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“EVIDENCE-BASED MEDICINE”: RATIONING CARE, HURTING PATIENTS

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Introduction

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

At first glance, this concept seems to make sense. Any term with the word “evidence” automatically confers a sense of scientific authority. Assuming that to be true, the United States Congress and some state legislatures have begun adding “evidence-based” requirements to health care laws. Several laws even link physician payment for medical services to compliance with EBM in an initiative called “pay for performance.”

Of concern to patients and doctors, the terms “evidence-based medicine” and “evidence-based guidelines” are often not defined in these laws, access to individualized care is not preserved, and the integrity of medical decisionmaking has not been protected.

Some say EBM is “the development of best health-care practices based on data that show which treatment and protocols work and which do not.”¹ Others say EBM-based guidelines are dangerous, outdated, value-laden, politicized, and biased. Claims of health care rationing have also emerged.

This paper will explain the debate surrounding EBM, question the emphasis on evidence and guidelines for medical decisionmaking, demonstrate how EBM harms the doctor-patient relationship and why EBM won’t guard against frivolous lawsuits, and describe various iterations of evidence-based medicine being enacted and implemented today—in particular, Medicaid Preferred Drug Lists.

A word about terminology: this report uses “guidelines,” “best practices,” “practice parameters,” and “protocols” interchangeably.

The Evidence-Based Medicine Debate

Best Practices?

Evidence-based medicine has been defined as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.”² EBM advocates say best evidence should be derived from the findings of randomized controlled trials (RCTs)³—the so-called “gold standard” in research—and meta-analysis,⁴ a systematic review of research studies.

Supporters of EBM argue that there are no systems in place for ensuring that best practices are consistently implemented.⁵ Many claim physician compliance with clinical guidelines—essentially practice directives—will reduce “overuse,” “underuse” and “misuse” of health care services.^{6 7} According to the Institute of Medicine (IOM)—the federally funded organization providing the United

States Congress with health care policy research—these three terms describe the primary “quality” problem in health care today.⁸

EBM supporters further claim, “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.”⁹ Others point to a 2003 RAND study which concludes that Americans receive about half of recommended medical care processes.¹⁰

But some physicians, like Earl P. Steinberg, counter that assertion. Writing in *The New England Journal of Medicine*, Steinberg contends that the RAND study does not mean adults have only a 50 percent chance of getting adequate care. Instead, he notes that the actual outcomes of patients may be much better than indicated by simply ascertaining compliance with a list of treatment protocols.¹¹

Advocates say that the goal of EBM is the standardization, not individualization, of patient care.¹² But relatively few patients, perhaps less than 25 percent, fit the evidence-based therapeutic paradigm.¹³ In fact, individuals vary by physiology, mental capacity, emotional stamina, time constraints, family and cultural considerations, financial status, drug and food allergies, willingness to comply, ethnic background, ability to travel, relationship resources, and side effects to medication, among other factors. As genetic researchers increasingly demonstrate, patients are as different as their DNA.

Cookbook Medicine?

Clinical practice guidelines (CPGs) are the embodiment of evidence-based medicine.¹⁴ HMOs and other managed care organizations began developing these guidelines in the 1990s to identify medical care they deemed inappropriate or unnecessary.¹⁵ As renowned Princeton University professor and health economist Dr. Uwe Reinhardt says, “EBM is the sine qua non of managed care, the whole foundation of it.”¹⁶

Evidence-based treatment guidelines are being developed to drive physician adherence to corporate medical decisions. Some managed care executives would prefer that physician training include compliance training from the start.¹⁷

To many doctors, these CPGs are viewed as a regimented “cookbook” for patient care.¹⁸ According to University of Pennsylvania Professor Arnold Rosoff,

“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.”¹⁹

The American Medical Association is said to endorse guideline flexibility that avoids “cookbook medicine.”²⁰ However, guidelines often do not feel like guidelines. One doctor, talking about administrators who question his treatment decisions, told *The Seattle Times*, “It’s always, ‘Why wasn’t it done this way?’ . . . From where I sit, I see guidelines become law, mandates.”²¹

More often than not, EBM proponents want guidelines to feel like mandates. Steinberg later says he left the field of health services research out of frustration that health care was being “delivered in a fashion that was [in]consistent with evidence-based guidelines and the results of outcomes research.” Instead, he wanted to “try to focus on the development of practical tools to *facilitate compliance* with what we already knew to be the right thing to do.”²² [*emphasis added*]

