Most people would probably be surprised to learn that there is a heated debate underway amongst health care professionals over the value and role of ‘Evidence-based Medicine’ (EBM). Surely, if medicine is to have a base, evidence is a good choice. It is certainly better than “vehemence-based medicine” or “eminence-based medicine”, as some of EBM’s more sarcastic defenders point out.\(^1\) The EBM movement, which now reaches into hospitals and university classrooms across North America and the UK, relies heavily on this initial impression.

Evidence-based Medicine has gained at least some of its popularity from the general and ‘intuitively obvious’ nature of its title as well as its apparently innocent and widely accepted goals. It is the motivations and assumptions behind these goals, as well as their implications, that I will be discussing in this essay. I will argue that the frustration currently expressed by physicians in debates over EBM stems from the fact that the most important questions in the philosophy of medicine have been answered and then shelved (as ‘solved’) by the designers of EBM. These questions include (but are not limited to): What counts as good evidence? Who decides what counts as good evidence? What is the role of scientific evidence in medicine? What is the best method for decision-making within the context of clinical practice? What approach to medicine is best for the individual patient? and How valuable is generalized scientific data to the individual clinician?

It is the answers to these questions, whether explicit or implicit, which have shaped the development of the ‘evidence hierarchy’ advocated by EBM practitioners. The hierarchy of evidence (the centerpiece of the EBM movement) provides specific and, I will argue, value-laden, ideologically driven answers to the sorts of important questions asked above. The continued resistance to EBM on the part of physicians is a result of their inability to access and engage with the ‘real’ questions that underlie medical research and clinical practice. This is not only a source of frustration for physicians, but it also, I suggest, undermines at least one of the implicit goals of EBM itself: objectivity.

I. Background: History and Development of Evidence-based Medicine

In the 1970’s and 1980’s, physicians in Canada and the United States began to shift their attention to a new approach to medicine that was based on the increasingly popular methods of clinical epidemiology. In the early 1990’s, the *Journal of the American Medical Association* (*JAMA*) published a series of articles in which the authors introduced and carefully outlined a new (and ostensibly improved) approach to medical teaching and practice. Evidence-based Medicine was initially heralded by advocates as “a new paradigm for medical practice” that “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.” Recognizing that evidence in medicine comes in many different forms, EBM proponents introduced a ‘hierarchy of evidence’ designed to help physicians determine the relative value of different studies and research results. They placed systematic reviews of large-scale randomized controlled trials (RCT’s) at the top as the highest quality of evidence, and evidence from sources such as case studies and qualitative research at the bottom of the hierarchy as the least reliable types of evidence. This hierarchy of evidence was designed to aid physicians in their day-to-day medical decision-making. The primary role of the physician, as proclaimed by initial EBM enthusiasts, was to keep on top of, and critically appraise, current research on a given disease or medical issue, and then to apply the results of this meta-analysis to individual patients.

Reactions to the introduction of EBM were swift. While some of the initial responses were cautiously optimistic, there was also a strong critical reaction from many physicians. Editorial and short articles began to appear in medical journals voicing concerns that the art of clinical proficiency and conscientious individual judgment were being lost under the weight of

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4 EBM Working Group: 2420.

meta-analyses of RCT’s. A few years later (1996), the authors of the original *JAMA* essays on EBM published an article entitled, “Evidence-based Medicine: what it is and what it isn’t,” designed to clarify (and tone-down) some of the more contentious claims from the initial formulation. In this oft-quoted article, Sackett et al. offer a more thoughtful and carefully worded description of their approach to medicine: “Evidence-based Medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” This latest definition reflects an attempt on the part of EBM advocates to recognize the ‘art’ as well as the ‘science’ of good medical practice.

