreement among cardiologists, according to *The New York Times*.[146] While one Cleveland Clinic physician says the scanner's ability to provide quick diagnosis will "revolutionize medicine," another is calling for strict guidelines to limit access to the innovative procedure.

The potential for patient harm becomes even greater as policy makers and health plans advance so-called "decision support" systems—treatment protocols placed on computer screens used at the point of care. Decision support could become decision control. The IOM reports that decision support systems can "reduce variation in practice through improved compliance with practice guidelines."[147] Senator Hillary Clinton (D-NY) writing in support of computerized systems, asserts:

> Why rely solely on the doctor's brain to store that information? Computers could crunch the variables on a particular patient's medical history, constantly update the algorithms with the latest scientific evidence and put that information at the clinician's fingertips at the point of care…Reminders can take the form of…computerized questions to remind a doctor of the conditions that must be fulfilled before surgery is considered appropriate.[148]

However, Mr. Sackett warns against lockstep adherence to scientific evidence, computerized or otherwise. As author of the EBM definition and professor at NHS Research and Development Centre for Evidence Based Medicine in England, he writes, "Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient.[149]

"Kids could die because of these guidelines."

Guideline Disagreement – One Example

Many physicians have already felt the tyranny of guidelines. The experience of several physicians with one guideline developer, Milliman USA, provides an example of the problems physicians and patients can face when guidelines are developed and disseminated for use. Milliman has approximately 975 Care Guidelines, which are reviewed every 12 – 18 months.[150] The guidelines, commonly used to determine length of stay in health care facilities, are licensed to insurers covering about 100 million insured individuals.[151]

According to news reports, Milliman's Guidelines have angered doctors and patients. A few years ago, Milliman suggested limiting elderly patients to cataract surgery on one eye since two-eyed vision was not considered essential.[152] Public outrage caused a change of heart.

As of January 2004, Milliman was still involved in a lawsuit that began in 1999.[153] Two physicians who disagreed with a pediatric-care guideline found their names under "contributing authors" in one Milliman guideline book. Thomas Cleary, M.D., professor of pediatric infectious disease at the University of Texas Medical School in Houston, says that he told Milliman the guidelines were "outrageous," adding:

> They're dangerous. Kids could die because of these guidelines.[154]

Cleary, and his colleague, William Riley, M.D., filed a fraud and defamation lawsuit charging that their names were used without permission, the clinical recommendations have no basis in sound medical practice, and Milliman tried to buy scientific legitimacy by giving $100,000 to the University of Texas' pediatrics department.[155] Cleary remains critical of Milliman's length-of-stay guidelines, writing that many feel the guidelines "do not conform to standard of care and reflect poor practice rather than 'best practice.'" [156]

Bill Stewart, M.D., a Seattle-based physician, shares Dr. Cleary's opinion of Milliman's guidelines, and the administrators who questioned his treatments, saying,

> "It's always, 'Why wasn't it done this way?'…From where I sit, I see guidelines become law, mandates."[157]

Milliman is now expanding access to their practice guidelines, and extending the guidelines into real-time bedside decisions. On January 20, 2004, Milliman announced that it will give their care guidelines free-of-charge to organizations that review the quality and appropriateness of care for Medicare and Medicaid.[158] And last year, the company made the guidelines available through handheld personal digital assistants (PDAs)—the devices that physicians carry with them as they see patients and make treatment decisions.[159]

Cost, Quantity and Time

Guidelines are plentiful, and derived from many sources besides Milliman. Notably, about 454 guidelines were published annually between 1993 and 1997, compared to just one per year between 1975 and 1980.[160] The American Medical Association lists 1,700 guidelines in its Directory of Clinical Practice Guidelines.[161]

The U.S. Agency for Healthcare Research and Quality (AHRQ) maintains the National Guidelines Clearinghouse (NGC) for the collection and dissemination of private-sector practice guidelines.[162] The Clearinghouse contains over 1000 accessible guidelines.[163] At least 720 are updated, and an additional 507 obsolete guidelines are archived.[164] However, the NGC website informs visitors that, "The majority of guidelines produced by AHRQ are no longer included in NGC" because they are considered out of date.[165]

Guideline production takes time. According to Steven Woolf, M.D. speaking at an conference sponsored by the federal Agency for Healthcare Research and Quality (AHRQ), it takes one to two years to produce a guideline.[166] The average cost is about $80,000 – $100,000, says Woolf—unless the government does it:

> "The federal government usually spends about $800,000 when they do it, but you know how that works," he said.[167]

Elaine Larson, R.N., Ph.D. provides additional evidence that resource requirements are significant:

Inflation of health-care costs after the 1965 enactment of Medicare and Medicaid caused third-party payers to begin developing guidelines.

