Project MUSE®
Scholarly journals online

Iconoclast or Creed?

objectivism, pragmatism, and the hierarchy of evidence

Maya J. Goldenberg

ABSTRACT Because "evidence" is at issue in evidence-based medicine (EBM), the critical responses to the movement have taken up themes from post-positivist philosophy of science to demonstrate the untenability of the objectivist account of evidence. While these post-positivist critiques seem largely correct, I propose that when they focus their analyses on what counts as evidence, the critics miss important and desirable pragmatic features of the evidence-based approach. This article redirects critical attention toward EBM's rigid hierarchy of evidence as the culprit of its objectionable epistemic practices. It reframes the EBM discourse in light of a distinction between objectivist and pragmatic epistemology, which allows for a more nuanced analysis of EBM than previously offered: one that is not either/or in its evaluation of the decision-making technology as either iconoclastic or creedal.

As the name "evidence-based medicine" (EBM) should suggest, the concept of "evidence" is central to the methodological innovation that the evidence-based approach introduces to medicine. Recognizing this to be the case, the critical responses to the movement have championed post-positivist motifs, where the thinking of Quine, Kuhn, and Popper has been drawn upon to demonstrate the flawed objectivist account of evidence underwriting EBM

Department of Philosophy, University of Guelph, Guelph, ON, N1G 2W1, Canada.
E-mail: mgolden@uoguelph.ca.

Perspectives in Biology and Medicine, volume 52, number 2 (spring 2009):168–87
© 2009 by The Johns Hopkins University Press

(Djulbegovic 2006; Harari 2001; Shahar 1997).[1] (In discussing *objectivity*, I refer to its contemporary formulation as the antithesis of *subjectivity*, the latter being popularly understood to be a pejorative intrusion on scientific investigation. See Daston and Galison 1992.) Objectivity is an epistemic virtue in science that stands for an aperspectival "view from nowhere," certainty, and freedom from bias, values, interpretation, and prejudice. Even if objectivity cannot be achieved, it is perceived to be an ideal worth striving for.

The anti-objectivist direction of EBM critique seems fitting. The proposed practice of EBM calls for the evaluation and use of the best available evidence for clinical use in patient care. EBM offers a definitive interpretation of what counts as "best evidence" and encourages its cultivation and application by a hierarchy of methods, clinical guidelines, and authoritative evidentiary sources. This results in problems of knowledge translation, where EBM's stratification of evidence is unlikely to lead to better recommendations for therapy because of the considerable gap between the characteristics of clinical trial populations and actual patient populations seeking care (Bluhm 2005; Upshur 2005). Trial results show comparative efficacy of treatment for an "average" randomized patient, and not for pertinent subgroups formed by such cogent clinical features as severity of symptoms, illness, and co-morbidity. The problem of generalizability calls EBM's alleged objectivism—namely, the objectivity of rigorous clinical evidence—into question.

There is also the overlapping yet distinct epistemological criticism that focuses on the role of values and contingent social practices in belief formation and justification. The evidence-based approach remains noticeably silent on the values, preferences, and other subjective content that inescapably enter into all decision-making schemas. Its supporters unreflectively endorse the evidence-based valuing of the quantitative at the expense of the qualitative, and the aggregate over the personal. EBM's configuration of evidence has been charged in various critiques with being objectivist, reductionist, positivist, and foundationalist (De Simone 2006b; Goldenberg 2006; Holmes et al. 2006; Lambert, Gordon, and Bogdan-Lovis 2006; Upshur 2002; Welsby 1999). The general conclusion coming out of these critiques is that EBM's "evidence base" is simply inadequate for properly capturing the complex nuances of medical decision making in the clinical context.

Objectivism. Reductionism. Positivism. Foundationalism. These distinct yet overlapping *isms* are familiar tropes used in science studies for capturing features of the flawed "textbook" account of the nature of science—a narrative of enlightened, truth-seeking, and value-free inquiry. This line of criticism has been

[1] *Post-positivist* refers to the post–World War II reaction against logical positivism, especially against the view of scientific knowledge as being grounded in objective reality. Post-positivism is marked by a linguistic turn in philosophy, and the position that science is situated in both historical and social contexts.

taken up in EBM critiques to deny the presumed unmitigated gate-keeping ability of "the evidence" for delineating effective treatment from ineffective and harmful alternatives (Goldenberg 2006). As DeVries and Lemmens (2006) argue, "evidence" is a social product, influenced by the variable power and authority held by different stakeholders (patients, medical researchers, hospital administrators, clinicians, policy makers, etc.) in producing and determining the parameters for what counts as evidence. The displacement of these normative considerations in favor of technical and methodological considerations like the criteria of best evidence or scientific rigor is regarded as ethically suspect (Goldenberg 2005). While evidence-based approaches are concerned with finding the *best* evidence (according to their predefined standards) to answer research and treatment questions, the critics ask the challenging question: *whose* evidence is setting the standard of best practice (Harari 2001; Shahar 1997; Stewart 2001; Walsh 1996; Witkin and Harrison 2001)?

What we see emerging in the critical investigations into evidence-based practice is not only a picture of an objectivist account of evidence underlying EBM, but a broader objectivist worldview in which the evidence-based approach is poised to operate. It has already been mentioned that the term *objectivity* carries considerable epistemic weight in science and other knowledge-pursuing activities. It has been described allegorically as a "figure cast in stone, standing in our cultural pantheon among symbols of divine knowledge" (Burnett 2008). Objectivity's typical association with such equally powerful concepts as reality, truth, and reliability further emphasizes its cognitive might.

Yet this objectivist ontology, where the evidence "speaks" and reliable knowledge follows, presents an occupational hazard to (actual) medical practice. Subjective content muddies up even the most rigorous evidence-based practice by the inescapable layers of interpretation and sociocultural influence that enter in the setting of research agendas (including what projects gets funded and why), the production of evidence in primary research, and the selection of which evidence is chosen to inform policy and practice. For instance, DeVries and Lemmens's (2006) examination of the influence of pharmaceutical companies on the conduct and reporting of clinical trials has demonstrated the nonevidentiary forces shaping what is the basis of evidence-based medicine. Bogdan-Lovis and Sousa (2006) have shown how the positive evidence in favor of midwife-led births has not been implemented in American obstetrics units, thereby highlighting how ideology can impede evidentiary uptake. Looking at the health policy-making process for daily hemodialysis therapy, Gordon (2006) demonstrates how even what is required as evidence may be politically determined. Conflicting value judgments about evidence and pressures exerted by stakeholders render health policy making a political process, and EBM does not serve to quiet special interests and agendas. Instead, Gordon characterizes EBM as a political endeavor with vital ethical implications for clinical care. These examples lead to the same conclusion about EBM's so-called evidence base: against the appar-

ent value-neutrality of letting the evidence "speak," EBM can only to be true to its principled "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett et al. 1996, p. 71) if it takes these structural and sociocultural influences on the production and application of evidence into account.

