Legitimacy, Authority, and Hierarchy: Critical Challenges for Evidence-Based Medicine

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This paper examines four challenges that proponents of evidence-based medicine (EBM) must address to establish its claims to universality and legitimacy. It is argued that the failures to meet the evidence-of-effectiveness challenge, the authority challenge, the conflicting hierarchy challenge, and the definition-of-evidence challenge diminish arguments for the superiority of EBM. In the second part of the essay, recent developments in the theory of EBM are discussed with specific reference to what is termed the Oslerian turn, and a relationship between EBM and rationality is entertained. [Brief Treatment and Crisis Intervention 4:197–204 (2004)]

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Evidence-based medicine (EBM) announced itself in the Journal of the American Medical Association in the 1990s (Evidence-Based Medicine Working Group, 1992). A direct quotation is required to capture fully the iconoclasm that accompanied the budding movement:

A new paradigm for medical practice is emerging. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience and pathophysiologic rationale as sufficient grounds for clinical decision making, and stresses the examination of evidence from clinical research. Evidence-based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature. (p. 2420)

This open challenge to the traditional manner of delivering clinical care and the self-characterization of EBM as entirely new and original exemplifies the élan and, some might argue, arrogance of the early pronouncements by its architects.

Serial refinements to the original definition of EBM quoted above were forthcoming. These
have included: “Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996, p. 71) and “EBM is the integration of best research evidence with clinical expertise and patient values” (Centre for Evidence-Based Medicine, n.d.).

The success of “evidence-based medicine” in terms of its dissemination and its proliferation as a slogan or catchphrase can neither be underestimated nor gainsaid. Today virtually every health care endeavor—from social work and occupational therapy to humanitarian intervention, policy, and planning—refers to or invokes evidence in its mission. Given the tight linkage of EBM with the advent of information technology, it is not surprising that a quick search of the term evidence-based medicine in the PubMed database yields over 12,000 citations. Such widespread use of a term is not sufficient substantiation of its veracity, however.

For a movement such as EBM to claim legitimacy or even superiority, there must be positive arguments to provide its justification, and these must advance beyond proclamation of correctness, popularity, or endorsement by others (such as the New York Times Magazine). The purpose of this paper is to examine the legitimacy of EBM. This will be achieved in a threefold manner. In the first section, we will pose four challenges to the central assumptions of EBM that we think raise significant weakness in any arguments about either the necessity or superiority of evidence-based approaches. Then, we will document the subtle transformation of the self-image of EBM (we call this new direction the Oslerian turn to EBM). Finally, we will discuss the relationship between deliberative rationality and EBM. We begin with a brief review of the model of EBM.

The Process of Evidence-Based Medicine

The core of the practice of EBM consists of five steps:

1. formulating clinical questions,
2. searching for the best evidence,
3. critically appraising this evidence,
4. applying this evidence to patients, and
5. evaluating the impact of this application.

To satisfactorily answer a clinical question, EBM articulates parts of its anatomy, viz., the patient or problem being addressed; the intervention or exposure under consideration; the comparison intervention or exposure, when relevant; and the clinical outcomes of interest.

Even though the explicit aim of recent reformulations of EBM involves the integration of individual clinical experience and patient values, it is interesting to note that patients do not become relevant until Step 4. In fact, patients are seen as passive objects that have evidence applied to them after the information has been extracted from them. This “extract and apply” model of EBM will be discussed in greater detail below.

Four Challenges for Evidence-Based Medicine

What are the present challenges to the increasingly dominant model of EBM? The four challenges we have identified are (1) the evidence-of-effectiveness challenge, (2) the authority challenge, (3) the conflicting hierarchy challenge, and (4) the definition-of-evidence challenge.

The Evidence-of-Effectiveness Challenge

A question often posed to advocates of EBM is, what is the evidence that EBM provides
superior clinical care and that its practitioners have better clinical outcomes? That EBM produces better outcomes is one of its regulating assumptions. As Brian Haynes recently wrote:

A fundamental assumption of EBM is that practitioners whose practice is based on an understanding of evidence from applied health care research will provide superior patient care compared with practitioners who rely on understanding of basic mechanisms and their own clinical experience. (Haynes, 2002, p. 2)

This basic assumption is not a testable hypothesis, however. The impossibility of providing any empirical demonstration of the superiority of EBM to any other mode of medical care has been recognized from the beginning. As stated in the initial manifesto (Evidence-Based Medicine Working Group, 1992):

The proof of the pudding of evidence-based medicine lies in whether patients cared for in this fashion enjoy better health. This proof is no more achievable for the new paradigm than it is for the old, for no long-term randomized trials of traditional and evidence-based medicine are likely to be carried out. (p. 2424)