> The average time to prepare a HICPAC[1] guideline, for example, is about 2 years and involves dozens of experts. Additional resources are required for disseminating and implementing guidelines, and because guidelines become outdated within a few years, there is additional cost for updating them on a regular basis.[168]

[1] CDC's Healthcare Infection Control Practices Advisory Committee

In 1999, AHRQ's director stated that the National Guideline Clearinghouse was a $6.5 million, four-year program, and the Evidence-Based Practice Reports program (*see next page*) cost $3 million a year.[169] In addition, several million dollars more per year were used for outcomes and quality research. AHRQ's cost to review and update guidelines in 2001 was $250,000 per guideline.[170] Yet, there have been no studies to measure the cost of guideline implementation.[171] Nor is it clear that guidelines save money. Cook and Giacomini from McMaster University in Ontario write in *JAMA*:

> [G]uidelines designed to promote cost-effectiveness at the patient level may not maximize cost-effectiveness at the population level.[172]

The Institute of Medicine made clear their goal for guideline development in *Crossing the Quality Chasm*. Although they initially recommend establishing treatment protocols for at least 15 priority health care conditions, they also recommend that the "number of priority conditions identified [by AHRQ] grow over time to eventually cover the majority (e.g., 80 percent) of the care provided to patients." [173] This suggests an expectation that guidelines will be developed for almost all health care conditions experienced by patients.

Growth Industry

Although the cost of creating practice guidelines is expensive, there is money to be made in the production of "evidence" used for guideline development. For example, Oregon's Center for Evidence-Based Policy has contracts with three federally-designated and federally-funded Evidence-based Practice Centers. Simply put, the Center receives federal funding to produce "evidence." In addition, after the evidence is produced, the Center goes in search of state taxpayer dollars. According to the National Mental Health Association, the Center:

> …is approaching Medicaid agencies in reportedly over a dozen states who, for a fee of $100,000 (General Fund dollars), can gain access to this scientific review of evidence [on drug effectiveness] and obtain guidance on which medications have an 'evidence base' to be included in a PDL [preferred drug list].[174]

Federal Support for Guidelines

Proposals to require physician use of practice guidelines are not new, but have intensified. While the earliest guidelines were developed over 50 years ago,[175] Eleanor Kinney, chronicling the history of medical standards, notes that the "sharp inflation in health-care costs" after the 1965 enactment of Medicare and Medicaid caused third-party payers to begin developing treatment protocols. She quotes the federal Physician Payment Review Commission in 1988:

> Practice guidelines may be unique among available methods to contain costs in that they can increase the quality and efficiency of care in the process of slowing increases in expenditures.[176]

In 1988, according to Kinney, the Health Care Financing Administration and the Public Health Service poured millions of dollars into research aimed at "develop[ing] the scientific basis for medical standards of care."[177]

In 1993, the Clinton administration's sweeping Health Security Act included clinical guideline requirements.[178] Had the Act passed, the proposed National Quality Management Council would have been required to "disseminate information documenting clinically ineffective treatments and procedures" and "establish priorities for research with respect to the quality, appropriateness, and effectiveness of health care." In addition, it states:

> The National Quality Management Council shall direct the Administrator for Health Care Policy and Research to develop and periodi-

The U.S. Congress has taken steps to begin directing the practice of medicine.

> cally review and update clinically relevant guidelines that may be used by health care providers to assist in determining how disease, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically. [179]

Found among the thousands of documents from the Clinton White House Health Care Interdepartmental Working Group were papers from the Institute for Clinical Systems Integration (ICSI, pronouced "ick-see").[180] ICSI is a guideline development organization which was later renamed the Institute for Clinical Systems Improvement. ICSI is now involved in guideline development in Minnesota.[181]

Although the Clinton Health Security Act failed to become law, promotion of government-issued guidelines by the federal Agency for Health Care Policy and Research (AHCPR) almost led to the agency's demise. At a 1999 congressional hearing to reauthorize AHCPR's funding, a quote from a Congressional House Budget Committee report for fiscal year 1996 was read:

