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The Philosophical Limits of Evidence-based Medicine

ABSTRACT

Evidence-based medicine (EBM) has already had a profound effect on both medical education and clinical practice. The benefits of EBM, which defines the value of medical interventions in terms of empirical evidence from clinical trials, are enormous and well described. Not clearly acknowledged, however, are the limits of EBM. An intrinsic gap exists between clinical research and clinical practice. Failure to recognize and account for this gap may lead to unintended and untoward consequences. Under the current understanding of EBM, the individuality of patients tends to be devalued, the focus of clinical practice is subtly shifted away from the care of individuals toward the care of populations, and the complex nature of sound clinical judgment is not fully appreciated. Despite its promise, EBM currently fails to provide an adequate account of optimal medical practice. A broader understanding of medical knowledge and reasoning is necessary.

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Evidence-based medicine (EBM) has rapidly become an integral part of medical training. From its inception, EBM has been envisioned as a "new paradigm" for the teaching of medicine, a new set of skills and methods of reasoning that allows physicians to incorporate a growing body of medical evidence into practice.[1] The impact of EBM on medical education, and ultimately on practice, has already been significant. Today's physicians-in-training are taught skepticism of anecdotal experience. Consensus recommendations of medical experts, previously accepted as the definitive word on many subjects, are now offered apologetically, with the expectation that they will be quickly supplanted when the appropriate clinical trial or meta-analysis is performed. The authority of experienced clinicians is readily challenged by appeals to published data. Although sound clinical judgment is still praised as a necessary skill of a good physician, the understanding of clinical judgment itself has changed. The defense of a particular medical decision on the basis of clinical judgment alone is considered the hallmark of the threatened, non-scientific, "authoritarian" clinician.[2]

The promise of EBM is a more systematic and scientific practice of clinical medicine. Examples abound of well-designed clinical trials that have not only put to rest enduring medical controversies but have also demonstrated some generally accepted interventions to be more likely to do harm than good. Physicians, insurers, and patients are uniform in their calls for more and better evidence to support medical decision making. The potential benefits of EBM are myriad and well described.[1–6]

But EBM is not without its critics,[7–11] many of whom argue that important aspects of clinical medicine are minimized or overlooked by focusing on the results of clinical research. Defenders counter that these critics misinterpret or misunderstand the goals and techniques of EBM.[12]

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For related articles, see pages 1221 and 1229 .

The current boundaries of EBM are generally defined in relation to the obstacles to the development, dissemination, and incorporation of medical evidence. Such practical concerns, however, do not represent the only constraints; there are also philosophical limits to the scope of EBM.[13] Failure to recognize these limits early in the development of EBM, or misinterpreting its aims and methods, may lead to unexpected and untoward consequences. Approaching EBM from a philosophical perspective may allow for a more rigorous delineation of the promises and pitfalls of this nascent discipline.

WHAT IS EVIDENCE-BASED MEDICINE?

The term, "evidence-based," is perhaps ill-chosen[14] and occasionally misapplied, and the concept of EBM does take varied forms. Yet every species of EBM must share some common attribute or else the term itself loses meaning, becoming yet another buzzword in the expanding medical lexicon. Any careful examination of EBM, then, must define the essential characteristics of the discipline.

Broadly speaking, EBM describes two separate but related entities. First, EBM deals with the issue of knowledge in medicine, defining optimal ways to develop knowledge and describing hierarchies of medical evidence. Therefore, it represents a school of medical epistemology. Epistemology, that branch of philosophy concerned with the nature of knowledge, examines the foundations and validity of various ways of knowing. EBM seeks to define at least one aspect of medical knowledge, that which derives from the results of clinical research. Other forms of medical knowledge are also generally acknowledged by EBM. Examples of "non-evidentiary" knowledge include individual clinical experience, physiologic principles, expert opinion, and understanding of professional and patient values.

Next, EBM attempts to describe a clinical practice centered on evidence derived from clinical studies. In this sense, EBM goes beyond the realm of epistemology to the practical world of providing health care. The literature of EBM often presupposes the validity of the epistemologic framework and tends to focus on the incorporation of evidence into clinical practice. This incorporation of the evidence requires a specific kind of clinical reasoning, a type generally considered "scientific," as it attempts to objectively and deductively apply empirical knowledge to specific cases.