Why Science Is Subjective

Built-In Bias

What is the “right thing”? Researchers caution against depending solely on research evidence for the answer, noting the potential for harmful bias in treatment decisions. Authors Ian Kerridge et al., writing in *The British Medical Journal*, say,

“[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).”²³

Such allocation, they add,

“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 judgments, 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.’”²⁴

Dr. Gary Belkin, author of one of the most comprehensive papers on the motivation and philosophy behind EBM, 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.”²⁵

“Profit-Maximizing under the Guise of Science”

David Sackett warns against lockstep adherence to scientific evidence, computerized or otherwise. As author of the EBM definition and a professor at Britain’s National Health Service Research and Development Centre for Evidence Based Medicine, 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.”²⁶

Similarly, Reinhardt hopes the “whole evidence-based enterprise doesn’t become cumbersome, ethically compromised, and ultimately useless.”²⁷ 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.”²⁸

Canadian physician R. Brian Haynes says evidence-based medicine is not authoritative in medical decisionmaking. Invited to travel from McMaster University in Canada to present at a federally-funded U.S. conference on medicine and law, 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.”²⁹

Belkin critiques the evidence-based scientific focus of medicine today, writing, “There is great variability within scientific communities as to what evidence, techniques, assumptions, and so on, count as scientific.”³⁰ He adds,

“Social roles, needs and political agendas often determine what scientific claims and methods (outcomes studies vs. individual physician judgment) gain authority such that, what was once anathema becomes gold standard.”³¹

The Problem with Using “Evidence” and “Guidelines” for Medical Decisionmaking

Gaps & Inconsistencies

Clinical practice guidelines are supposed to be based on evidence.³² But what research counts as evidence? Between 1990 and 1999, more than two million research articles were published per year in more than 20,000 biomedical journals, and more than 250,000 controlled medical research trials were conducted.³³

Yet few “gold standard” randomized clinical trials exist for much of what is practiced in clinics and hospitals every day.^{34 35} Cost may be a limiting factor. Clinical trialist and cardiologist Dr. Sidney Goldstein estimates that a randomized clinical trial typically costs \$50 million to \$100 million.³⁶

As defined by the IOM, evidence-based guidelines emphasize using clear evidence from the existing literature, rather than expert opinion alone.³⁷ However, as the IOM notes in *Patient Safety: Achieving a New Standard for Care*, determining what classifies as authoritative evidence for medical decisionmaking 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.”³⁸

Alarming Contradiction

In fact, “evidence-based” research results can strongly contradict each other. In July 2002, scientists were alarmed to learn that hormone replacement therapy using the drug Prempro had risks, including heart attacks. These new results, coming from a large federal randomized control 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.³⁹

At issue in this conundrum is the reliability of all medical research. Rather than being the final authoritative word on medical practice, each study is a contribution of an evolving body of evidence.⁴⁰ What is known is known only until another study proves differently. Even the results of a study may be biased or may not be transferable to all patients everywhere.⁴¹

More “Evidence” Problems

Other well-recognized problems with the evidence used to develop “evidence-based” 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.”⁴²
- **Discordant views.** What counts as best evidence varies by interpreter.⁴³ As a former director of the U.S. Agency for Healthcare Research and Quality (AHRQ) writes, “Who will determine what evidence should be followed?”⁴⁴
- **Levels of evidence.** Evidence exists in a hierarchy of importance, and several different evidence hierarchies exist, introducing confusion.⁴⁵
- **Conflicting evidence.** Evidence can be “murky, dubious, narrow, conflicting, or irrelevant.”⁴⁶
- **Editor error.** Research reported in peer-reviewed research journals is often classified as evidence, but not all editors are qualified to distinguish between sound or flawed research protocols.⁴⁷
- **Insufficient reporting.** Not all results of studies, particularly negative ones, are reported or available.^{48 49 50}
- **Flawed research.** Guideline developers often fail to notice that many clinical studies have poor methodology and should not be used to draw conclusions.^{51 52 53}
- **Selection bias.** Assembly and critique of evidence is not necessarily neutral, objective, comprehensive or rooted in science.⁵⁴
- **Possibilities of fraud.** The principal investigator of the sole positive trial of autologous bone marrow transplant in stage II breast cancer confessed to falsifying the data.⁵⁵
- **Loss of compassion.** Efforts to quantify the quality of care may threaten, rather than strengthen, the physician’s commitment to sick people.⁵⁶
- **Insufficient evidence.** “[O]ur current infrastructure for evidence, harvesting the evidence, and so forth, is woefully inadequate.”⁵⁷

Validity Questioned

Not only is the evidence of EBM in question, the guidelines themselves are in doubt. Researchers who study guideline development have expressed serious concerns about the reliability of current guidelines. Many protocols have recommended out-of-date practices, struggle with value-laden bias, and are of insufficient scientific rigor.