> The agency is supposed to support research and information dissemination on health care services and technology, medical effectiveness, and patient outcomes, but performed an advocacy role in the health care debate the past 2 years while its funding increased from $125 million in 1992 to $163 million in 1994.[182]

Charles N. Kahn III, then president of the Health Insurance Association of America, testified at the 1999 hearing. As a former staff member of U.S. Senator David Durenberger, Mr. Kahn said that he had drafted "one of the early pieces of authorizing legislation on health outcomes research," and also, as a staff member of Bill Gradison, he had helped draft legislation to create the agency. After noting that "Congressional opposition to AHCPR funding also was fomented by complaints by some practitioners, who saw themselves as losers under practice guidelines developed by the agency,"[183] Mr. Kahn argued in support of reauthorized funding:

> In response to Congressional pressure, AHCPR sidestepped conflicts with medical specialty groups and other providers by redirecting medical guideline activities to the development of methodologies, promotion of guidelines use, and synthesis of the literature on treatments rather than actually establishing guidelines. In addition, the agency's senior staff and health services researchers spent a great deal of time discussing the unique role and contributions of the AHCPR with Congress.[184]

As to federal involvement in practice guidelines, Mr. Kahn claimed, "Clearly, without the type of support from AHCPR outlined above, private health plans alone would have too few resources and too little capacity to produce these types of measures and evidence."[185]

Current Federal Efforts

The AHCPR was reauthorized by Congress, and renamed the Agency for Healthcare Research and Quality (AHRQ). The agency now has five-year contracts with 13 Evidence-based Practice Centers (EPCs) scattered around the country. EPCs analyze and generate evidence for distribution to guideline writers and developers in the private sector.[186]

According to Kenneth Fink, M.D., director of the EPC Program at AHRQ, topics are determined through an annual nomination process. The EPCs are each guaranteed one topic per year, and given the opportunity to compete for contracts on 10 - 20 additional topics offered throughout the year. At present, nearly 100 federally-funded "evidence reports" are available.[187]

Besides funding the creation of "evidence," the U.S. Congress has recently taken steps to begin directing the practice of medicine. The Medicare Modernization Act of 2003 requires the Secretary of Health and Human Services to "establish a pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology and evidence-based outcomes measures..."[188] Those who meet or exceed the Secretary's performance standards will receive additional reimbursement. Those who do not may find

"Variations from these best practices should be defined as medical errors..."

themselves at the bottom of the Medicare pay scale.

During the three-year pilot project, participating physicians must demonstrate:

> the ability…to use evidence-based guidelines and meet such clinical quality and outcome measures as the Secretary shall require."[189]

Managed care organizations may support a strong role for government in directing the practice of medicine. As Alan Muney, M.D., from Oxford Health Plans, says:

> An alliance between AMCs [academic medical centers] and MCOs [managed care organizations] should jointly recommend disciplinary action to licensing agencies for those providers whose practice patterns are significantly deviant from the norm, and after educational interventions, do not improve as a result.... MCOs should identify these *recalcitrant physicians*, but discipline should primarily involve governmental agencies.[190] *[my emphasis]*

A less obvious attempt to control medical practice is taking place in the area of medical errors and patient safety. The U.S. House of Representatives passed the Patient Safety and Quality Improvement Act (H.R. 663) in March 2003.[191] The U.S. Senate passed its version (S. 720) on July 22, 2004.[192] Differences must now be reconciled before some form of medical error reporting becomes federal law.

Importantly, the definition of "medical error" is up for grabs. Though the public may not agree, some people in high-level positions appear to equate non-adherence with "best practices" as a medical error. At the first National Summit on Medical Errors and Patient Safety Research in 2000, comments made by Robert F. Meenan, M.D., Dean of the Boston University School of Public Health, seem to identify such a connection. Regarding treatment for chronic diseases, he said,

> Variations from these best practices should be defined as medical errors and their causes and corrections should be pursued.[193]

Varying efforts to require physician compliance with a myriad of differing practice guidelines could eventually lead many hassled and harried physicians to call for the establishment of one set of national practice guidelines—a single set of treatment directives for all Americans. Although Professor Rosoff believes it politically inconceivable, he notes that such an agreement:

> would require designating some entity, presumably a governmental agency, as the sole arbiter of what is considered acceptable medical practice.[194]

Malpractice Considerations

"Acceptable medical practice" is often a point of considerable debate in litigation pertaining to medical malpractice. Practice guidelines have therefore been viewed as a promising strategy for tort reform.