The conception of EBM, despite its brief history, has already undergone a subtle but important change. Early statements asserted that EBM "*de-emphasizes* intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making" [italics mine].[1] An initial goal of EBM, it appears, was to minimize the use of non-evidentiary knowledge and reasoning in clinical practice. More recently, the focus has shifted to *integrating* clinical expertise, pathophysiologic knowledge, and patient preferences in making decisions regarding the care of individual patients.[12,15] This shift marks a critical and, I will argue, necessary recognition of the value of alternative forms of medical knowledge and reasoning.

Such a broad definition of EBM, however, is itself problematic. Certainly the integration of clinical experience, pathophysiologic rationale, patient and professional values (I would add expert opinion), and empirically derived evidence is the hallmark of good clinical practice, but without further explication the appellation "evidence-based" is undeserved. That is, unless EBM specifically tells us something about the relationship and priorities of the various forms of medical knowledge, it represents not a "new paradigm," but rather a new name for a still nebulous process called clinical medicine. Defined so broadly, there is certainly not a physician alive who would not claim to practice EBM; we physicians strive to use all our knowledge, in its various forms, to benefit our patients.

If it is to be meaningful, EBM must specifically address how to integrate various types of medical knowledge. Although recent descriptions of EBM shy away from making such claims, the literature of EBM is centered on the notion of the general priority of knowledge obtained by clinical research over other forms of medical knowledge. By acknowledging this general priority of knowledge derived from clinical research, EBM differentiates itself from possible alternatives, such as "experientially-based," "emotionally-based," "physiologically-based," "opinion-based," or "value-based" medicine. Each of these alternatives might recognize the value of empirically derived evidence, but would presumably not grant it general priority. Such a claim of priority is necessary if the term "EBM" is to be meaningful. Still, critics of EBM must not interpret this general priority of empirical evidence to mean that empirical evidence must take priority in each individual case. The difficulty, then, becomes defining the appropriate situations when other forms of knowledge and reasoning take precedence.

As generally conceived, EBM represents the development, acquisition, critical appraisal, and incorporation of a rapidly developing body of evidence into clinical practice.[16] EBM is envisioned as a way to "close the gulf between good clinical research and clinical practice."[2] The choice of metaphor illustrates the primary philosophical limit to EBM. The "gulf" between evidence derived from clinical trials and clinical medicine can never be completely closed because it represents an intrinsic, philosophical gap.[17]

THE RELATIONSHIP BETWEEN EVIDENCE AND PRACTICE

The general approach of EBM is to formulate a clear clinical question in relation to an individual patient, search the literature for relevant evidence related to that question, critically evaluate that evidence, and then implement the findings.[2] A clear pathway from the patient to the evidence and back to the patient is described. The acknowledged limitations of such an approach are generally the lack of good evidence and/or difficulty obtaining and interpreting that evidence.[11,18] These are practical problems that many in EBM are dedicated to solving.

The availability of all the well-designed clinical trials and systematic reviews imaginable, however, cannot completely overcome the gap between clinical research and practice. First, the goals of clinical medicine are not directly addressed by the current techniques of clinical research. The primary goals of medical practice, for its entire history, have been defined in terms of benefit to the individual patient. Clinical medicine is fundamentally a prudential and personal discipline, relating one individual in need of healing with another, who professes and promises to heal.[19] It represents an attempt to improve or maintain the health of an individual. The discipline of public health, on the other hand, aims to benefit society at large by improving health across populations. Certainly, benefiting individuals and benefiting populations are not mutually exclusive, but they are distinct goals that, at times, come into conflict.

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The direct application of knowledge derived from population-based studies is likely to fulfill the goal of public health. The application of the same knowledge to the individual, however, is problematic. The size of the gap between such knowledge and the care of the individual depends, to a large degree, on the importance of individual variation in the process of healing. EBM aims to minimize this gap by making the relevant differences between individuals explicit. Quantifiable differences between individuals can be accounted and controlled for in the design and interpretation of clinical trials. The effects of other aspects of individual variability are effectively obscured by utilizing the statistical strategy of randomization.[20] Obscuring non-quantifiable clinical phenomena by randomization does not, however, mean these phenomena are not clinically relevant.