Response to the latest version of EBM has, once again, been mixed. Some physicians find the idea of basing medical practice on the best available evidence to be beyond reproach - even ‘obvious’. Others direct their attention to the precise meaning and interpretation of the terms conscientious and judicious in the EBM definition. Still others continue to write in to medical journals with concerns about the shortcomings of the new approach, including: the persistent “Grey Zones of Clinical Practice”, the primacy accorded to RCT’s in the evidence hierarchy, the absence of discussion on the role of values in medical decision-making, and the tendency to downplay the individual and complex nature of the patient-physician interaction. Defenders of EBM maintain that these criticisms are ‘misguided’, ‘misunderstandings’, or even ‘clearly invalid’. They maintain that there is no reason for physicians to fear the newer, more inclusive version of EBM.

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13 Laupacis (2001): 7A.
II. Motivations, Goals, and Assumptions of the EBM Movement

In *The Social Construction of What?* Ian Hacking offers some practical advice for the task of critical analysis. “Don’t first define. Ask for the point.”\(^{14}\) Now that we have an outline of the history of EBM, I suggest that we take this advice and consider the motivations of those who first introduced the idea of EBM, as well as the stated and implicit assumptions of the EBM movement.

Evidence-based Medicine was introduced in part as a response to surveys indicating that patients with similar symptoms were receiving different treatments depending on the particular physician they visited.\(^{15}\) This was true even in the case of illnesses where fairly conclusive evidence was present to indicate a particular treatment choice. This ‘troubling’ lack of consistency, along with the recognition that many physicians did not even bother to try to keep up with the results of current medical research, provided an incentive for the introduction of a different approach to medical decision-making. In addition to this driving force, the designers of EBM were also aware that a growing interest in the enterprise of biomedical research was producing results at an overwhelming rate. Physicians appeared ill-equipped and often, as a result, ill-motivated to stay on top of the massive quantity of research (of highly variant quality) published every day.\(^{16}\) EBM was developed as a response to these practical problems.

The principal goal of those involved in the design of EBM was the improvement of medical practice. Specification of ‘what exactly is meant by improvement’ or ‘how we will determine when medical practice is better’ (and even the underlying ‘who should decide what counts as good medical practice’) were the next necessary steps for EBM designers. It is these specifications and assumptions (both stated and implicit) that we turn to now. In the first published declaration of EBM (*JAMA* 1992), proponents outlined what they perceived to be their three main assumptions, each with corresponding implicit assumptions.

\(^{16}\) Technological innovations (especially the development and widespread use of computers and the internet), as well as other social variables (including the amount of money available for research and the increased public interest in scientific medicine) were also background factors in the development of EBM.
1) Assumption of the Value of Scientific Evidence - “Systematic attempts to record observations in a reproducible and unbiased fashion markedly increase the confidence [a physician] can have…”\(^\text{17}\). While clinical experience and instinct are still valuable, “one must be cautious” with them because they can be “misleading.”\(^\text{18}\) The assumption is that physicians will be (and should be) more confident in their clinical decisions if they stem from unbiased scientific evidence rather than from intuition and individual clinical experience. This is supplemented later in the paper with the final assumption that “physicians whose practice is based on an understanding of the underlying evidence will provide superior patient care.”\(^\text{19}\)

This first assumption ties medicine closely to science. Good evidence is characterized as ‘unbiased’, ‘systematic’ and ‘reproducible’. Personal experience and intuitions fail to meet these standards. The value placed on these qualities reflects the authors’ belief that medicine would be improved by becoming more objective. For our purposes, it is critical that we recognize that this decision to shape medicine into a more objective scientific enterprise is based on certain values and beliefs that are open to question. That is why EBM advocates have included this as an assumption rather than as an established fact. The idea that physicians’ confidence levels (which are meant to be a reflection of better patient care) should be tied to the degree to which evidence is properly scientific, is assumed. If, by the authors’ own standards, we should be interested in asking for some evidence for this relationship between scientific evidence and better patient care, we would find that no such evidence currently exists.\(^\text{20}\)

2) Assumption of the Value of Outcomes Research - “The study and understanding of basic mechanisms of disease are necessary but insufficient guides for clinical practice.” Pathophysiologic reasoning (tracing possible causal mechanisms of disease based on scientific theories) is contrasted with outcomes-centered research, with the former often leading to “incorrect” and “inaccurate” medical predictions.\(^\text{21}\) The assumption is that outcomes research is less likely to lead to error in medical decision-making.