Medical malpractice has become a major issue. A 2002 Harris Poll of 300 physicians found nearly 80% ordering more tests than medically necessary for fear of litigation.[195] Some say such "defensive medicine" costs $45 billion per year.[196] Skyrocketing malpractice insurance premiums are reportedly forcing physicians to discontinue certain procedures (eg. delivering babies[197]) or reconsider their profession.[198] [199] Malpractice insurance premiums have increased rapidly, with some specialists paying premiums in excess of $100,000 per year.[200] And in 2002, hospitals in New Jersey saw malpractice insurance premiums increase 250 percent.[201]

In October 1992, then presidential candidate Bill Clinton was one of the first to mention use of practice guidelines as a defense against medical malpractice lawsuits. During the second presidential debate, he 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.[202]

However, meshing law and medicine is not an easy task. Daniel W. Shuman, J.D., of Southern Methodist University School of Law in Dallas, explains:

"Malpractice relief can serve as a political chip to enlist physician support for controversial changes"—such as government-issued guidelines.

> Almost always, the health care people talk about population-based evidence, and, almost always, the legal people talk about evidence based at the level of the individual.[203]

Speakers at an April 2000 federal health and law workshop spoke about the difficulties of using practice guidelines in the legal system. Cynthia Mulrow, from the University of Texas Health Science Center, and Kathleen Lohr at the University of North Carolina's School of Public Health, point out that deficiencies in current guidelines make it difficult for the court to rely on them for legal decision making. They also add, "Guidelines are meant to be flexible and amenable to tailoring to meet individual circumstances…"[204]

John Eisenberg, M.D., MBA, then director of the Agency for Healthcare Research and Quality, discussed the sharp differences between the practice of law and the practice of medicine:

> Law relies on evidence of the instance: healthcare relies on evidence of the generalizable…Although the law of evidence is a standard set of rules that overlooks particular individualized situations, the law is largely based upon tenets of individual rights, wrongs, and harms, and the use of evidence is in evaluating causation in a particular instance.[205]

The American Medical Association has opposed adoption of guidelines as legal standards, even for use in a physician's defense against a patient's allegations:

> 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.[206]

Nor do physicians appear to rest secure in practice guidelines as a form of protection from medical malpractice litigation. A survey by the American College of Physicians published in January 1996, according to the *American Medical Association News*, found that less than one-fifth of physicians thought practice guidelines would reduce malpractice lawsuits.[207] Instead, some physicians feel that failure to follow a guideline could lead to a lawsuit.[208] [209]

State "Litigation Protection" Laws

At the state level, Maine, Florida, and Minnesota have experimented with protecting physicians from malpractice litigation.[210] And, as noted in *The Wall Street Journal*, "malpractice relief can serve as a political chip to enlist physician support for controversial changes"[211]—such as government-issued clinical guidelines.

For example, in 1990, the Maine legislature approved a five-year experiment to develop state-approved checklists for patient care—and to offer litigation protection to physicians who used them.[212] Two years later, in 1992, the DFL-controlled Minnesota legislature established litigation protection as part of a managed care expansion law. The state health department was authorized to write what the law called, "practice parameters."[213] Doctors were permitted to use the government-issued practice parameters as a defense against accusations of medical malpractice but, as in Maine, patients were forbidden to cite noncompliance with guidelines as evidence of a physician's negligence.

Regarding this type of legislative protection, Professor Arnold Rosoff, J.D., says,

> [A]llowing the use of CPGs [clinical practice guidelines] only for defense purposes, as in Maine and Minnesota—was a political decision meant to stimulate the adoption and use of guidelines by a physician community otherwise reluctant to accept them, in part because of its fear of the liability consequences.[214]

Although the Minnesota law was repealed in 1995, a similar proposal resurfaced during the 2004 legislative session—this time sponsored primarily by Republican legislators. The initial language authorized "adherence to a best practice guideline approved by the Board of Medical Practice…[as] an absolute defense against an allegation that the provider did not comply with accepted standards of practice in the community."[215] How-

Allowing one-sided use of evidence in court raises disturbing questions of fairness and validity under the 5th and 4th Amendments.

ever, after members of the House author's own party objected, the language was stripped from the bill.