Pragmatism and EBM

While these post-positivist critiques seem largely correct to me, the focus on the nature of evidence inaccurately depicts EBM as suffering from wholesale objectivism. In fact, EBM demonstrates important pragmatist allegiances as well as the objectivist tendencies already highlighted, but these features of the evidence-based approach do not surface in the standard post-positivist critiques of how EBM construes "evidence." In addition to limiting our view of the scope of the evidence-based approach, the critics miss the desirable pragmatic features of evidence-based decision making. I propose to redirect critical attention toward EBM's fixed hierarchy of evidence as the guilty source of its questionable epistemic practices. This permits a more nuanced analysis of the various techniques and epistemological commitments that comprise the evidence-based approach, which, in turn, allows for consideration not only of EBM's problematic areas, but also of any advantageous attributes that ought to be maintained in revisions or radical alternatives to the evidence-based program.

"Pragmatism" is an American movement in philosophy founded by Charles Sanders Peirce and William James (ca. 1877, when Peirce published "The Fixation of Belief") and marked by the doctrines that (1) the meaning of concepts is to be sought in their practical bearings; (2) the function of thought is to guide action; and (3) truth is preeminently to be tested by the practical consequences of belief. The term *pragmatic* is used colloquially to mean a "matter of fact" or "practical" approach to problem solving, and it is often placed in opposition to principled approaches. In philosophy, it invites empirical investigation over rationalist inquiry and, following the important contributions by W. V. Quine, denies the analytic-synthetic divide (Haack 2006; Menand 1997).

In his 1907 lecture "What Pragmatism Means," James characterized pragmatism as standing for "the open air and possibilities of nature, as against dogma, artificiality and the pretence of finality in truth" (p. 145). Pragmatists, he writes, "turn towards concreteness and adequacy, towards facts, towards action, and towards power. That means the empiricist temper regnant, and the rationalist temper sincerely given up." Lastly, pragmatism "does not stand for any special results [or doctrines]. It is a method only" (pp. 144–45). While pragmatism has evolved since James and has even diverged into feminist, analytic, and continental strains, it still retains this general commitment to ad hoc experiential investigative approaches and rejects the distinction between transcendental and empirical truths.

EBM: Pragmatic and Objectivist

Although pragmatism and objectivism might seem mutually exclusive, as the former emphasizes context and practice while the latter pursues universals, EBM demonstrates affinity to both. The objectivist features of EBM have already been discussed. The pragmatic tenor, interestingly, is captured in the evidence-based allegiance to the randomized controlled trial (RCT). The evidence-based method of choice is, in certain important respects, a pragmatic methodology: RCTs temporarily suspend prior knowledge of human physiology, disease, and pharmacology, all of which might allow for inferences regarding the effectiveness of a particular drug in treating a given condition, and instead determine whether a treatment works by *trying* the treatment in a large number of cases under controlled conditions. Because RCTs are ostensibly unhindered by the pre-theoretic expectations and commitments that can bias the deductive methods of basic science and the less systematic experimental methods of clinical experience and observational studies, RCTs seem to best promote the open inquiry and democratism of empirical science. Absent the influence of anticipated outcomes, scientists faced with recalcitrant empirical data should be more open to revising even well-established views about treatment efficacy. The reliability of the RCT as an evidentiary source over, say, clinical experience or observational studies comes from its careful controls. The controls imposed by RCTs give us, to use Quinean terms, "firmer observational checkpoints and stronger inferences from observations to conclusions—particularly conclusions about interventions" (Sehon and Stanley 2003).

The pragmatic commitments are readily apparent in EBM's clear allegiance to experimental methods of inquiry that set aside past habitual thinking in favor of purely empirical investigation. Indeed, EBM's promise of "the application of the best research evidence to medical decision-making" (EBMWG 1992) could have been achieved by strictly pragmatic scientific methodology. Critics like Benitez-Bribiesca (1999) who charge EBM with being "nothing new"—biomedicine, they contend, has *always* been evidence based—certainly think that this is all there is to EBM.

Against this pragmatic spirit, however, is the famed hierarchy of evidence. The hierarchy is a ranking of study designs based on their supposed methodological rigor. EBM proponents hold that the trustworthiness or validity of evidence is a function of the design of the study from which the evidence is obtained (Canadian Medical Association 1994; Sackett 1997; Sackett et al. 1991), and so the desire to use only the best evidence from clinical research in the management of individual patients has resulted in elaborate classificatory schemes for ranking the value of different types of studies (Sackett and Haynes 1995). The numerous published formulations consistently place randomized controlled trials (RCTs) or the systematic review of these trials at the top, with retrospective studies well down the list; clinical anecdotes are seen as providing little if any evi-

dence for the value of intervention (Canadian Medical Association 1994; Centre for Evidence-Based Medicine 2006).

Unlike some other features of EBM, the hierarchy of evidence is notably non-pragmatic, as pragmatism carries no pre-theoretical notions of evidence. Quine insisted that no standards or methods are laid down prior to the business of constructing theories to explain and predict what we experience. Pragmatists hold that there is "no simple formula for distinguishing viable theories or research programs from nonviable ones," but rather an "inevitable need for extensive and multifaceted evaluation" (Nelson 1993, p. 184). RCTs, for instance, have proven their worth for answering certain intervention questions, but, as I will argue, their placement at the top of a preset hierarchy of evidence has yet to be justified.

