COMMENTARY

Evidence-Based Medicine and the Physician-Patient Dyad

Howard I Kushner, PhD

Introduction

As the current debates throughout the US attest, there are wide disagreements about the shape of future US health care delivery. Nevertheless, a general consensus has emerged about the need for more efficient interventions that are based on reliable scientific evidence. This need has been filled by evidence-based medicine (EBM), which employs meta-analyses and randomized controlled trials (RCTs) to examine the effectiveness of interventions on large populations. These findings are reviewed by the Cochrane Collaboration, a group of volunteers from around the globe who publish their findings quarterly in the Cochrane Database of Systematic Reviews.[1,2]

Although it seems difficult to deny the efficacy of statistically robust research, medical practitioners, especially those involved in primary care, are often skeptical about EBM, fearing that the physician-patient encounter will be undermined, and with it, the most appropriate mechanism to determine a diagnosis and treatment.[3,4] These physicians are sometimes portrayed as representing an older, more traditional segment of the profession, but their hesitancy also represents more than fear of change. Increasingly sensitive to this resistance, advocates continue to reassure practitioners that EBM will not subvert the physician-patient encounter but instead will integrate "the values and preferences of the informed patient."[5] Certainly before EBM becomes legislated by agencies and insurance companies alike, it deserves the same careful examination that it claims to have made of specific conditions. Although the RCT gold standard requires prospective studies, EBM is best evaluated through retrospective analysis—that is, in historical perspective.

I argue that EBM must be closely evaluated and critically appraised because it is subject to its own set of defects. Such a revised EBM would be best implemented in a context that maintains sensitivity to individuality and to physician-patient interactions.

Background

The ascendency of EBM in North America and the United Kingdom has its roots in the exponential growth of medical scientific research in the post–World War II years.[6] By the third quarter of the 20th century, medical research had become a scientific enterprise, whereas much of medical care remained an art. The goal of EBM was to transform the art of medical care into a science.[7] However, as Kathryn Montgomery has recently argued so eloquently, despite its reliance on scientific knowledge and its use of technology, medicine is not a science. Rather, it is a science-using practice whose goals are to prevent illness and care for the sick.[8,9] The issue remains of whether EBM enables physicians to more fully practice their craft or whether instead, as a number of authors whose works are discussed here indicate, EBM has created an additional barrier to doing so.[10]

EBM was envisioned as a division of labor in which scientific evidence would be generated by researchers at prestigious research and medical institutions and implementation would take place in practitioners' clinics. In reality, many clinical trials are done in the private offices of specialist physicians who derive a significant amount of income from the pharmaceutical industry. Nevertheless, such a system, whether intended or not, has produced a growing schism between academic medicine and clinical practice that often finds expression in concerns over the impact of EBM on the integrity of the physician-patient relationship.[3,4] This tension has its roots in the 1970s, when academic medicine, emphasizing its connection to research, began to distinguish itself from normal clinical practice. By the 1980s, it became clear that medical research was not easily translated into practice. Thus, research-based medicine was augmented by the establishment of professional clinical practice guidelines based on evidence gleaned from retrospective reviews of published RCTs. Practitioners, however, did not apply the

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guidelines consistently, if at all. (Kaiser Permanente [KP] established the Care Management Institute in 1997 to summarize and disseminate "best practices" and to assist "in the care of KP members by synthesizing knowledge about superior clinical approaches including the creation, implementation and evaluation of effective care management practices."[11]) If clinical medicine were to become a science, statistically significant research findings would have to be translated in a user-friendly fashion for everyday practice.

The Evidence-Based Manifesto

This was the context for the EBM manifesto of the clinical epidemiology program at McMaster University in Canada published in the *Journal of the American Medical Association* (*JAMA*) in 1992.[12] The manifesto called for the replacement of clinical decision making that was based on anecdotal and idiosyncratic physician experiences with scientifically informed and statistically significant findings from population-based studies.[13] The most frequently cited definition of EBM is reliance on the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients," which is based on an integration of "individual clinical expertise with the best available external clinical evidence from systematic research."[13] Evidence-based practices have been launched in general medicine and specialized fields.[14,15] In 2001, the prestigious Institute of Medicine's Committee on Quality of Health Care in America endorsed "evidence-based, patient-centered, health care delivery" as essential to the quality of health care.[16]

Initially, EBM rejected medical practices that were based on anecdotal and idiosyncratic physician experiences in favor of statistically significant findings from population-based studies. Interventions based on individual cases or small cohorts were portrayed as suspect and quaint. Instead, practitioners were urged to apply findings from population-based studies to their own clinical practice. Not surprisingly, this stance resulted in more than a little resistance and much criticism from a number of practitioners. In response, advocates of EBM increasingly have attempted to portray it as complementary to clinical experience, and there have been calls for a more integrated approach.[17]