\(^{17}\) EBM Working Group: 2421.  
\(^{18}\) Ibid.  
\(^{19}\) Ibid.  
\(^{20}\) This is commonly raised as an ironic problem for EBM: there isn’t any conclusive evidence to indicate that EBM is a more successful approach to individual patient care. EBM advocates rely on ‘common sense’ and even a certain sort of ‘pathophysiologic’ reasoning to suggest that they are on the right track. EBM advocates are currently in the process of collecting evidence for this claim.  
\(^{21}\) EBM Working Group: 2421.
According to EBM advocates, the ‘traditional’ model of medical decision-making involved an appeal to authority and wisdom (in the form of accumulated years of clinical experience), as well as an appeal to plausible scientific mechanisms of disease. EBM not only “puts a much lower value on authority,”\(^{22}\) it also moves away from positing possible mechanisms of disease. The focus of physicians is no longer whether we have a plausible biochemical or physical explanation for a particular treatment, but whether there are studies showing that patients recover as a basis of the treatment. *How* something works has taken a backseat to *whether* something works. The assumption that the current focus on outcomes will result in better patient care has yet to be fully tested and established. At this point, it remains an assumption that reflects a certain ideological shift in clinical research.

3) **Assumption of the Need for Rules of Evidence** - “Understanding certain rules of evidence is necessary to correctly interpret literature on causation, prognosis, diagnostic tests, and treatment strategy.”\(^{23}\) The assumption is that physicians need guidelines and rules in order to correctly evaluate current medical evidence.

This assumption is supported by the further assumptions: 1) ‘Good evidence’ is an objective, free-standing concept, 2) Experts are in the best position to understand what makes something good evidence, and 3) Scientific evidence, and the qualities that make it good, are directly transferable to the medical field. Guidelines and rules of evidence can and should be designed by experts, and then followed and applied by physicians. The practice of ranking different types of evidence (as in the evidence hierarchy) is one that follows quite clearly from scientific standards. Scientific values such as generalizability and simplicity can be used to evaluate the strength of medical evidence and form the hierarchy.

### III. Critical Analysis

It would appear that the assumptions and motivations of EBM outlined thus far resolve broadly into answers to two main questions: 1) What will make medical decision-making better? EBM Answer: A stronger scientific basis, 2) How can we achieve a stronger scientific basis for medical decision-making? EBM Answer: Through the development of rules of evidence that can

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\(^{22}\) Ibid.

\(^{23}\) Ibid.
be standardized and applied by individual physicians. In what follows, I will critically analyze these answers and consider whether they can or should form the basis of a ‘new paradigm’ of medicine.

1) A stronger scientific basis is required to improve medical decision-making.

Should medicine be more scientific? Is it even possible? In recent publications, physicians have drawn attention to some of the main differences between medicine and science. It is not necessarily the case that the values underlying science can be easily transferred to the medical field. For example, the virtue of simplicity has had a long and highly successful history in scientific research. Medical research attempts to live up to this ideal by producing large-scale research on simple causal relationships between treatments and their effects. In contrast, medical practice is concerned almost exclusively with complex problems. Physicians constantly have to exercise their judgment in order to determine whether a particular patient will benefit from the results of a recent study. In many cases, a particular patient would never have qualified for the study because they have other underlying illnesses, or don’t meet certain age, gender, economic, or ‘wellness’ requirements. Physicians are constantly called upon to judge how simple research results can apply to extraordinarily complex patient situations. The difficulty, as one physician pointed out, is that “excellent evidence does not necessarily translate into excellent or successful therapy.”

This complexity raises problems even at the level of RCT’s. Black argues, “When there are many variables with an effect on outcome, as in coronary thrombosis, or when an apparently simple label conceals taxonomic complexity as in the nephritic syndrome, then the results of RCT’s tend to be inconclusive or conflicting.”

The complexity of medicine on a large scale, combined with the complexity of individual patient situations, raise questions about the value of simplicity in medical research.