According to one study, 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 federal Agency for Healthcare Research and Quality (AHRQ)—13 were in need of an update. Seven needed a major update, six needed a minor update, three were judged to still be valid, and no conclusion was made about the last one.⁵⁸ Adding evidence of unreliability, nine out of 18 prominent guideline organizations around the world in 2003 reported a lack of formal procedures for keeping their guidelines up to date.⁵⁹

Guidelines also fail to make explicit how recommendations are devised. In one study of 279 guidelines, 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.⁶⁰ Failure to explain the process and the values used essentially asks practitioners to comply in blind faith with the views and values of developers.

Finally, many guidelines are of dubious quality.⁶¹ In one study, researchers found that only 14.7 percent of 217 drug therapy guidelines developed or endorsed by Canadian organizations over a five-year period met half or more of their criteria for rigor in the development process.^{62 63} Independent reviewers rated only 9.2 percent of the guidelines as sound without modification.⁶⁴ They noted, “The quality of the guidelines assessed varied significantly by developer, publication status and drug company sponsorship.”⁶⁵

More “Guideline” Problems

Other notable concerns regarding the content and use of practice guidelines:

- **Conflicting guidelines.** One guideline conflicts with another guideline.⁶⁶
- **Individual vs. population.** What is best for patients overall, as recommended in guidelines, may be inappropriate for individuals.^{67 68 69}
- **Narrow focus.** “[I]t is impossible for guidelines to consider all variations in patient populations and physician practice styles.”⁷⁰
- **Specialty bias.** Specialists who write guidelines see the world through their own specialty.⁷¹
- **Poor research.** “[G]uideline developers must often reckon with research that is modest in rigor, discordant, or nonexistent.”^{72 73}
- **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.”⁷⁴
- **Comorbidities.** Many patients have more than one disease process, while guidelines focus on a single disease.⁷⁵
- **Special interests.** “Guidelines allow narrow interest groups to impose their priorities on the health service.”⁷⁶
- **Researcher opposition.** Researchers in evidence-based medicine are not comfortable with prescriptive use of guidelines.⁷⁷
- **Selective interpretation.** Utilization managers can interpret guidelines according to their own “biases, assumptions, history, mood, distractions, and personalities.”⁷⁸
- **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.^{79 80 81}

- **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 and less patient compliance, and the practice is not limited to a narrow group of patients.⁸²
- **Narrow focus on science.** Medical decisions involve not only matters of the head, but also matters of the heart.⁸³
- **Reduction in care.** Eliminating variation in practice can reduce individualized care, particularly for those who have special needs.^{84 85}
- **Patients are not involved in development.** Eighteen prominent guideline organizations around the world do not include patients in guideline development.⁸⁶
- **Impact not studied.** Despite publishing criteria for guideline development, federal agencies provide little information or guidance on assessing the clinical impact of guidelines.⁸⁷
- **Hinder medical advances.** Rigid guidelines could impede adoption of new medical technologies.^{88 89}

Profusion of Guidelines

Despite these significant problems, guideline development is a booming industry, pushed forward with significant taxpayer financing. The growth in guideline production is impressive. For example, 454 guidelines were published annually between 1993 and 1997, compared to just one per year between 1975 and 1980.⁹⁰

The federal government provides significant funding for guideline development. In 1999, AHRQ's director said the agency's Evidence-Based Practice Reports program cost \$3 million a year.⁹¹ In 2007, 14 federally-designated Evidence-based Practice Centers (EPCs) were provided between \$50,000 and \$5 million each.⁹² AHRQ's cost to review and update guidelines in 2001 was \$250,000 per guideline.⁹³ This cost does not take into account the costs of sustaining the groups of researchers who produce and edit reviews.⁹⁴ There appear to have been no studies to measure the additional cost of guideline implementation.⁹⁵