The pragmatist tenets of method over doctrine, empiricism over rationalism, and practical over principled approaches all speak to a "bottom-up" theory of truth.[2] This approach for ascertaining true beliefs inductively arose as an "anti-theory" position, where pragmatists were greatly suspicious of grand normative theories that begin with axioms and then proceed to deduce the theorems and corollaries that guide normative practice. The worry was that deductive or "top-down" procedure, where arguments move from abstract and general propositions to conclusions about particular cases, can be too far removed from the intricate workings of context and experience. Without constant and vigilant experiential checks on even the most widely held beliefs, inaccurate theoretical commitments could be dogmatically maintained. The recommended alternative is a bottom-up approach, starting with judgments about particular cases and ending with low-level principles that are concrete and contextual rather than abstract and general (Coleman 2001). It now becomes apparent why pragmatists regarded experimental inquiry so highly: problem solving is a leitmotif for pragmatism, and concrete problem solving and the advancement of knowledge is strongly held to be best advanced through a reflexive process where our basic commitments can be scrutinized and revised in light of new findings. It is for this reason that pragmatism is "disdainful of abstract theory and intellectual pretension" and asks instead what the consequences of particular decisions will be (Posner 2003).

EBM's rigid and rule-based hierarchy of evidence stands in contrast to the open-ended and ad hoc style of pragmatic scientific inquiry. The hierarchy's ranking has been explained by the EBM originators as being based on levels of certainty (Sackett et al. 1991). It stands as EBM's point of departure from pragmatic science to a more objectivist epistemology, as the RCT's gold standard status will be shown to be problematically upheld by various abstract commitments to the universal rigor and applicability of randomized trial methods that are not substantiated in the actual practices of health research. Instead, different health

[2]The pragmatic theory of truth holds that truths are beliefs that are confirmed in the course of experience (where experience is the ongoing transaction of organism and environment).

research studies call for different designs and so there is no gold standard methodology.

This pragmatist investigation into the hierarchy of evidence will consider, first, the gold standard status of the RCT, then the legitimacy of its pride of place at the top of the hierarchy, and, finally, the implications of this methodological ranking for democracy and anti-authoritarianism in science.

Hierarchy and Gold

The RCT is both a component of the objectivist ontology to which EBM subscribes *and* the pragmatist's method of choice. To understand the RCT's dual citizenship, the distinction must be made between the RCT methodology and the RCT's placement at the top of the hierarchy of evidence. We have seen already that the randomized trial method promotes unhindered, open-ended empirical inquiry. The "gold standard" status, however, is unwarranted, and it introduces theoretical commitments that are not consistent with pragmatic scientific inquiry.

To be the "gold standard" is to be "a method, procedure or measurement that is widely accepted as being the best available" (*Bandolier Glossary of Terms*). The status of the RCT as the gold standard in medical research is a well-known tenet of the evidence-based program. The Evidence-Based Medicine Working Group claimed that: "Because the randomised trial, and especially the systematic review of several randomised trials, is so much more likely to inform us and so much less likely to mislead us, it has become the 'gold standard' for judging whether a treatment does more good than harm" (Sackett et al. 1996, p. 72). Yet against this widely accepted view, the critics warn us to watch out for "fool's gold" (Rosner 2002). Nancy Cartwright (2007) asked "Are RCTs the Gold Standard?" and responded with a vigorous "no." Gold standard methods, she explained, are "whatever methods will provide (a) the information you need, (b) reliably, (c) from what you can do and from what you can know on that occasion" (p. 11). Because the RCT sometimes does this well, but underperforms in other contexts, it has no claim to methodological gold (Glasziou et al. 2004; Grossman and Mackenzie 2005).

What follows in this section is largely a rehearsal of the body of literature challenging the RCT's gold standard status in health research (Black 1996; Cartwright 2007; Grossman and Mackenzie 2005; Timmermans and Berg 2003). From a pragmatist perspective, the problem is not so much that the gold standard status is tenuous, but that the RCT's placement of at the top of the hierarchy is so insistently maintained. It is largely in the interest of avoiding dogmatic theoretical commitments that pragmatists endorse a bottom-up approach to theory construction, where localized beliefs must pass the test of experience in order to be elevated to generalizable knowledge claims. There are numerous experimental scenarios in health research where the RCT would *not* be the

methodology of choice, which suggests that the hierarchy of evidence would not pass the rigors of the bottom-up approach to theory building. (It is arguable, of course, that it should not meet the standards of the top-down, deductive approaches either.)

The claims that RCTs are the gold standard and therefore deserve placement at the top of the hierarchy of evidence rest on the certainty that deductive methods permit in scientific investigation. However, the place of RCTs as the gold standard in health research—where real-world RCTs rather than idealized randomized experiments are conducted—is contestable.[3] Purely deductive methods like the ideal RCT are admirably rigorous: if the inputs (auxiliary assumptions) are true, the methods are applied correctly, and the outcomes (evidence) are true and have the right form, then the hypothesis *must* be true (Cartwright 2007). But RCTs suffer, as do all deductive methods, from narrowness of scope. Their results are formally valid for the group enrolled in the study, but only for that group. The success of the deductive method rests on the auxiliary assumptions being extremely restrictive, allowing only a very specialized type of evidence as input, and having only special forms of conclusion as output. This is a familiar trade-off between internal and external validity where we can ask for methods that "clinch" their conclusions, even though the conclusions are likely to be very limited in their range of application (Cartwright 2007).[4]

Once internal validity has been established, the next step in health research is to export the causal claim validated through the RCT from the experimental population to a target patient population. Here, Cartwright tells us, the rigor gives out. Various methods are employed to try to take into account all possible sources of difference between the test and target populations, yet all of them are underwritten by our fallible judgments about possible sources of difference. As a result, none of the conclusions reached meet the standard that advocates of the exclusive use of RCTs hold on to. RCTs, as we know, provide averaged effects of treatment, and treatment effects are always heterogeneous. They will, to use Cartwright's phraseology, at best *vouch* for the conclusion rather than *clinch* it. In conclusion, the RCT "takes us only a very small part of the way we need to go for practical knowledge" (p. 18).

Even with Cartwright's warning about the vanity of rigor in RCTs, many EBM critics will concede that RCTs are effective for gathering even broadly applicable practical knowledge about *some* interventions, but fail in other contexts. For example, RCTs are widely regarded as offering good experimental design for large drug trials. Randomization is thought to effectively guard against

[3]Ideal RCTs have no measurement error and the assured balance of all co-variants (ceteris paribus condition).