In addition, there has been a growing acceptance in recent medical literature of the idea that individual patients require individual treatments. Not every case of a particular disease is the same. A famous quote attributed to Hippocrates emphasizes this same point: “It is more important to know what kind of person has the disease than what kind of disease the person has.”

In contrast, scientists have always valued generalizability of research results. Most medical research, following scientific standards, is designed to apply to the greatest possible number of people. This discrepancy between highly generalized scientific research and the individual focus of clinical care has led physicians such as Brian Hayes to argue that most of the biomedical literature is inappropriate for clinical decision-making.\textsuperscript{26} The applicability of scientific evidence, especially large-scale, single-factor studies, “depends on the individual being conformable to the group in all relevant aspects,”\textsuperscript{27} which is rarely the case. Individuals share some characteristics with the group, and so generalized research results retain some applicability, but physicians are faced every day with the limitations of highly general research results.

Even if there are biological similarities between several different cases of a disease, the values and other non-quantifiable factors introduced by each of the individual patients could radically shift the medical decision being made. The move toward a more inclusive decision-making process that has been occurring in medicine over the last half century has forced physicians to become more aware of the inherent limits and uncertainty of medical practice. Recent attention to bioethical principles of autonomy and informed decision-making have pushed the medical model away from ‘doctor knows best’ paternalism and raised new questions about the role of patients in medical decision-making. The more we recognize the role of patients and of patients’ values in medical decision-making, the further the original EBM project is from reality. No matter how decisive the evidence is, without patient input, there is no clear ‘right’ decision. This move toward inclusive decision-making can be seen as going against the tide of EBM – quite successfully.

In medical literature over the last decade, commitment to the idea that medical care needs to be more consistent, standardized and predictable has been slowly diminishing. This comes as a result of a closer examination of the differences between science and medicine, but also with a greater awareness of the role of values in medical decision-making. EBM advocates have gradually admitted the need to recognize the myriad of ways in which medical practice cannot simply be thought of as an application of scientific research. Even with the best available evidence, different physicians will continue to treat individual patients differently, and this is not

\textsuperscript{26} Haynes RB, “Loose connections between peer-reviewed clinical journals and clinical practice,” (1990) 113: 724-728.
\textsuperscript{27} Black D: 1.
necessarily the evil it was thought to be when EBM was first conceived. This does not mean that
generalized or simplified studies are useless for medical practice, but it does raise important
questions about the decision to place such studies at the top of the hierarchy of evidence.

We have now recognized the surprising fact that evidence is neither necessary nor
sufficient for medical decision-making: Particular patient decisions are often made in areas
where evidence does not exist (and therefore physicians must decide on the basis of other
factors) and there are also areas where extensive evidence exists but clashes with the patient’s
values (in which case even the best evidence is not sufficient for a good decision because values
may sway the decision in another direction). What, then, of the original EBM goal of improving
medicine through a stronger scientific basis? It is still possible that this goal could enhance
medical decision-making, if it was advanced in such a way that the concerns over inclusion of
values and complexity were recognized? Certainly there are aspects of EBM (including its
emphasis on the incorporation of critical analysis of scientific studies) that might be designed to
account for these concerns. I will now consider the response to the second main question
shaping EBM. This will hopefully aid us in determining whether the methods chosen by EBM to
improve the scientific basis of medicine have responded to the concerns we have just raised.

2) *The scientific basis of medicine can be strengthened through application of the
evidence hierarchy (rules of evidence).*

The evidence hierarchy was designed to reflect the methodological strength of scientific
studies. It is assumed that ‘better’ evidence on this scale is less likely to be infected by bias. A
simplified version of the hierarchy is offered in the *Western Journal of Medicine*:

- Systematic reviews of randomized clinical trials
- Randomized clinical trials
- Non-randomized trials and observational studies
- Case-series, case studies, surveys, qualitative research, anecdotes

A physician who is presented with any sort of outcomes research should consult the
evidence hierarchy in order to determine its objective quality and strength. Once a full critical
appraisal has been performed, s/he can then weigh the particularities of the individual case
against the determined objective strength of the evidence. The goal of the evidence hierarchy is
to eliminate as much bias as possible in the physician’s decision by elevating the status and value of studies perceived to be more objective. The evidence hierarchy was created to assist physicians in weeding out biased research from high quality research. EBM advocates do not make any claims about the complete or perfect objectivity of any particular types of studies. They would be the first to say that they have simply evaluated the relative objectivity of different types of medical evidence, and that some evidence fares better in this evaluation. The final result of this evaluation is that “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.”29

The best evidence comes closest to the goal of objectivity.