For instance, it is easy to imagine two patients, both suffering from abdominal pain and identical in all quantifiable aspects of history, examination, and laboratory data, where one proves to have appendicitis at surgery while the other does not. Yet there may be non-quantifiable differences between patients, perhaps detectable by an experienced surgeon, that provide additional clues to the diagnosis. EBM has recognized the importance of difficult-to-measure but clinically relevant phenomena, such as pain, and has responded by attempting to quantify them using visual analog or ordinal rating scales.[20] But a clear philosophical boundary to EBM is drawn: To the extent that relevant differences between individuals cannot be made explicit and quantified, an epistemologic gap between research and practice must remain.

The gap between clinical research and clinical medicine can be viewed in a different manner as well. A traditional distinction in moral philosophy between statements of fact and statements of value maintains that value statements can never follow directly from statements of fact. That is, no amount of empiric data can ever tell us what we ought to do in any particular situation, as conclusions regarding what ought to be done are value-based.

In clinical medicine the problem can be summarized succinctly. Evidence from clinical trials provides the information to create hypothetical imperatives, in the form of "If you want to maximize the chances of outcome 'A,' then do 'B.'" Whether the chances of outcome 'A' should be maximized is not an empirical question; it not answerable by an appeal to evidence. Rather, it represents a normative (ethical) question. In the practice of medicine, the question of whether to maximize the chances of a particular outcome cannot be made without specific and detailed knowledge of the individual. Understanding the goals, values, and preferences of the individual patient are necessary to any determination about what medical intervention should be offered. The gap between research and practice, then, is not only an epistemologic but also an ethical gap.

Evidence-based medicine has rightfully acknowledged the importance of values, particularly patient values, in medical decision making.[21] However, the methods used to incorporate these values, usually in the form of "patient utilities," remain awkward. The use of standardized evaluative tools to convert values into a quantifiable format is not demonstrably better than simply asking pertinent value-oriented questions. Still, such an approach does represent an attempt at

integrating patient preferences with empirically derived knowledge.

The shift in EBM from explicitly "de-emphasizing" toward "integrating" other forms of medical knowledge represents the recognition of the intrinsic gap between clinical research and clinical practice. By focusing on the results of well-designed clinical studies, EBM allows for a practice of medicine that avoids many of the pitfalls of clinical practice. New technologies and therapies are required to demonstrate efficacy before they are accepted, hopefully preventing the mistaken adoption of ineffective and even harmful interventions into the medical armamentarium. In medical education, EBM offers the opportunity for the formation of a more universal fund of clinical knowledge. It teaches critical thinking and the value of scientific skepticism. It allows clinicians to provide patients with information that can promote shared decision making. Properly understood and applied, with its limits well delineated, EBM improves the practice of medicine.

Misunderstanding the nature of EBM or failing to adequately acknowledge its limitations, however, has potentially untoward consequences. Such consequences include the devaluation of the individual, a shift in the focus of medical practice from the individual to society at large, and the failure to appreciate and cultivate the complex nature of sound clinical judgment.

THE IMPORTANCE OF THE INDIVIDUAL

Although the notion that non-quantifiable individual variation between patients is of minimal clinical importance may fit well with the traditional allopathic description of disease, it seems unlikely to be embraced by patients. For the individual, illness is inseparable from other aspects of existence. Even in seeking a scientific understanding of their ailments, patients must ultimately reincorporate this medical interpretation of illness back into their own lives.[22] The practice of medicine that is focused on the results of controlled clinical trials runs the risk of devaluing individuality by limiting the significance of individual variation to those things that can be quantified. Although we may still argue that such an approach will produce the best overall outcomes, individual patients may see such end-points as an insufficient defense. The popularity of unconventional medical therapies despite the undeniable successes of modern allopathic medicine[23] supports this interpretation.

Alternative theories of healing generally contend that the treatment of disease rests upon understanding the illness in the context of the individual patient. Unconventional therapies are sought out not only when conventional therapies have failed, but when they are perceived to be emotionally or spiritually without benefit.[24] Focusing primarily on the results of clinical trials minimizes the importance of the intangible physical, emotional, and spiritual aspects of illness in the healing process. Unconventional schools, however, stress such distinctions between individuals, tailoring therapy not simply on the basis of the disease, but on how the disease manifests in a particular patient. Randomized clinical trials are generally rejected as a means of developing knowledge within these disciplines, since such studies fail to adequately appreciate and account for these variations. We can continue to dismiss such arguments as anti-scientific, but our patients appear unlikely to do so. To devalue the intangible differences between individuals is to devalue individuals.