The National Guideline Clearinghouse (NGC)—established in 1999 to collect and disseminate EPC and other practice guidelines—currently contains 5,899 guidelines.^{96 97} These treatment protocols may be short or long. For instance, the 360 cardiovascular disease guidelines held by the NGC range from two pages to at least 211 pages. And there is often more than one guideline for a condition. For example, the Clearinghouse contains nine guidelines totaling 165 pages written by seven different organizations for the treatment of middle ear infection (otitis media).⁹⁸

Guidelines are not simple lists of action steps or a set of flowcharts. Instead, they are often complex high-level documents that require concentrated reading. Within the guidelines are abstracts, introductory statements, decisionmaking methods, treatment recommendations, flowcharts, matrices, supporting evidence, benefit vs. risk statements, concluding statements and information on the developers. Perhaps to avoid liability due to questions of validity, the NGC includes the following disclaimer at the end of each guideline summary: “The National Guideline Clearinghouse (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.”⁹⁹

Most importantly, despite claims otherwise, EBM guidelines may not significantly reduce health care costs. Cook and Giacomini from McMaster University in Ontario write in *The Journal of the American Medical Association*, “[G]uidelines designed to promote cost-effectiveness at the patient level may not maximize cost-effectiveness at the population level.”¹⁰⁰

Evidence-Based Medicine and the Doctor-Patient Relationship

Directing the Doctor

Kaiser Permanente Senior Advisor Dr. David M. Eddy 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.”¹⁰¹ He further cautions, “It is not stretching things too far to say that whoever controls

practice policies controls medicine.”¹⁰²

Whether physicians are ready to abandon their autonomy is not yet known. However, 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.”¹⁰³ 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.¹⁰⁴ 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.”¹⁰⁵ This environment could include computer-embedded guidelines, regulatory stimuli, and financial incentives.¹⁰⁶

Pay for Compliance

Health plans, government agencies, employer groups, and the U.S. Congress are already developing payment models to incent physician compliance with guidelines.¹⁰⁷ Payment for doing what is dubbed “right” does not sit well with physicians who take umbrage at the very idea of “pay for performance” (P4P). For example, Dr. Roy Verdery says P4P advocates “would have us conform to stasis norms and care for uniform patients, with money as our primary reward.”¹⁰⁸

Doctors who provide patients with this definition of “quality care” are often eligible to receive bonuses from health plans.¹⁰⁹ Brandeis University’s Debra Stone warns that when payment is based on behavior, the physician’s criterion for decisionmaking can be “changed from medically necessary to medically necessary for the patient and financially tolerable for the primary care doctor.”¹¹⁰

Dr. Linda Peeno, 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.”¹¹¹

IOM similarly reports a “cycle of fear” that 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.”¹¹² One study has already found 39 percent of physicians falsifying insurance records to secure needed health care services for patients.¹¹³

Maintaining responsiveness to individual medical needs will require physician freedom from population-based treatment mandates. Physicians must use their expertise and medical judgment for the benefit of individual patients. One doctor says, “[C]ompliance with guidelines does not necessarily translate into appropriate patient care... [P]hysicians who do not follow guidelines are not always wrong.”¹¹⁴ Another warns, “Practice policies are intended to influence thousands, even millions, of decisions. If a policy is wrong, the harm can be huge.”¹¹⁵

Evidence-Based Rationing

Critics warn that practice guidelines can be used to ration health care services—to withhold treatment options and sanction denial of medical 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’”¹¹⁶—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.”¹¹⁷ Decisionmaking 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.”¹¹⁸ 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.”¹¹⁹

Widget-Based Care

Health care rationing has many names. Practice standardization—limiting variation in treatment decisions—is one. Dr. Marshall de Graffenried Ruffin, Jr., in *The Physician Executive*, says, “Evidence-based medicine can be seen as an acceptable, even necessary, limitation of clinical freedom, because it leads to practice guidelines meant to standardize and reduce the variation in clinical care.”¹²⁰

AHRQ agrees, preferring standardized treatment protocols for all patients. Equating standardization with health care quality in the 2007 *National Healthcare Quality Report*, it writes, “One goal of quality improvement efforts nationally is to reduce differences in health care quality that patients receive in one state versus another. There is no justification, for example, for a patient hospitalized for a heart attack in California to have different care than a patient in Alabama...”¹²¹

Some even classify variations from treatment protocols as medical errors. In reference to treating chronic conditions, Dr. Robert F. Meenan, dean of the Boston University School of Public Health, said the following to attendees of the first-ever National Summit on Medical Errors and Patient Safety Research, “Variations from these best practices should be defined as medical errors and their causes and corrections should be pursued.”¹²²

However, Dr. George E. Thibault says control over the practice of medicine must always remain in the hand 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.”¹²³

Does Evidence-Based Medicine Prohibit Frivolous Lawsuits?