The question asked by early EBM advocates was, how can we assist physicians in determining when studies are biased, so that they can make decisions based on the most objective evidence possible? The answer was the evidence hierarchy. In designing the evidence hierarchy, however, EBM advocates were only able to account for one type of bias – that of weak methodology (seen as those studies which are not applicable to a wide range of people). There are some problems with this. First, it is only on the basis of assumptions about the value of certain qualities (ex/ generalizability) – transferred from science – that certain studies would appear more methodologically sound. And while the criteria developed by EBM designers may be good, this does not preclude the development of other such criteria and other equally relevant ‘evidence hierarchies’. If, for example, the values of ‘complexity’ and ‘individuality’ became more prominent in medicine, the evidence hierarchy might look quite different, and would be as justified.

Second, even if the criteria were to remain as tied to scientific standards as they are, there is no reason to limit medical evidence to quantitative research. A well-designed and carefully executed qualitative study attains only the lowest level of recognition within this scheme. This reflects a long tradition of emphasis on quantitative research within science. It is, of course, so much easier and simpler to deal with numbers than with abstract concepts like ‘quality of life’, ‘wellness’ and ‘harm’, though it is arguable whether a focus on quantifiable aspects of health is necessarily the best approach to health care. Decisions about what types of studies are best reflect some of the underlying assumptions of EBM that were identified earlier in this paper,

including the desire to tie medicine more closely to a traditional conception of good science. Qualitative studies are assumed to be more biased, and less objective, than quantitative studies. In contrast with this traditional assumption, qualitative research has recently been gaining ground as a legitimate and important form of inquiry into complex problems. Qualitative research methods have advanced considerably, particularly in the last half-century. The decision to categorize qualitative research as ‘lowest quality’ is a throwback to a scientific tradition that devalues qualitative studies as unscientific. This sort of assumption is no longer acceptable.

The third problem with this attempt to diminish the effect of bias is that there are many different sources of bias that it does not address. This might be acceptable if people applying the hierarchy of evidence to their own research were aware of the other forms of bias, but the hierarchy is usually presented as an objective tool: one that eliminates as much bias as possible. This, I suggest, fosters an uncritical attitude on the part of physicians who are evaluating studies on the basis of the hierarchy. They are carrying out the requirements of the EBM protocol if they critically evaluate the study on the basis of the hierarchy and then apply it judiciously in their practice. Critical evaluation comes in only after the study quality is determined by the standards of evidence outlined in the hierarchy. This seriously limits the ability of ‘critical evaluation’ to pick up on certain types of bias. What are these other possible sources of bias? As Parker summarizes, “selective presentation of the facts, corporate influence, publication bias, the role of personal and social values and preferences, systematic bias in purchasing decisions based on ability to show effectiveness, and inequalities in research funding due to expected differences in financial returns.”

There has been much attention in recent years to the social forces shaping the direction of medical research. This can occur on many levels, from the way a certain society defines health, to the economic interests shaping research toward marketable treatments. We are learning the truth of the statement “the evidence we seek to use is partly constituted by what we value and what we need to know.” Consider, as a thought experiment, a society where people have a deep belief that all diseases, illnesses and problems will be cured by small pills. In fact, many researchers in this society today are hard at work developing pills to overcome the hacking

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cough and headaches some members of society have developed while smoking cigarettes and living in large cities with polluted air. When they achieve their goal, a large-scale RCT is performed to test the efficacy of the pill on the population. The study is then published, and a few years later a physician sits down with the hierarchy of evidence in order to evaluate the study. ‘Hmm…Good methodology. Large trial size. The patient seems to like the idea of this treatment… [members of this society really do want pills to solve all of their problems] I suppose given the best evidence my choice is clear.’ It is true that the RCT’s were carried out carefully and methodically, and that they indicate some effectiveness of the pill being studied.