This is a curious concession, particularly for a method that upholds empirical evidence as the most compelling justification for belief and action. This paradox has not gone unnoticed by other commentators. Dr. Geoffrey Norman states:

While it may not be easy to devise a rigorous study of EBM, it is incumbent on the practitioners of EBM to provide leadership and do their best, if their appeals that clinical practice should be based primarily on evidence are to ring true. (Norman, 1999, p. 145)

It is also worth noting that evidence that EBM can be effectively transmitted into practice is lacking. Indeed, Gord Guyatt and colleagues have admitted that

[after a decade of unsystematic observation of an internal medicine residency program committed to systematic training of evidence-based practitioners, we have concluded, consistent with predictions, that not all trainees are interested in attaining an advanced level of evidence-based medicine skills. Our trainees’ responses mirror those of British general practitioners, who often use evidence-based summaries generated by others (72%) and evidence-based practice guidelines or protocols (84%) but who overwhelmingly (95%) believe that “learning the skills of evidence-based medicine” is not the most appropriate method for “moving to evidence-based medicine.” (Guyatt, Meade, Jaeschke, Cook, & Haynes, 2000, p. 954)

Hence, even proponents of EBM argue that high-level EBM skills are not considered essential for clinicians and that the evidence seems to point to their desire not to become full-fledged evidence-based practitioners, but rather “evidence users.” This leads us to the second challenge.

The Authority Challenge

Quoting from the original article once more: “The new paradigm puts a much lower value on authority. The underlying belief is that physicians can gain the skills to make independent assessment of evidence and thus evaluate the credibility of opinions being offered by experts” (Evidence-Based Medicine Working Group, 1992). As we have noted, however, this has not turned out to be the case. The assumption that physicians can gain the skills to make independent assessment of the evidence has thus far been shown to be unsustain-
able, and this has spawned the distinction between the evidence user and the evidence-based practitioner.

The evidence user is one who accesses preappraised literature, that is, evidence that has been vetted and evaluated by others (evidence-based practitioners presumably) for application in clinical practice. One must ask, however, what secures the authority of appraisers and disseminators of evidence? There are no standards of accreditation or quality control for those who appraise evidence and disseminate it through such vehicles as the American College of Physicians Journal Club, EBM digests, or the POEM (Patient Oriented Evidence that Matters) database (or the Cochrane Collaboration for that matter). In essence, we have the replacement of one system of authority with another. Of course, despite the maligning of authority figures, this has been an essential, although unacknowledged, aspect of EBM all along. Is acceptance of the tenets of EBM required to participate in the creation of evidence digests to be disseminated and used by evidence users?

**The Conflicting Hierarchy Challenge**

The initial creation of an evidence hierarchy was intended to link the quality of evidence to the soundness of the recommendations based on the evidence. This was grounded in an unargued epistemological stance that favored certain designs (i.e., randomized controlled trials and meta-analyses) in the belief that these methods were less susceptible to bias than observational designs. The key is the ability of randomization to eliminate specific forms of bias, notably selection bias. In addition, this attributed lower reliability to expert judgment, specifically to theory and pathophysiological reasoning.

The concept of an evidence hierarchy was first used successfully by the Canadian Task Force on Preventive Health Care; however, there has been a proliferation of such hierarchies, each applying different nomenclature and employing slightly different language concerning recommendations (Upshur, 2003). It is now clear that what constitutes best evidence varies according to the hierarchy, and the hierarchies are not commensurable. At last count, we have identified seven such creatures, all of which have strikingly different characteristics for their highest-rated evidence and their best recommendations derived from it. Some admit the use of consensus deliberations and some banish them. Some allow the contemplation of physiology and some do not. For example, a recent 1A “strongly recommended” category by the U.S. Centers for Disease Control and Prevention (2002) defines best evidence as being “strongly supported by well-designed experimental, clinical, or epidemiological studies.” This definition is in marked contrast to that of the Centre for Evidence-Based Medicine, which puts meta-analysis or systematic review, with homogeneity of all of the randomized controlled trials, at the top of its hierarchy. Similarly, categorical nostrums such as “1 + 1A” and “1 level 1” are leading to needless complication and inconsistencies in application. However, once again a greater irony exists because the entire edifice of evidence hierarchies is not based on systematic research at all, but on expert judgment or consensus. In other words, the warrant or justification for viewing evidence in such a hierarchical structure rests on the lowest form of evidence, that is, the beliefs of a few.