Clinical research, as currently envisioned, must inevitably ignore what may be important, yet non-quantifiable, differences between individuals. Defining medical knowledge solely on the basis of such studies, then, would necessarily eliminate the importance of individual variation from the practice of medicine. The good clinician, however, cannot ignore these individual differences, at least if clinical medicine is to remain a discipline aimed at the treatment of individuals.

THE SHIFTING FOCUS OF MEDICINE

A subtle but significant shift in the focus of clinical medicine has occurred over the last several decades. In attempting to make clinical decision making more objective, many techniques of EBM encourage physicians to maximize the likelihood of positive outcomes over many patients, rather than just the patient at hand. Like investing in an index mutual fund rather than stock picking, or always pinch hitting a left-handed batter against a right-handed pitcher, using decision analysis or tightly adhering to practice guidelines promises better average outcomes over the course of time. What it does not promise is the best decision in a particular situation.[25] Yet the goals of medicine have always been formulated in a manner that requires the physician to use medical expertise to respond to the needs of a particular individual.[26] EBM recognizes this limitation, and most thoughtful examples of decision rules or clinical practice guidelines allow for deviation when justified by the "clinical judgment" of the physician. Still, the specific acceptable reasons for acting in a manner contrary to an evidence-based method are not well articulated. Action with an apparent evidentiary basis is easily defensible, but deviating from guidelines is immediately suspect and demands justification, although the standards by which to judge these actions are lacking. EBM, perhaps unwittingly, makes it easier to practice medicine focused on providing benefit across a group of patients (e.g., those with pneumonia) rather than always

concentrating on the individual patient (e.g., Mrs. Jones with pneumonia).

Interestingly, this shift in the focus of clinical medicine from the individual to a population has been vigorously resisted by physicians when it has been viewed from the perspective of changing health care economics. Managed care has met with repeated challenges that it prevents physicians from acting in accordance with the best interests of individual patients.[27-29] Yet EBM and managed care share a common ethical and epistemologic focus on outcomes measured across populations.[8,30] For physicians to embrace EBM despite this shift in focus away from the individual, while at the same time railing against the economic embodiment of the same principles and assumptions, managed care, appears intellectually inconsistent.

To the extent that relevant differences between individuals cannot be made explicit and quantified, an epistemologic gap between research and practice must remain.

CLINICAL JUDGMENT

In seeking to improve medical decision making, EBM redefines clinical judgment in medicine. Clearly, clinical judgment employs different types of reasons and reasoning, both scientific and otherwise.[31] EBM initially placed those types of reasons and reasoning into a dichotomous hierarchy: Reasoning from the evidence was explicitly identified as preferred, while other types of reasoning, whether intuitive, experiential, or physiologic were considered inferior.[1] More recently, the complexity of clinical judgment has been acknowledged, but the thrust of EBM remains on the "scientific" components. Explicit models of clinical decision making, often in the form of decision analyses or diagnostic algorithms, are advanced as reliable guides to medical practice. These models, however, may bear little resemblance to the actual reasoning of expert clinicians.[32] Thoughtful proponents of EBM recognize that reasoning from evidence can never completely substitute for complex medical judgment,[3] but little is said about the ultimate limits to the expansion of this type of reasoning.

Clinical judgment appears to contain a tacit element, one that cannot be captured by decision analysis or any other explicit model.[17,33] The experienced physician can appreciate the existence of this element by reflecting upon the nature of telephone consultations. Over phone and fax, the elements of a particular case that can be made explicit can be relayed to the consultant. When the caller is a physician, accurate objective elements of the physical examination may also be transmitted. Arguably, the amount of explicit information regarding individual patients available in such an exchange is greater than that presented in most clinical studies. Yet this type of clinical encounter is generally suboptimal. What the consulting physician cannot obtain is the immeasurable information made available by actually seeing, speaking with, and examining the patient. At times, a perfectly satisfactory recommendation can be made without this additional information, but most physicians will easily recall instances where the impression formed after personally evaluating the patient differed markedly from that formed after a telephone consultation, despite the fact that all the information provided over the phone was accurate.