The physician in this example is led to believe that she is basing her decision on objective scientific evidence. But what sense of ‘objective’ really applies in this situation? After all, from our knowledge as outsiders looking in on this society, we can tell that the social and economic value placed on pills has guided research away from other possible solutions to this health problem (such as the value of quitting smoking, or the value of cleaning up the environment so that there is less air pollution). Because of the social value placed on simple, easy, affordable ‘pill-based’ solutions, it is unlikely that there will be any significant investigation of these other possibilities. Research will continue to reflect this society’s values, and the evidence hierarchy will be of no use in critically evaluating the existence or effect of these values.

Social forces shape the general direction of research, but there are also forces infiltrating research far beyond the doors of the laboratory. If we look at the influence of corporations as an example, evidence has been found of serious corporate influence beyond even the large-scale direction of research projects. Specific drugs studies were examined in one review, and the authors found that, “while there was no relationship between drug company funding and study quality, those studies which were supported by a drug company were significantly more likely to have an outcome favouring the drug of interest (98% vs. 79%).” In other words, despite equally good methodology in the different studies, bias still played a role in the research outcome. Even if we were to set aside global social concerns about corporate influence on the direction of research and scientists’ concerns with publication bias, this finding suggests that bias can and does continue to play a role in research. Even in the most methodologically rigorous studies, significant biases can occur. Especially in the case of larger studies and meta-analyses,

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“While trials can be scrutinized for gross errors of methodology, and excluded if such are found, less obvious but still material differences in procedure may not be apparent to a scrutiny diffused over a number of protocols.”\(^{33}\) These differences in procedure can be manipulated to achieve different effects. These findings have direct implications for an evidence hierarchy that claims to diminish bias through methodological rigour.

Evidence-based Medicine focuses the physician’s attention on the evaluation of answers offered by medical research. The critical stage of EBM occurs after the evidence hierarchy has been applied to determine the objective quality of the study, when the physician is determining how the study might best be applied to clinical care. This engages the physician’s knowledge of the clinical setting and some of the practical challenges posed by the integration of new research. It does not engage the physician in critical discussion about the social, economic, or political forces that may have shaped the questions asked by researchers in the first place. After all, the evidence hierarchy is thought to take care of those aspects of critical evaluation when it determines that certain studies are biased or weak and therefore at bottom of the hierarchy. We are unable to determine the extent to which social forces are, at any given moment, shaping the direction of research in our society and our world. Because of this, physicians will always need to think critically about the type of questions that were initially asked in a study, and how those questions shaped the type of answers that resulted. In addition, they will need to consider the social and economic interests behind research. It is not enough to think critically about the answers or study results. Without careful attention to the questions that form the basis of research, physicians lose a vital part of the critical process.

A thoughtful defender of EBM is likely to concede that various social forces can shape research and that it is true that the evidence hierarchy does not address many of these sorts of influences. But, they would argue, that does not mean that it is impossible to add these further steps to the EBM process. When the physician sits down to evaluate a study, they can simply apply the evidence hierarchy, and then as a part of their critical analysis, include questions about the source of the study or the type of research that was chosen. So EBM practitioners can include critical analysis of these sorts of social issues in the later stages of individual evaluation.

What would this sort of solution suggest about the role of the ‘rules of evidence’ within EBM? Once again, I argue, we are forced to recognize the precarious nature of the evidence

\(^{33}\) Black D: 1.
hierarchy. We saw earlier that the hierarchy is based on assumptions made by early EBM advocates about the value of certain types of evidence. The goal was to provide a framework for more objective decision-making within the medical field, but this framework and the hierarchy were based on assumptions about ‘good science’ that don’t necessarily translate into ‘good clinical practice’. In addition, we now see that even the assumptions about what constitutes good science (i.e. good methodology) fall short of the goal of objectivity. When the physician sits down to evaluate medical research, the evidence hierarchy provides only one small part of the critical evaluative process. A careful and serious evaluation of evidence not only goes far beyond the hierarchy, it asks the sorts of questions that the hierarchy claims to be answering.