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1Of course, this leaves undisturbed concerns about affluence bias, that is, the ability of certain interests to purchase and disseminate evidence; or the relevance bias, that is, the ability of interests to set the evidence agenda.
The Definition-of-Evidence Challenge

This definitional challenge is an important one, not just semantically but constitutively. Many critics of EBM have argued that its definition of evidence is reductive and far too restrictive and fails to admit a broad range of inputs that should be part of the deliberation of reason. Recently, in response to this, Haynes (2002) wrote:

Thus it is hardly surprising that the term “evidence-based medicine” is confusing to many who do not appreciate that its evidence is narrowly defined as having to do with systematic observations from certain types of research. The very name has been an impediment to getting across its main objective, namely, that health care research is nowadays producing important results that, if applied, can benefit patients more than the treatments that clinicians are experienced in recommending. Using the technical definition of EBM, evidence from health care research is a modern, never before available complement to traditional medicine. Perhaps a better name would be “certain-types-of-high-quality-and-clinically-relevant-evidence-from-health-care-research-in-support-of-health-care-decision-making” . . . an accurate but mind-numbing descriptor. (pp. 4–5)

As argued above, however, this narrow definition of evidence cannot be sustained because the hierarchy has been advanced on the basis of expert opinion rather than reasoned argument. Also, the benefit that evidence-based approaches bring to patients is as unproven as the evidence hierarchy itself. Hence, the technical definition is difficult to understand not because there are those of us who confuse its narrowness or fail to understand that it has to do with systematic observation from certain types (and we must say privileged types) of research, but because of criticism of the way that EBM has been constructed and disseminated.

Modern health care is multidisciplinary; many distinct professional and academic cultures contribute to research and patient care. Practitioners from backgrounds in the social sciences and humanities (to say nothing of law) may differ with colleagues in clinical epidemiology in their conceptualization of evidence. The concept of a univocal understanding of evidence may therefore not be sustainable. Modern health care is also delivered in a variety of distinct locations, with varying access to resources. The context of application is crucial to the understanding and relevance of evidence in a clinical or policy context (Dobrow, Goel, & Upshur, 2004).

Qualitative inputs, which are a species of structured and systematic observation and are largely banished from EBM, are well suited for illuminating aspects of health care related to dimensions of meaning. It is for this reason that alternative models of evidence have been proposed that attempt to accommodate both meaning and measurement, the particular and the general aspects of context, in order to create different modes of evidence that would incorporate both the qualitative and quantitative dimensions of decision making (Upshur, VandenKerkhof, & Goel, 2001).

It is also crucial to understand certain properties of evidence and what purpose evidence serves in clinical decision making. Evidence is not synonymous with truth, but rather serves as a type of justification for certain claims. Evidence has distinct properties which are important to note. Evidence derived from clinical studies is provisional, defeasible, emergent, incomplete, constrained (by ethical, economic, and computational forces), collective in nature, asymmetrically distributed across help disciplines, historically limited, and influenced by markets (Upshur, 2000). Simply put, the
stipulative definition of evidence proposed by proponents of EBM is not sufficient for the purposes of health care.

We believe that these four challenges cast serious doubt on claims of the superiority and legitimacy of EBM. These issues have been glossed over or ignored by proponents of EBM who prefer to invoke a simple inference from the existence of certain types of evidence to the legitimization of a clinical or policy action. That this neglects a multitude of moral and epistemological complexities has not gone without notice (Gupta, 2003; Sehon & Stanley, 2003). Obviously, the claim by proponents of EBM that there is a moral responsibility to practice EBM rests on a very shaky foundation.

The Oslerian Turn: Clinical Expertise, Patient Preferences, and Rationality

Haynes, Devereaux, and Guyatt (2002) reconfigured EBM as the intersection of three concentric circles: research evidence, patients’ preferences and actions, and clinical state and circumstances, with clinical expertise represented by the overlapping area at the center. We wonder whether this most recent reconfiguration represents a new Oslerian turn. Indeed, putting clinical expertise at the center brings to mind the writings of Sir William Osler, who maintained that

\[\text{[t]he art of the practice of medicine is to be learned only by experience. It is not an inheritance. It cannot be revealed. Learn to see, learn to hear, learn to feel, learn to smell, and know that by practice alone you can become expert. (Osler, 1968)}\]

Hence, clinical expertise is at the center of that learning, and “learning to hear” may include listening to patients rather more early in the process of the delivery of evidence-based care.