Supporters of EBM claim that strict adherence to prescribed treatment guidelines will protect physicians from malpractice litigation, limit variation in physician practice patterns, and improve quality of care. Advocates also claim that EBM adherence will cut costs by reducing the practice of “defensive medicine”—the ordering of “tests and procedures, or avoidance of high risk patients or procedures, primarily (but not necessarily solely) to reduce physician exposure to malpractice risk.”¹²⁴

Concerns about medical malpractice have already impacted medical practice. A 2002 Harris Poll of 300 physicians found nearly 80 percent ordering more tests than medically necessary for fear of litigation.¹²⁵ Some say such defensive medicine costs \$45 billion per year.¹²⁶

Rising medical malpractice insurance premiums are also reportedly forcing physicians to discontinue certain procedures (e.g., delivering babies¹²⁷) or reconsider their profession.^{128 129} Some specialists are paying malpractice insurance premiums in excess of \$100,000 per year.¹³⁰ New Jersey hospitals’ premiums increased 250 percent in 2002.¹³¹

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.¹³² But meshing law and medicine is not an easy task. Dr. Daniel W. Shuman of Southern Methodist University School of Law explains, “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.”¹³³ [*emphasis added*]

There are difficulties with using practice guidelines in the legal system. Dr. John Eisenberg, then-director of AHRQ, 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.”¹³⁴

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.¹³⁵ In fact, physicians do not believe practice guidelines will protect them from being sued for medical malpractice. A 1996 survey by the American College of Physicians found that less than one-fifth of physicians thought practice guidelines would reduce malpractice lawsuits.¹³⁶ Instead, some physicians believe that failure to follow a guideline could lead to a lawsuit.^{137 138}

At the state level, Maine, Minnesota, Florida and Vermont have experimented with using guidelines to protect doctors from malpractice litigation^{139 140}—perhaps for more reasons than the stated purpose. As noted in *The Wall Street Journal*, “malpractice relief can serve as a political chip to enlist physician support for controversial changes”¹⁴¹—such as government-issued clinical guidelines.

For example, in 1990, Maine developed checklists for patient care—and provided litigation protection to physicians who used them.¹⁴² In 1992, Minnesota established litigation protection as part of legislation implementing statewide expansion of managed care.¹⁴³ Until it was repealed in 1995, Minnesota doctors were permitted to use government-issued practice parameters as a defense against accusations of medical malpractice.¹⁴⁴ In both Maine and Minnesota, patients were forbidden to cite noncompliance with guidelines as evidence of a physician’s negligence.

University of Pennsylvania Professor Arnold 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*,¹⁴⁵ *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 noncompliance 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.”¹⁴⁶
- **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.¹⁴⁷
- **Jury has the last word.** The jury still determines the legal standard of care in each case.¹⁴⁸

Medicaid Preferred Drug Lists and the Rationing of Care

Preferred Drug Lists: A Primer

Evidence-based guidelines have made their way into medication decisions. To reduce costs, state policymakers have gravitated toward preferred drug lists (PDLs) in Medicaid, defined as “a list of medications that Medicaid will cover the cost for without the need to request a prior authorization (PA).”¹⁴⁹ This list is said to be a group of “preferred drugs selected for their efficacy, safety, and cost-effectiveness, based on documented scientific evidence.”¹⁵⁰

Forty-five states and the District of Columbia are using PDLs.¹⁵¹ At a cost of around \$96,000 per year,¹⁵² 14 states use Oregon’s Drug Effectiveness Review Project (DERP) to evaluate evidence prior to adding medications to their PDLs.¹⁵³

Science vs. Subjectivity

Detractors say Oregon’s reviews of medications “often omit many studies and that the evidence from a systematic review process is necessary but not sufficient to adequately inform health care decision-makers designing a PDL.”¹⁵⁴ Opponents of PDLs also argue that the drug lists “can limit access to important medications, require extra work for physicians, and put certain Medicaid recipients’ health at risk.”¹⁵⁵