[4]Against the previous articulation of how the RCT is the pragmatists' method of choice in certain respects, their emphasis on practical knowledge solving suggests that they would find the experimental scenario that trades off on external validity to be highly problematic.

bias in the allocation of subjects to the experimental and control arms, and the various controls assist in firmly establishing the causal relationship between the active chemical agent and the targeted measurable outcomes. However, even without calling those claims into question—as has been done by Howson and Urbach (1993), Worrall (2002), and Borgerson (this issue)—such techniques as randomization and blinding are not always appropriate. Randomization, for instance, is a futile exercise when the sample size is small compared to the number of variables. Even RCT and EBM advocates recognize that randomization and blinding are not always possible, due to the nature of the investigation or for ethical reasons. For instance, it would be impossible to randomize or blind participants to assess the negative effects of smoking. And when comparing a surgical versus a nonsurgical intervention, it may be unethical to subject participants in the non-surgical group to sham surgeries in order to maintain blinding (Stirrat 2004). Grossman and Mackenzie (2005) have pointed out that even when the limited applicability of RCTs is conceded by its advocates, one will inevitably find an accompanying note stating that the alternative observational or historically controlled trials that must be done instead are suboptimal in comparison to an RCT and therefore must be carried out only if there is absolutely no way to do an RCT. This inability to perform an RCT is lamented because the methodology is presumed to be the gold standard. Yet, the authors ask, how can a design with limited applicability still be held as the gold standard in all treatment scenarios? If an experimental design is impossible or unethical, it presumably is not the best method. Thus the sense of regret at not being able to execute an RCT may be unfounded.

It is surely more convincing for the argument that RCTs are not the gold standard *sub specie aeternitatis* to consider scenarios where RCTs are both possible and ethical, but are *inferior* to other study designs. For example, in areas where treatment advances are occurring rapidly, the use of observational databases is a preferable option to avoid the results being out of date by the time the study is complete (Grossman and Mackenzie 2005). HIV research provides numerous instances where this time frame problem is encountered (Millson and Rachlis 1999; Sabin and Phillips 2001). Bakheit (2004) outlines the specific case of examining the effectiveness of botulinum toxin treatment on post-stroke muscle spasticity, where RCTs are less suitable due to their inferior ability to address the impact of the intervention on functional abilities and social participation.

Grossman and Mackenzie (2005) also challenge the belief held by many EBM advocates that public health interventions should be evaluated in the same way as pharmacological interventions (Sackett 1994). RCTs are a suboptimal study design in social contexts due to the problem of bleeding of effects (which hinders effective comparison) between the intervention group and the control group. This problem arises frequently in trials using "free-living" human subject populations. For example, subjects in blinded drug trials sometimes share their drugs with friends who are also participating in the study, in the hope that every-

one can benefit from the promising new, albeit unconfirmed, therapeutic agent. Such activities are disastrous to the RCT. Often the best solution in such cases is to analyze the study's results according to the drugs actually taken by each subject, rather than by the drug delivered to each subject. This is easiest to organize if the study is deliberately *not* blinded, because in a blind study the subjects have an extra incentive to lie about their actions (for fear of being reprimanded for breaking the blinding). Another way to avoid this effect would be to use a historical, nonrandomized control group.

The best methodology will depend on the details of the social interaction of the subjects with the researchers, and the necessity of taking these interactions into account argues against the automatic privileging of a particular simple research methodology such as the RCT (Grossman and Mackenzie 2005). This scenario should prompt us to amend the previous statement that RCTs are widely recognized to be the best experimental design for drug trials. Instead, they may be the best design for large phase III pharmaceutical trials in compliant populations. Different studies call for different design (Black 1996; Britton et al. 1998).

And where does the hierarchy of evidence fit in? The evidence-based hierarchy only reinforces the RCT's privileged status. The hierarchy applies to all evaluations of the medical trial literature, and so the RCT is presumably *always* better than the alternatives. There have been numerous challenges to the legitimacy of the evidentiary hierarchy (Concato, Shah, and Horwitz 2000; Grossman and Mackenzie 2005; Rosner 2000, 2002; Vandenbrouke 1998, 2004). Petticrew and Roberts (2003) maintain that "in certain circumstances the hierarchy may even be inverted, placing for example qualitative research methods on the top rung" (p. 528). Grossman and Mackenzie (2005) reject any hierarchy entirely, while Bluhm (2005) exchanges the hierarchy for a network of evidence that takes into account the relationship between epidemiological and laboratory research.

Hierarchy and Authority

In addition to taking us away from pragmatic scientific practices, the hierarchy of evidence distances EBM from the pragmatist emphasis on democracy in science. Classical and feminist pragmatism's political stake in "getting to label who knows, how she goes about knowing, and what she should and does know" (Seigfried 1993, p. 1) clashes with the supposed universality of the hierarchy. The hierarchy of evidence is the point at which evidence-based methodology can be charged with authoritarianism. Amidst the broad EBM discourse, there has been a small politicized debate regarding whether EBM represents a democratizing or repressive force in biomedicine. EBM certainly proposed to be iconoclastic in its early programmatic literature, and it invoked pragmatic methods meant to rid medicine of its unwarranted habits of thought and practice (see for example EBMWG 1992).

EBM's inaugural manifesto in *JAMA* captured the movement's anti-authoritarian spirit. The Evidence Based Medicine Working Group (1992) stated: "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" (p. 2421). In his recollections of his medical training in clinical epidemiology at McMaster University by many of the faculty members who later initiated the Evidence Based Medicine Working Group, Ross Upshur (2005) remembers being attracted to its critical rationality. During rounds, students and residents were challenged to explicitly justify their proposed diagnostic strategy or therapeutic regimen with the pointed question, "What is your evidence?" The call for evidence in this context "was a call for something more than preference or convention, a call to an external standard that could be adjudicated and discussed" (p. 480). The transparency and accountability of critical appraisal techniques and EBM's procedural emphasis on enhancing the cognitive skills of clinicians suggested a certain democratic iconoclasm that greatly appealed to earnest new physicians like Upshur. Jo Ann Rosenfeld (2004), for instance, recounts:

> We would read it for ourselves and make our own judgments whether to get prostate-specific antibodies as screening for prostate disease on all men or not. Clinical Evidence went even further. It made no judgments. It assembled the evidence in one spot so that the practicing doctors could judge and decide for them. Practicing doctors were expected to be able to think and judge. You might not do it for every case, but you could look up the evidence on women's incontinence today and screening for colon cancer tomorrow. (p. 154)

Despite EBM's apparent populism, both Upshur and Rosenfeld associate current applications of EBM with authoritarianism. Rosenfeld tracks EBM's historical movement from populism in its early years to its authoritarian present. She argues that "evidence-based medicine at first promised to be a popularistic movement, bringing the fruits of research to all practicing physicians. Instead it has created its own religion and dogma, further codifying daily practice" (Rosenfeld 2004, p. 153):

> During the last 3 years, EBM has gone from a tool to a religious doctrine and fixed dogma. There are its priests—men and women who are known for practicing and preaching EBM and changing the books and literature. You have to have one of these priests on every board and journal, or you are not up to date. Anyone who speaks against these priests is blaspheming EBM, and obviously unscientific or backward. There are thousands of acolytes, those who have heard the word and will accept nothing else. (pp. 154–55)

As a result, she argues that "we have come full circle to faith-based medicine" (p. 153; see also De Simone 2006a), where we have replaced one form of author-

ity—namely, the habits and opinions passed down from one generation of clinicians to the next—with another, EBM.

This charge of evidence-based dogmatism is legitimated in part by EBM proponents' confidence in evidence-based methodology despite no empirical evidence being available to demonstrate EBM's superiority (Haynes 2002; Upshur and Tracy 2007).[5] In a 2004 special edition of the *British Medical Journal* dedicated to philosophical issues surrounding EBM, one contributor surmised:

> Few would disown the EBM hypothesis—providing evidence-based clinical interventions will result in better outcomes for patients, on average, than providing non-evidence-based interventions. This remains hypothetical only because, as a general proposition, it cannot be proved empirically. *But anyone in medicine today who does not believe it is in the wrong business*. (Reilly 2004, p. 991, emphasis added)

Some critics have identified EBM's shift from being iconoclastic to becoming a creed in its penchant for guidelines and the resulting codification of daily clinical practice (Berg 1997; Denny 1999; Timmermans 2005). Upshur and Tracy (2007) have indicted the hierarchy of evidence as the offender. Interestingly, the hierarchy of evidence promotes methodological transparency and encourages reasoned argument by providing a highly rationalized method for evaluating clinical research, yet the hierarchy itself has no empirical legitimacy. As Upshur and Tracy have argued, the entire edifice of evidence hierarchies is not based on systematic research or empirical data, but upon expert judgment or consensus. They charge that "the structuring of evidence according to a hierarchy is by no means natural, intuitive, or even logically justified. In other words, the warrant or justification for viewing evidence on such a hierarchical structure rests on what EBM proponents consider the lowest form of evidence: the beliefs of a few" (p. 159). Upshur and Tracy propose that 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 stance was grounded in an unsubstantiated epistemological position that favors certain study designs (RCTs and meta-analyses) on the belief that these methods are less susceptible than observational designs to bias. The key is the ability of randomization to eliminate selection bias and the unprovable claim that randomization balances all relevant known and unknown factors in a probabilistic sense (Worrall 2002). The hierarchy attributes lower reliability to expert judgment, and specifically subordinates

[5] The near impossibility of empirically demonstrating the superiority of EBM over any other mode of medical care by the methods regarded as persuasive by EBM itself has been recognized from the outset. EBM's initial manifesto states: "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" (EBMWG 1992).

theory and pathophysiological reasoning to designs with randomization. The reasoning behind the latter subordination is unclear, as pathophysiology often provides more fundamental understanding of causation and is in no way scientifically inferior. Thus, Upshur and Tracy conclude, the hierarchy has been advanced on the basis of expert opinion rather than reasoned argument—a move unbefitting of evidence-based thought and practice.

EBM guidelines and clinical summaries invoke charges of authoritarianism for codifying daily practice and creating a hierarchy of EBM expertise. Given the demands of keeping up with the literature, the time associated with evaluating the abundance of clinical research, and the importance of "getting it right," it did not take long for EBM to replace its earlier call for individual critical appraisal of the evidence by practicing clinicians with a veritable industry of systematic review and meta-analysis (available for a fee, typically through electronic databases). While thought by many to be timely and useful, the availability of meta-analyses and clinical summaries immediately derails EBM's early anti-authoritarian programmatic. The initial program of equipping all practicing physicians with critical appraisal skills (and "a computer at every bedside") was intended to democratize medicine by discarding the hierarchical nature of expert opinion and received wisdom. That very authoritarianism seems to be restored by the creation of "expert" EBM sources that proliferate clinical guidelines, meta-analyses, educational products, electronic decision support systems, and all things worthy of the brand name "evidence-based medicine" to a captive and paying audience of clinicians who desire to be "evidence-based practitioners."

The various EBM organizations, such as the Cochrane Collaboration, Best Evidence, and the Task Force are further criticized for being secretive institutions. This system is not terribly different from the prior methods of peer review with respect to assuring credible professional literature, however the internalizing of medical expertise *within* the various evidence-based institutions diminishes the likeliness of receiving disinterested (external) reviews. Even if the current system creates evidence that is no worse than before, EBM had proposed that it could do better. Rosenfeld (2004) asks:

> Who are these people? We know where they are located and sometimes their names, but we must blindly believe in their methods. They come up with conclusions that are published and then the conclusions become codified. The Cochrane conclusions and abstracts are published on the web, but only those who pay can get the full written method and evidence. Few practicing doctors will pay for access to the Cochrane database. Who knows how Problem-Oriented Evidence that Matters (POEMs) decide their evidence? The practicing doctor has little access to these articles. Even Clinical Evidence, that source that believed the practicing doctor can make his or her own conclusions, has published "Concise" conclusions. Are we too busy, too stupid, or too unreliable to use EBM for ourselves? (p. 155)

Rosenfeld's chronicle suggests that like EBM's hierarchy of evidence, there is now a hierarchy of EBM. Specifically, "only a few sources are now considered 'true' or reliable EBM. Some organizations list 11–15 'proper' and 'acceptable' sources of EBM. All else, including good research, books, and reviews, are not evidenced-based, and may not be used" (p. 155). This EBM structure is indeed commercially profitable, and it has generated concern about financial conflict of interest and publication bias within the medical literature. The BMJ Publishing Group, for instance, has a significant stake in the EBM market through its production and sales of costly EBM textbooks and evidence databases. The conflict of interest is suggested by the finding that a significantly greater number of EBM studies have been published in the *British Medical Journal* as compared to the similarly ranked *New England Journal of Medicine*, which has no commercial investment in EBM (Upshur et al. 2006). Elsewhere, Charlton and Miles (1998) were less tactful in their description of EBM as "in bed with the BMJ" (p. 373).