We have alluded earlier to the fact that the patient often appears only quite late in the definitions and conceptualizations of EBM. Increasingly, primary care providers are urged to adhere to a model of patient-centered or patient-focused care, in which case the center circle comprises the patient’s condition, preferences, and values rather than the clinical expertise of the clinician. EBM is very much oriented in favor of the health care provider, in that it privileges the rationality of the professional and her clinical skills and puts these at the center of the model, rather than patient-centered criteria.

However, this introduces new dimensions of complexity. A distinction needs to be drawn between patient-driven and patient-centered care. Increasingly, physicians and other health care providers are inundated by health information and the pervasive view that the health care provider is probably less aware of emerging and burgeoning health care information than is the patient or the media. Consequently, the provider/patient relationship is viewed as a consumeristic one in which the physician or health care provider is the gatekeeper to resources. Indeed, in a recent survey of a random sample of family physicians, we found that if an 80-year-old woman with congestive heart failure (and therefore not likely to benefit from preventive health care) demanded a screening mammogram, she was five times more likely to receive it than an 80-year-old woman who simply wondered aloud to her physician whether she needed it (Tracy, Dantas, Moineddin, & Upshur, 2003). Understanding patient demands is important; we need to move toward ascertaining and understanding patient preferences and modulating patient demands.

Another issue concerns how to build therapeutic relationships and alliances with patients. In our view, if you extract information from a patient and then try to apply it to him, that
sets up a trump situation that could have been sidestepped by taking a dialogical perspective in the first place. What would be a concrete example of this? Consider a 45-year-old male patient with hypertension, whose physician is considering which antihypertensive drug to try. Now apply the five steps of EBM. The intervention being considered is drug therapy compared with no drug therapy, and the outcome of interest is prevention of stroke. Having formulated the clinical question, the physician searches the evidence, finds a Cochrane meta-analysis, critically appraises it, and finds that it applies in this case. When the physician reaches for his prescription pad, however, the patient says, “Well, thank you very much, but I’m not interested in taking medication.” Regardless of the strength of the evidence of risk reduction—and there is evidence of marked difference in the perception and threshold for risk reduction between patients and physicians (Steel, 2000)—one ought to think that formulating the clinical questions involves an intimate understanding of patients and their values as part of the problem being addressed at the outset. Now, the EBM supporter might reply that this is what is meant, but it needs to be clearly articulated as one of the four parts of the anatomy (see “The Process of Evidence-Based Medicine” above); that is, getting to know your patient and her preferences/wishes/desires and determining whether evidence is even needed in the particular clinical circumstance. The physician and patient can certainly come to a treatment decision without requiring evidence, and this would be considered reasonable by all standards (Upshur & Colak, 2003).

There is also the sense in which patient preferences can lead to contrary decisions, though both can be considered reasonable based on patient perspective. Consider, for example, two brothers who are patients in the first author’s practice. They are just a few years apart in age. They are extremely well educated. Both have similar cholesterol profiles. Their family history is negative for coronary artery disease and they have no other risk factors; that is, neither smokes and neither has hypertension or diabetes. One brother wishes to start on a statin to lower his mildly elevated low-density lipoprotein and boost his normal high-density lipoprotein. The other brother prefers not to start on medication, favoring exercise and diet as a better way to achieve lipoprotein regulation. Both brothers looked at virtually the same numbers and same perspectives and came to completely different decisions. In neither case was consideration of the evidence for effectiveness the deciding factor. We believe that both decisions are reasonable, and it is interesting to reflect on the extent to which both decisions are evidence based.

Thus, to conclude, we argue that there are four central challenges for EBM. A common characteristic relates to the lack of any consideration of theory in a purely empirically driven model of knowledge. The four challenges have substantial ethical and epistemological implications and strike to the heart of the legitimacy of EBM. To date, they have not been met by defenders of EBM. We have argued for a reconstructed vision of decision making that is dialogical in nature and does not privilege one form of evidence over another.

What is the future of EBM? It is hard to stop this juggernaut. As some commentators have said, EBM is here to stay, as it has become an indispensable part of medicine (Laupacis, 2001). It is unlikely that the catchphrase of “evidence-based medicine” will abate in attractiveness or popularity, as contrary options are not tenable. Who, after all, would admit to the practice of whimsy-based or inclination-based medicine? We see two possible future scenarios. In the first, the concepts of EBM are molded and adapted by a serious interaction with the theoretical basis of its ideas and what it
means to incorporate patient (or even societal) preferences into decision making. The focus of attention will be less on the elimination of bias and more on understanding what a well-reasoned and well-justified decision can be. A darker future would be an entrenchment of the current concepts of EBM with a dogmatic acceptance of its legitimacy both morally and scientifically. If our analysis above is at all cogent, the supremacy of current visions of EBM should not go unchallenged.

References


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