State officials and beneficiary advocacy groups are concerned that some state pharmaceutical and therapeutics committees are not “sufficiently familiar with the principles of evidence-based medicine to understand the critical clinical issues presented in the DERP reports.”¹⁵⁶

The “evidence” is often just part of the decision of a state’s pharmaceutical and therapeutics committee. In a 2005 study of PDL programs in three states, the Colorado Health Institute notes, “Evidence-based preferred drug lists (PDLs) are a relatively new policy option for states, and no two PDL programs are exactly alike.”¹⁵⁷ This distinctive nature highlights the subjectivity of the evidence—and the decision. Different committees weigh evidence differently. Some also include comparative costs and testimony from consumers and drug manufacturers.¹⁵⁸ Some do not. Thus, the decision on drug availability differs by state and is based on cost and other criteria beyond whatever evidence is chosen for review.

Cost Savings Questioned

While there have been reports of \$500,000 per week in cost savings from Michigan’s PDL,¹⁵⁹ some reported savings, like \$22 million from Iowa’s PDL in 2006, may not have taken into consideration the additional administrative costs of PDLs.¹⁶⁰ Additional costs may include:

- Forming and executing pharmaceutical and therapeutics committee meetings, including salaries.
- Contracting with pharmaceutical benefit management companies to negotiate rebates with drug manufacturers.
- Contracts with prior authorization service companies to receive and analyze authorization requests, and eventually approve or deny them.

- Administrative costs of physician offices and pharmacies.¹⁶¹

For instance, one physician said, “It takes too much time to fill out forms and that time could be spent returning patient calls and reaching patients.” Similarly, another provider indicated, “[the PA process] requires additional staff to meet the paper work needs. Ten to fifteen hours weekly are spent filing PA’s, on the phone with [staff], and combing through charts for the increasing amount of information demanded to get PA’s approved.”¹⁶²

Due to the high cost of administering prior authorization, several health plans have dropped their PA requirements. The result has been positive. UnitedHealth saved \$110 million in administrative expenses and experienced a 26 percent decrease in member complaints as well as a 21 percent growth in membership the following year.¹⁶³

PDLs have also been found to increase patient care costs. One study found higher costs associated with higher use of medical services when drugs were limited:

“[A] statistically significant increase in the number of outpatient hospital visits and physician visits for the test group compared with the control group in the first 6 months after PDL implementation...As a result, estimated average Medicaid reimbursement costs for cardiovascular patients in the state *increased* during that year.”¹⁶⁴ *[emphasis added]*

De Facto Rationing

Whatever the PDL-issued “evidence” may say, it does not say it for all patients. As the Colorado Health Institute notes, “Exemptions and other safeguards to protect the treatment regimens of special populations who require exceptions to a PDL are warranted to maintain patients’ health and safety.”¹⁶⁵

One doctor, commenting specifically on patient distinctiveness, says, “Medications that successfully manage schizophrenia for person A may or may not be effective in managing person B’s schizophrenia. One size definitely does not fit all.”¹⁶⁶ Another says that PDL-based denial of medication is “de facto rationing of health care that particularly affects older

patients, who constitute a substantial fraction of Medicaid recipients.”¹⁶⁷

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 technocratic 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 centralized decisionmaking, guideline development, clinical surveillance, and pay-for-performance.

EBM, which is gaining momentum across the United States, is not patient-friendly. It threatens the integrity of the patient-doctor relationship, the doctor’s ability to meet professional and ethical obligations, and the patient’s right to personal autonomy.

Fully implemented, EBM could lead to a limited list of approved health care services as determined by the agendas and values of powerful individuals in corporate and government offices far from the patient’s bedside. All across the United States, the two people closest to any medical problem—the patient and the doctor—may soon have little say over critically important medical treatment decisions.

The danger to patients is real. If EBM becomes the legal standard of care, physicians and doctors—the trained professionals whom patients rely on for treatment when they are sick, injured or dying—will no longer have medical decisionmaking authority or professional autonomy. Patients in every corner

of the nation will be left vulnerable to the personal preferences, financial agendas, value-laden opinions, and political biases of people who do not even know their name.

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The views expressed in this paper are solely those of the author.

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