Evidence-based medicine rightly cautions that reliance upon such an "intuitive" notion of clinical judgment is problematic. But ignoring the value of the tacit component of clinical judgment is equally problematic. Some critics of EBM have argued that, under a strict understanding of the discipline, a medical librarian with access to clinical practice guidelines, systematic reviews, and Medline might be expected to provide the same quality of care as an experienced physician.[9] This is too strong. EBM clearly acknowledges the importance of mastery of the clinical skills of history taking and physical examination,[34] but has yet to acknowledge the tacit interpretive aspect of clinical judgment that rests upon, but is not identical to, these skills.

Knowledge of the results of clinical trials has become a necessary component of medical expertise, but it is not, nor can it ever be, sufficient. Many factors other than evidence may legitimately influence clinical decision making. Both clinical scientists[3,35] and their detractors[22] recognize that personal experience in the care of patients is necessary and invaluable to sound clinical judgment. General rules derived from such experience can be efficient guides for clinical decisions.[36] The rise of bioethics as a discipline has focused attention on the importance of the values of both patient and physician. Cost concerns have made it to the bedside. Physiologic rationale may provide guidance in complex and novel cases. Even unsystematic observations of individual physicians may occasionally be more relevant to an individual case than published data. These other ways of knowing and reasoning may, at times, dictate medical decisions that are in apparent conflict with empirical evidence. EBM rightly points out the limits of these forms of reasoning, but we must also acknowledge the limits of EBM. The necessary gap between clinical research and medical practice means that

evidence can never directly dictate care; the evidence cannot tell us when it is best to ignore the evidence. Clinical judgment is and must be the ability to negotiate these independent and occasionally conflicting warrants for action and to arrive at a decision or recommendation thought best for the patient at hand.

EBM acknowledges the importance of the process of integrating different types of medical knowledge. Yet despite attempts to define itself more broadly, EBM continues to be viewed as placing the tacit, the personal, and the value-based aspects of medical decision making secondary to the proper application of empirical evidence. By focusing on the development, acquisition, critical appraisal, and incorporation of evidence into practice, EBM has diverted interest in understanding and teaching the portions of clinical judgment that are not related to empirical evidence.

The necessary gap between clinical research and medical practice means that evidence can never directly dictate care; the evidence cannot tell us when it is best to ignore the evidence.

Clinical medicine is, by its very nature, practical, prudential, and personal, and its practice more closely resembles casuistry than it does science.[37] In the casuistic model, the process of clinical reasoning involves comparisons of the patient at hand with similar patients, with careful attention to relevant similarities and differences. Rather than deductive, reasoning is primarily by analogy. Clinical research, "the evidence," provides a rich source of "similar patients" for comparison. One task of the physician, rightfully acknowledged by EBM, is to determine whether these similar patients resemble closely enough the patient at hand. In the same way, comparisons are made with previous patients known directly by the physician, colleagues, and consultants or found in case reports. In reasoning by analogy, physiologic, emotional, and spiritual differences between individuals are all relevant considerations. The reasoning is not scientific, not deductive, but this does not mean it cannot be rigorous. The recognition that clinical judgment is not scientific does not mean that it is simply a hunch. Clinical judgment will, however, remain a personal judgment.[37]

CONCLUSION

The progress and promise represented by EBM are enormous and the embracing of this medical epistemology by academic physicians is understandable. Clearly, advances in the quality and quantity of evidence available to practicing physicians has led to more informed decisions by physicians and patients alike. The recognition of the philosophical limits to EBM must not be interpreted as a rejection of the value of knowledge obtained from clinical research for clinical practice. Misunderstanding EBM or failing to acknowledge its limitations, however, impedes the efforts to expand our understanding of clinical medicine.

Evidence-based medicine may provide the foundation for a new era in clinical medicine, but we must seek to broaden our understanding of medical knowledge and reasoning. From the perspective of a medical educator, the overwhelming influence of EBM appears to have left few interested in understanding and teaching the non-evidentiary aspects of medical practice. The recognition of the value of other forms of medical knowledge and reasoning by EBM represents an important step in developing a complete and coherent account of the unique undertaking that is clinical medicine. The question remains whether academic physicians will be willing to risk being labeled "unscientific" as they seek to examine and teach the non-evidentiary aspects of clinical medicine. Failure to devote such attention, however, runs the real risk of producing a generation of physicians who cannot help but practice "cookbook" medicine, for they will have been provided none of the insight or skills that would enable them to successfully deviate from the "recipe."

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