Levels of Certainty

While it would be premature to suggest that there is a link between objectivist epistemology and authoritarianism, the threat of global skepticism that motivates the former can certainly minimize tolerance of fallibility and ad hoc and local investigative practices—the very characteristics of science proper—among more ideological proponents of science. The pragmatists were well aware of the connection between fallibilism and anti-skepticism, both of which concepts characterize important features of pragmatist thought.[6] This sort of absolutist search for certainty can explain the appeal and rapid uptake of EBM. We have seen how the positivist account of evidence underlying EBM is criticized for failing to properly recognize the fallibility of scientific evidence. The worry that all of our representations could be wrong can motivate the search for epistemic certainty, and trouble arises because this quest is undertaken using a method of inquiry that is supposed (and even desired) to be irrevocably fallible. Critics argue that this promise of medical certainty is unrealistic, and they suggest that evidence-based decision making must be replaced with a more nuanced model of knowledge translation that can grapple with contingency and the uncertain path of application of knowledge in practice (Champagne, Lemieux-Charles, and McGuire 2004).

[6]In "Some Consequences of Four Incapacities," Peirce (1868) reacted against modern academic skepticism by insisting that contrary to Descartes's influential methodology in the *Meditations on First Philosophy*, doubt cannot be created for the purpose of conducting philosophical inquiry. Doubt, much like belief, requires justification. It arises from confrontation with some specific recalcitrant matter of fact, which unsettles our belief in some specific proposition. Inquiry is then the rationally self-controlled process of attempting to return to a settled state of belief about the matter. (See also Dewey 1929, where he argues against the reification of concepts and theories.)

The proposal that the quest for certainty drives science and scientific medicine is a familiar thesis within critical science studies. Paul Feyerabend (1978) has described science as being obsessed with its own mythology of objectivity and universality, while in medicine, Katherine Montgomery (2006) has argued that medicine mis-specifies itself as a science, with an image of science that is antiquated and that does justice to neither medicine nor science. Science has also been described, again by Feyerabend among others, as a repressing ideology that started as a liberating movement. EBM reinforces these images, to a certain extent, with its objectivist account of scientific medicine and rigid hierarchy of evidence. If the hierarchy of evidence was put in place to refute skepticism and ensure certainty, it stands as an example of what Feyerabend abhorred: science making claims to truth well beyond its actual capacity. Science, the critics insist, cannot fulfill this epistemic quest for certainty. Science is at best—and is at its best—when it is recognized to be democratic, ad hoc, and fallible.

However, the philosophical obsession with skepticism is not necessarily the driver of EBM. The knowledge problems motivating the evidence-based approach are regarded by some to be much more local and modest, for instance, trying to minimize the presence of small area variations and the desire for increased reliability and access to the best confirmed interventions. Howard Brody and colleagues' distinction between "crude" versus "sophisticated" EBM distinguishes between the different ways in which EBM has been understood and employed by supportive practitioners (Brody, Miller, and Bogdan-Lovis 2005). It also manages to capture the ideological/truth-seeking versus practical motivation for adopting an evidence-based approach to medicine. The more "practical" users being described here are those clinicians who find in EBM no more than a tool to assist in clinical decision making, a task fraught with difficulties for the very reason that the context always carries elements of uncertainty. It is inappropriate for both supporters and detractors to ascribe the appeal of EBM to one mindset or sensibility among its clinical followers.

AN OBJECTION

These critiques regarding the properly recognized fallibility of science and the authoritarianism of EBM do not discount the possibility that guidelines generally help reduce error and improve medical outcomes. One can reasonably concede that the rise of authoritarianism in EBM is a departure from its origins and represents a shift from iconoclasm to creed, but still insist that guidelines, protocols, and checklists are valuable instruments for reducing medical errors. For instance, better compliance with the accepted guideline for physicians to wash their hands before seeing each and every patient would certainly reduce the spread of infection and illness. The general conclusion coming out of the guidelines literature is that guidelines are effective and easily implemented in standard cases where prognosis, symptomology, diagnosis, and treatment are well-defined.

Once the cases are less run-of-the-mill, however, there are a variety of obstacles to the implementation of guidelines (see, for example, Dahan et al. 2007). There is disagreement, of course, whether those challenges are surmountable, or whether algorithms, protocols, and guidelines completely fail in these difficult scenarios.

In *How Doctors Think* (2007), Jerome Groopman expressed the worry that preset algorithms and practice guidelines "discourage physicians from thinking independently and creatively. Instead of expanding a doctor's thinking they constrain it" (p. 5). While the dissenter might be justified in not wanting doctors to think about washing their hands and instead to just do it, the relaxing of physicians' critical thinking skills can seriously compromise medical care in other situations where symptoms are vague, multiple, or confusing, or when test results are inexact. Like many EBM critics, Groopman criticizes "today's rigid reliance on evidence-based medicine" for having physicians "choose care passively, solely by the numbers" (p. 6). Reflecting on his motivation for writing a book on how doctors think, Groopman recalls:

> Each morning as rounds began, I watched the students and residents eye their algorithms and then invoke statistics from recent studies. I concluded that the next generation of doctors was being conditioned to function like a well-programmed computer that operates within a strict binary framework. After several weeks of unease about the students' and residents' reliance on algorithms and evidence-based therapies alone, and the equally unsettling sense that I didn't know how to broaden their perspective and show them otherwise, I asked myself a simple question: How should a doctor think? (p. 6)

This appeal to Groopman's position is not intended to be an argument by authority—Groopman could, after all, have some sort of axe to grind against EBM. But what should strike both EBM proponents and dissenters as pertinent is that the EBM community was founded upon the same interest in promoting critical thinking in medicine. The movement's penchant for developing clinical guidelines is not merely a philosophical contradiction, but, by its own account, dangerous to medical practice. EBM was one response to the perceived need to improve doctors' reasoning skills as an important component of medical training, and EBM continues to promote critical thinking alongside its clinical guidelines, clinical summaries, and other time-saving devices for reading the medical literature. For example, Jenicek's *A Physician's Self-Paced Guide to Critical Thinking* (2006) strongly promotes critical thinking as integral to modern medicine.[7] While one might strongly support EBM's methodology, that endorsement need not include overconfidence in EBM's ability to somehow encompass the neces-

[7]For a review of the debates over guidelines, critical thinking, and other related conceptual and methodological issues in the medical literature, see Miles, Loughlin, and Polychronis (2007).

sary critical thinking piece of medicine into their (presumably) well-researched and well-thought-out guidelines.