Nevertheless, as it has developed since 1992, EBM relies on the elaborate system of publication and peer review of medical research. It requires that clinicians keep themselves updated on new research findings, become skilled literature researchers and methodologists, learn how to apply and interpret sophisticated statistical analyses, and translate all these findings into everyday clinical practice.[5,12] The challenge is to find time to do so, including interpreting and translating the findings as presented.[6,18] Although practical concerns have been raised about physicians relying on electronic databases, their ability to determine the validity of the data that constitute EBM is more problematic.[19] Moreover, as Timmermans and Mauck observed, in practice EBM "is loosely used and can refer to anything from conducting a statistical meta-analysis of accumulated research to promoting randomized clinical trials, to supporting uniform reporting styles for research, to a personal orientation toward critical self-evaluation."[20]

Evidence-Based Authority

Although there is no formal single EBM information authority in the US or Canada, in Britain the National Institute of Clinical Excellence (NICE) was established by the government in 1999 and expanded in 2005. NICE serves as an independent health authority responsible for producing evidence-based public health and clinical guidance for the National Health Service. Recently there have been calls for a similar body in the US.[5,21]

Tied as it is to external funding, EBM has been enthusiastically supported by medical school administrators, who judge and reward faculty by the number and dollar amount of their external grant funding. EBM has also gained much impetus from the pharmaceutical industry, which provides substantial funding for clinical trials.

EBM has transformed the transmission of medical knowledge. The disease mysteries and insights of the medical detectives that once populated medical journals have been relegated to the back pages. The patient increasingly has been replaced by the statistic. Patient narratives have become suspect and devalued as merely anecdotal. Moreover, human subject protection and ethics require that published cases be sufficiently altered so that the identity of a patient is not revealed.[22] Thus published patient narratives are, of necessity, fictions. Such narratives now provide material for books, op-ed columns, films, and television programming, but not for EBM.

The Critics

EBM is not without its critics, who warn that the art of medical practice is in danger of being overwhelmed by disinterested science, on the one hand, and cost-cutting corporate bureaucrats, on the other.[10,19] These concerns

have grown over the years, including those of David L Sackett, one of the authors of the McMaster manifesto. Sackett questioned the direction that EBM was taking and expressed frustration over what he considered the harmful effects of expert claims.[23] Other critics have characterized reliance on data from population studies and clinical trials as Galenic scholasticism, in which the skills associated with close readings of texts have replaced the actual physician-patient encounter.[24] In contrast, the physician's familiarity with a patient's life history is portrayed as local knowledge that enables the clinician to tailor contextualized diagnoses, treatments, and advice that mesh with individual needs. Patient narratives serve as exemplars of what allegedly has been lost. These narratives are also literary devices that at once reveal the clinician's diagnostic and interpersonal skills, while exposing the danger of a mechanistic application of population studies. Case histories are presented as mirrors of the best of medical education in which individual cases are interrogated and, in the process, reveal why some patients fared well and others poorly when placed on similar regimens. What is at stake, these stories suggest, is nothing less than the clinical encounter itself.[25,26]

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Ghaemi reminds us that there is no such thing as "non-evidence-based" medicine, rather there are many levels of evidence, ranging from case series to double-blind RCTs. "In my reading of EBM," writes Ghaemi, "the basic idea is that we need to understand what kinds of evidence we use, and we need to use the best kinds we can."[27] But how robust is the evidence produced even by gold-standard RCTs? Not very, according to a recent study published in the *Annals of Internal Medicine*. The investigation, conducted by the Ottawa Health Research Institute, found that 15% of "best evidence" recommendations were reversed in two years; in three years, 23% were reversed; and in five and half years, 50%.[28] Commenting on the study, Groopman and Hartzband noted that "Americans have witnessed these reversals firsthand as firm 'expert' recommendations about the benefits of estrogen replacement therapy for postmenopausal women, low-fat diets for obesity, and tight control of blood sugar were overturned."[29] Who wants their care predicated on recommendations half of which are proven wrong within five years?

If clinical practice demands sensitivity, EBM, in contrast, requires specificity (reliability); each piece of data must be (as much as possible) identical to another. Thus, patients' complaints are evaluated in the context of the findings of population studies. However, according to Groopman, specificity can be misleading because patients present for treatment with combinations of conditions that do not match the evidence. For Groopman, EBM interferes with evaluating individual patient complaints because the physician is drawn toward statistical findings that seduce practitioners to cease listening even as their patients continue talking. Thus, EBM leads physicians to fail to incorporate the most important source of evidence, sensitivity to what their patients can reveal about their conditions.[30] Paying attention to a patient's narrative is crucial, argue EBM critics, because patients with similar signs and symptoms, even with the same diagnosis, often require different treatment.[9] Added to this is Michael Balint's observation[31] that "doctors see patients because of disease. Patients see doctors because of anxiety. Therein lies the problem between the two."

Evidence-Based Medicine and the Art of Medical Practice

"There is one aspect of medicine that will surely survive, the need for a compassionate, competent person to help another confront the suffering of illness," wrote Jerry Avorn of Boston's Brigham and Women's Hospital and author of *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs*.[26] Whereas such sentiments reflect the Oslerian ideal of the medical encounter,[32] one may reasonably wonder the extent to which these ideals reflect actual medical practices or nostalgia for a mythic golden age of physician-patient collaboration.