Mr. Rosoff highlights two problems with legislation that protects practitioners and not patients:

> Giving providers assurance that guidelines can be used only in their favor may be an important step toward gaining their support; but allowing 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.[216]

Rosoff and others warn that lawmakers do not have the final word on limiting legal exposure for physicians—even if practice guidelines are designated in statute as legal standards. The decision still rests on several considerations *(all by Rosoff, [217] unless otherwise noted):*

- **Appropriateness.** Determining if the proffered CPG was actually appropriate to the case.
- **Compliance**. If the proffered CPG was appropriate, judging compliance with the CPG.
- **Harm.** If there was non-compliance with the appropriate CPG, was there harm?
- **Conflicting guidelines.** No single authoritative guideline exists for each medical condition.
- **Conflicting evidence.** Judges face "murky, dubious, narrow, conflicting or irrelevant evidence."[218]
- **Bias.** What bias was used to configure, interpret and frame the results of scientific trials?
- **Opinion of experts.** Courts prefer to defer to expert opinion regarding the scientific validity of the guideline rather than making their own judgment.[219]
- **Jury has the last word.** The jury still determines the legal standard of care in each case. [220]

Malpractice – A Sidebar

The answer to rising medical malpractice costs is not simple. Although some claim that use of practice guidelines will reduce the cost of "defensive medicine" and simplify malpractice trials,[221] the Congressional Budget Office estimates that tort reform to address the estimated $24 billion in malpractice costs in 2002—less than 2% of health care spending—will not have a big impact on overall health care spending.[222] [223]

In addition, the true cost of "defensive medicine" is unknown. In 1994, the Office of Technology Assessment reported that "it is impossible to accurately measure the overall level and national cost of defensive medicine," [224] but claimed that the cost is less than 8 percent of all diagnostic procedures.[225]

Finally, it is important to note that not everyone agrees that there is a crisis in medical malpractice costs. J. Robert Hunter, former Federal Insurance Administrator under President Ford, in a July 2002 letter to President George W. Bush, wrote, "There is no 'explosion' of medical malpractice costs." Instead, he asserted, "In the last decade, medical malpractice rates stayed flat while costs (claims, including jury verdicts) rose by exactly the rate of medical inflation."[226]

Conclusion

Looming on the visible horizon of American health care is a new attempt to control the practice of medicine and limit—indeed, ration—patient access to health care services. While doctors often refer to it as "cookbook medicine," this quickly advancing strategy is best known by the name "evidence-based medicine" (EBM).

Although treatment decisions have long been an accepted amalgamation of medical science, personal expertise, ethics, patient preference, and the physician's best clinical judgment in the care of an individual patient, EBM proponents from both sides of the political aisle are rapidly moving to standardize patient care into universal, one-size-fits-all practice directives.

As this report makes clear, the EBM initiative involves a technocratic takeover of the practice of medicine through health data collection, guideline creation, intrusive clinical surveillance, pay-for-performance strategies, and centralized medical decision-making.

EBM, which is gaining momentum across the United States, is not patient-friendly. It threatens the integrity

EBM is aimed at stopping the heart of health care — the compassionate, first-do-not-harm, to-my-own-patient-be-true ethics of medicine.

of the patient-doctor relationship, the ability of doctors to meet professional and ethical obligations to individual patients, and the patient's right to personal autonomy.

In fact, the EBM guidelines are not guidelines at all. These so-called "best practices" are poised to become coercive mandates imposed by government agencies and third-party payers with political and financial incentives to ration health care—and the power to do it.

The public should be alarmed. Despite the positive ring of terms like "evidence-based medicine," "best practices," and "guidelines," EBM is aimed at stopping the heart of health care — the compassionate, first-do-no-harm, to-my-own-patient-be-true ethics of medicine.

Fully implemented, EBM will lead to a limited list of approved health care services—"best practices"—as determined by the agendas and values of a small cadre of politically-motivated, personally-biased individuals sitting around a table making treatment decisions somewhere far from the patient's bedside.

All around the United States, the two people closest to any medical problem—the patient and the doctor—will not be involved in that treatment decision.

There is no time to waste. Americans must become involved and engaged. Without immediate and focused intervention, physicians and doctors—the trained professionals that patients trust to treat them when they are sick, injured or dying—will soon be stripped of medical decision-making authority and professional autonomy. Vulnerable patients will be left to depend on the personal whims, financial agendas, and political biases of people who do not even know their name.

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