Conclusion

EBM has been argued to maintain both pragmatic and objectivist epistemological allegiances. It is pragmatic in its commitment to the comparative analyses offered by RCTs rather than basic science's interest in causal understandings of treatment interactions. The hierarchy of evidence, however, delves into nonpragmatic epistemology, as the pregraded ranking of research methods offers a priori normative properties for ascertaining maximal objectivity. In the interest of better science, I propose that EBM's pragmatic features are worth keeping. By this, I mean that the open-ended critical inquiry should be encouraged, as should comparative clinical research and problem-specific methodology (which may include uncontrolled methods and even reliance on clinical judgment). The rigid hierarchy of evidence, as we have seen, leads to considerable problems for EBM and should be dismantled. The EBM critics, writing from the post-positivist philosophy of science tradition, have amply demonstrated these problems. But the constructive project of revisioning or perhaps recasting the evidence-based approach to medicine requires that the worthwhile aspects of EBM not be discarded along with its flawed features.

References

Bakheit, A. M. O. 2004. Optimising the methods of evaluation of the effectiveness of botulinum toxin treatment on post-stroke muscle spasticity. *J Neurol Neurosurg Psychiatry* 75:665–66.

Benitez-Bribiesca, L. 1999. Evidence-based medicine: A new paradigm? *Arch Med Res* 30(2):77–79.

Berg, M. 1997. Problems and promises of the protocol. *Soc Sci Med* 44(8):1081–88.

Black, N. 1996. Why we need observational studies to evaluate the effectiveness of health care. *BMJ* 312:1215–18.

Bluhm, R. 2005. From hierarchy to network: A richer view of evidence for evidence-based medicine. *Perspect Biol Med* 48(4):535–47.

Bogdan-Lovis, E., and A. Sousa. 2006. The contextual influence of professional culture: Certified midwives' knowledge and reliance on evidence-based practice. *Soc Sci Med* 62(11):2681–93.

Britton, A., et al. 1998. Choosing between randomized and non-randomized studies: A systematic review. *Health Technol Assess* 2(13):1–19.

Brody, H., F. Miller, and E. Bogdan-Lovis. 2005. Evidence-based medicine: Watching out for its friends. *Perspect Biol Med* 48(4):570–84.

Burnett, D. G. 2008. Science and history: Do the claims of science transcend time and place? http://www.columbia.edu/cu/21stC/issue-4.2/burnett.html#notes.

Canadian Medical Association. 1994. Canadian task force on the periodic health examination. *Can Med Assoc J* 150(12):871–79; 1961–70.

Cartwright, N. 2007. Are RCTs the gold standard? *Biosocieties* 2(2):11–20.

Centre for Evidence-Based Medicine. 2006. Levels of evidence and grades of recommendation. http://www.cebm.net/levels_of_evidence.asp.

Champagne, F., L. Lemieux-Charles, and W. McGuire. 2004. Introduction: Toward a broader understanding of the use of knowledge and evidence in health care. In *Using knowledge and evidence in health care: Multidisciplinary perspectives*, ed. L. Lemieux-Charles and F. Champagne, 3–17. Toronto: Univ. of Toronto Press.

Charlton, B. G., and A. Miles. 1998. The rise and fall of EBM. *Q J Med* 91(5):371–74.

Coleman, J. 2001. *The practice of principles: In defense of a pragmatist approach to legal theory.* Oxford: Oxford Univ. Press.

Concato, J., N. Shah, and R. Horwitz. 2000. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Engl J Med* 342(25):1887.

Dahan, R., et al. 2007. The challenge of using the low pack pain guidelines: A qualitative research. *J Eval Clin Pract* 13(4):616–20.

Daston, L., and P. Galison. 1992. The image of objectivity. *Representations* 40:81–128.

De Simone, J. 2006a. Beyond "faith-based medicine" and EBM. *J Eval Clin Pract* 12(4): 438–44.

De Simone, J. 2006b. Reductionist inference-based medicine, i.e. EBM. *J Eval Clin Pract* 12(4):445–49.

De Vries, R., and T. Lemmens. 2006. The social and cultural shaping of medical evidence: Case studies from pharmaceutical research and obstetric science. *Soc Sci Med* 62(11): 2694–2706.

Denny, K. 1999. Evidence-based medicine and medical authority. *J Med Humanit* 20(4): 247–63.

Dewey, J. 1929. The quest for certainty. In *Pragmatism, old and new: Selected writings*, ed. S. Haack, 379–94. New York: Prometheus Books, 2006.

Djulbegovic, B. 2006. Evidence and decision making: Commentary on M. R. Tonelli (2006), "Integrating evidence into clinical practice: an alternative approach to evidence-based approaches." *J Eval Clin Pract* 12(3):257–59.

Evidence Based Medicine Working Group (EBMWG). 1992. Evidence-based medicine. *JAMA* 268(17):2420–25.

Feyerabend, P. 1978. *Against method*. London: Verso.

Glasziou, P., et al. 2004. Assessing the quality of research. *BMJ* 328(7430):39–41.

Goldenberg, M. J. 2005. Evidence-based ethics? On evidence based practice and the "empirical turn" from normative bioethics. *BMC Med Ethics* 6(11).

Goldenberg, M. J. 2006. On evidence and evidence-based medicine: Lessons from the philosophy of science. *Soc Sci Med* 62(11):2621–32.

Gordon, E. J. 2006. The political contexts of evidence-based medicine: Policymaking for daily hemodialysis. *Soc Sci Med* 62(11):2707–19.

Groopman, J. 2007. *How doctors think*. New York: Houghton Mifflin.