Some scholars, such as Australian medical ethicist Malcolm Parker, believe that there is no substantive reason for EBM to undercut the art of medical practice. Parker argues that such claims are based on "false dichotomies" because there is no necessary contradiction between medical science and medical art; that, in fact "EBM is a *necessary condition* for clinical freedom."[33] However, citing data from the NICE guidelines, Parker concedes that EBM has a number of structural weaknesses, not least of all that "rather than starting with health care priorities and setting the research agenda on that basis, the system tends to be inverted by EBM, with research often being performed as much for commercial as for scientific and health reasons." Of course, here Parker is alluding to the influence of the pharmaceutical industry in shaping the research agenda of EBM in the United Kingdom. As he notes, this agenda has a direct impact on patient care because "there appears to be little systematic inquiry into what areas are poorly researched, how research priorities are identified, and who runs research."

Evidence-Based Medicine and the Pharmaceutical Industry

Despite the idealized claim that EBM would be the product of objective research conducted by disinterested medical researchers, pharmaceutical industry–sponsored clinical trials can have a corrosive impact both on physicians who derive substantial income from their participation and, in turn, on evidence claims themselves. Moreover, not all clinical trial results are published, especially those whose results fail to demonstrate the benefits of an agent in a pharmaceutical-sponsored trial.[34]

This situation has attracted the attention of a number of respected North American and British medical academics. They argue that pharmaceutical companies have infiltrated the medical research enterprise, hijacking the peer-review process into a vehicle for drug marketing. These critics believe the validity and veracity of peer-reviewed research is being undermined, subverting the foundation of EBM.[35,36]

According to Harvard University internist John Abramson, the pharmaceutical industry has inserted itself into every aspect of medical practice, from medical education to basic research and clinical care, endangering the integrity of the American health care delivery system and subverting the trust between patient and practitioner.[24] Marcia Angell, former editor-in-chief of the *New England Journal of Medicine,* links the near collapse of health care in the US directly to the corrupting practices of the pharmaceutical industry.[37] In *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning Us All into Patients* (2005), British Columbia medical researchers Ray Moynihan and Alan Cassels argue that unfavorable research results are eliminated from or camouflaged in the texts of industry-influenced studies and that data often are remolded in ways that present favorable results when a more transparent analysis might reveal substantial risk for patients taking the "hyped" medications.[38] British psychiatrist David Healy has written eloquently about the influence of the pharmaceutical industry in silencing and marginalizing even its most balanced critics.[39]

Building on these concerns, a special communication published in January 2006 in *JAMA* by a consortium of distinguished researchers, practitioners, and ethicists from eight of North America's leading medical schools urged adoption of a series of measures aimed at insulating practitioners and academic medical researchers from what they believed to be the pharmaceutical industry's corrosive effect on medical research and practice.[40] These recommendations reveal the growing anxiety, at least among some highly regarded and influential medical faculty, that the pharmaceutical industry has placed the practice of medicine, especially EBM, at dire risk.

Thus, despite the logic of Parker's analysis, the context of the current debate, framed as it is by the pharmaceutical industry's influence over EBM, exacerbates practitioners' suspicions. It is difficult, though perhaps not impossible, to imagine that an independent EBM could strengthen the physician-patient collaboration. However, EBM has not been liberated from pharmaceutical industry influence. Until it is, EBM, as practiced rather than as imagined, may continue to interfere with, rather than enable, the type of physician-patient collaborations that critics wish to nurture. Once—and if—industry influence is contained, the knowledge claims of an unfettered EBM may be reintegrated with the art of practice. Even then, physicians should be vigilant against the inappropriate reliance on population health studies for treatment of individual patients.

Valuable Tool versus All-Encompassing Panacea

Since the late 20th century, physicians and public-health researchers have understood the value of identifying risk factors as a prophylactic against a number of chronic conditions, including lung cancer, heart disease, and diabetes. As a number of recent studies have warned, however, risks can often be exaggerated in self-serving studies, presenting greater health hazards than the ones they putatively protect against.[41–43] A similar danger is found with EBM. It can serve as a valuable tool when properly understood, but we should not regard it as the all-encompassing panacea for the future of medicine. As with the promiscuous and often exaggerated labeling of a variety of relatively benign behaviors and conditions as risk factors, uncritical reliance on EBM can result in serious side effects. ❖

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"Tropical Paradise"
Stained-glass window triptych

By Lester DR Thompson, MD and Pamela A Thompson, MFA

Lester DR Thompson, MD, is a Pathologist at the Woodland Hills Medical Center in Woodland Hills, CA. As a Pathologist, he looks through a microscope all day to try to separate colors and shapes into meaningful diagnoses. He finds that working with stained glass is a similar, though more creative, process.

Dr Thompson collaborated with his wife, Pamela, to create this piece to honor the 25th wedding anniversary of his sister-in-law and brother, Glynn M Thompson, MD, a physician in the Kaiser Permanente Mid-Atlantic Region.