Grossman, J. and F. MacKenzie. 2005. Randomized controlled trial: Gold standard, or merely standard? *Perspect Biol Med* 48(4):516–34.

Haack, S., ed. 2006. *Pragmatism, old and new: Selected readings*. New York: Prometheus Books.

Harari, E. 2001. Whose evidence? Lessons from the philosophy of science and the epistemology of medicine. *Aust N Z J Psychiatry* 35(6):724–30.

Haynes, R. B. 2002. What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to? *BMC Health Serv Res* 2(3).

Holmes, D., et al. 2006. Deconstructing the evidence-based discourse in health sciences: Truth, power and fascism. *Int J Evid Based Healthc* 4(3):180–86.

Howson, C., and P. Urbach. 1993. *Scientific reasoning: The Bayesian approach*. Chicago: Open Court.

James, W. 1907. What pragmatism means. In *Essays in pragmatism*, 141–58. Repr. New York: Hafner, 1948.

Jenicek, M. 2006. *A physician's self-paced guide to critical thinking*. Chicago: AMA Press.

Lambert, H., Gordon, E. J., and E. Bogdan-Lovis. 2006. Introduction: Gift horse or Trojan horse? Social science perspectives on evidence-based health care. *Soc Sci Med* 62(11): 2613–20.

Menand, L., ed. 1997. *Pragmatism: A reader*. London: Vintage.

Miles, A., Loughlin, M. and A. Polychronis. 2007. Medicine and evidence: Knowledge and action in clinical practice. *J Eval Clin Pract* 13(4):481–503.

Millson, M. E., and A. Rachlis. 1999. HIV clinical trials are not enough. *Can Med Assoc J* 160(5):669–70.

Montgomery, K. 2006. *How doctors think*. Oxford: Oxford Univ. Press.

Nelson, L. H. 1993. A question of evidence. *Hypatia* 8(2):172–90.

Peirce, C. S. 1868. Some consequences of four incapacities. In *Pragmatism, old and new: Selected writings*, ed. S. Haack, 69–106. New York: Prometheus Books, 2006.

Petticrew, M. and H. Roberts. 2003. Evidence, hierarchies, and typologies: Horses for courses. *J Epidemiol Comm Health* 57:527–29.

Posner, R. A. 2003. *Law, pragmatism, and democracy*. Cambridge: Harvard Univ. Press.

Reilly, B. M. 2004. The essence of EBM. *BMJ* 329(7473):991–92.

Rosenfeld, J. A. 2004. The view of evidence-based medicine from the trenches: Liberating or authoritarian? *J Eval Clin Pract* 10(2):153–55.

Rosner, A. 2000. Gilding the gold standard lily: The limits of evidence-based medicine. *Dyn Chiropr* 18(1):23–24.

Rosner, A. 2002. Reality-based evidence: Prospecting for the elusive gold standard. *Dyn Chiropr* 20:14–16.

Sabin, C. A., and A. N. Phillips. 2001. Treatment comparisons in HIV infection: The benefits and limitations of observational cohort studies. *J Antimicrob Chemother* 47(4):371–75.

Sackett, D. L. 1994. The Cochrane Collaboration. *ACP J Club* 120(suppl. 3):A3.

Sackett, D. L. 1997. A science for the art of consensus. *J Natl Cancer Inst* 89(2322):1003–5.

Sackett, D. L., and R. B. Haynes. 1995. On the need for evidence-based medicine. *Evid Based Med* 1:5–6.

Sackett, D. L., et al. 1991. *Clinical epidemiology: A basic science for clinical medicine*, 2nd ed. Boston: Little, Brown.

Sackett, D. L., et al. 1996. Evidence-based medicine: What it is and what it isn't. *BMJ* 312(7023):71–72.

Sehon, S. R., and D. Stanley. 2003. A philosophical analysis of the evidence-based medicine debate. *BMC Health Serv Res* 3:14

Seigfried, C. H. 1993. Shared communities of interest: Feminism and pragmatism. *Hypatia* 8(2):1.

Shahar, E. 1997. A Popperian perspective of the term "evidence based medicine." *J Eval Clin Pract* 3(2):109–16.

Stewart, M. 2001. Whose evidence counts? An exploration of health professionals' perceptions of evidence-based practice, focusing on the maternity services *Midwifery* 17(4):279–88.

Stirrat, G. M. 2004. Ethics and evidence based surgery. *J Med Ethics* 30(3):160–65.

Timmermans, S. 2005. From autonomy to accountability: The role of clinical practice guidelines in professional power. *Perspect Biol Med* 48(4):490–501.

Timmermans, S., and M. Berg. 2003. *The gold standard: The challenge of evidence-based medicine and standardization in health care*. Philadelphia: Temple Univ. Press.

Upshur, R. E. G. 2002. If not evidence, then what? Or does medicine really need a base? *J Eval Clin Pract* 8(2):113–19.

Upshur, R. E. G. 2005. Looking for rules in a world of exceptions: Reflections on evidence-based practice. *Perspect Biol Med* 48(4):477–89.

Upshur, R. E. G., and C. S. Tracy. 2007. Precision versus clinical experience: Family medicine does not need more evidence-based medicine than at present. In *Ideological debates in family medicine*, ed. S. Buetow and T. Kenealy, 153–64. New York: Nova Science.

Upshur, R. E. G., et al. 2006. Can academic and clinical journals be in financial conflict of interest situations? The case of evidence based incorporated. *J Eval Clin Pract* 12(4): 405–9.

Vandenbrouke, J. P. 1998. Observational research and evidence-based medicine: What should we teach young physicians? *J Clin Epidemiol* 51(6):467–72.

Vandenbrouke, J. P. 2004. Benefits and harms of drug treatments. *BMJ* 329:2–3.

Walsh, D. 1996. Evidence based practice: Whose evidence and on what basis? *J Midwifery* 4(8):454.

Welsby, P. D. 1999. Reductionism in medicine: Some thoughts on medical education from the clinical front line. *J Eval Clin Pract* 5(2):125–31.

Witkin, S. L., and W. D. Harrison. 2001. Whose evidence and for what purpose? *Soc Work* 46(4):293–96.

Worrall, J. 2002. What evidence is evidence-based medicine? *Philos Sci* 69(3):S316–S330.