The evidence hierarchy is meant to provide answers to questions like: What is the best evidence? What is the most objective medical research on this topic? How good is this particular study? and How much can I trust the results of this research? In order to establish the evidence hierarchy, EBM designers provided answers to the more fundamental questions: How do we determine the standards for best evidence? What sorts of qualities does good evidence have? and How can we determine when evidence is least biased/ most objective? What is interesting about recognition of the role of social values in research, and of the limits of methodological rigour as an indication of objectivity, is that it forces people to once again raise the more foundational questions. Physicians who want to critically evaluate medical evidence in light of a wider range of possible contaminators (sources of bias) – or even in light of different assumptions regarding the role of science in medicine – will end up raising new possible answers to the fundamental questions.

When EBM advocates suggest that physicians will be able to ‘add’ whatever critical questions they want to the evidence hierarchy, they fail to recognize that any such true critical evaluation will uncover, and raise questions about, the assumptions behind the evidence hierarchy. Data becomes ‘evidence’ only in light of background assumptions. When we speak of evidence, we have either some explicit or implicit idea of the framework within which some particular data becomes evidence. Someone dropping a piece of chalk to the ground may be evidence that gravity is still working on earth, or conversely, that the professor is feeling anxious in front of a new class. The same data becomes ‘evidence that…’ in light of different hypotheses.

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and background assumptions. “Evidence itself does not recommend its own interpretation.”\textsuperscript{35} So if all evidence is really evidence \textit{that}..., depending on background assumptions, how is it that the evidence hierarchy is able to specify simply ‘good evidence’? As we have seen, this is because the background assumptions have been filled in. Good evidence in the hierarchy is evidence \textit{that} meets criteria assigned by early EBM advocates. These criteria and assumptions, as we know, are open to question. It is likely that sustained critical attention to these assumptions, prompted by a \textit{full} critical analysis of medical research, will make it even clearer that the evidence hierarchy is, at best, just one dimension of an evaluative process used by physicians to interpret the results of medical evidence and make clinical decisions. Any proposal that these rules of evidence are somehow ‘the base’ of critical evaluation is misguided.

Physicians today are moving closer to a realization that the evidence hierarchy is simply one small element in a larger critical analysis that requires physicians to engage with the fundamental issues underlying the evaluation of medical evidence. Good evidence produced by the evidence hierarchy is neither necessary nor sufficient for good clinical practice. In addition, it reflects a commitment to certain methodologies that, while scientific (in some sense), may not be best suited for medicine. EBM does not achieve its own stated goal of objectivity. It misleads practitioners by suggesting that it does reflect degrees of objectivity and bias (through assumptions about different methodologies) even though it addresses only one source of bias. Each of these assumptions about evidence can be questioned, and alternatives can be discussed. Critical responses to these assumptions are not ‘illegitimate’ or ‘misguided’. Physicians are not ‘irrational’ when they raise concerns about the effects of this process on medical practice.

The suggestion that EBM can be saved by adding these new critical questions to the EBM process seriously underestimates the power of the questions being asked, and the inability of the EBM framework to provide answers to such questions. Physicians expressing frustration with EBM are, I think, responding to the fact that they really want to raise and discuss questions at the foundational level. Because the evidence hierarchy is built on assumed answers to these questions, it is not possible for true critical discussion to occur only within the framework of EBM. EBM advocates want medicine to be more scientific and more objective, but in setting up a rigid framework of rules they narrow the discussion to the point that it would not be able to meet the needs of physicians as members of a scientific community.

In her book *Science as Social Knowledge*, contemporary philosopher of science Helen Longino suggests that scientific communities are objective to the degree that they meet four criteria:

1) There must be recognized avenues for criticism of evidence, of methods, and of assumptions and reasoning.
2) There must exist shared standards that critics can invoke.
3) The community as a whole must be responsive to such criticism.
4) Intellectual authority must be shared equally among qualified practitioners.  

Given that one of the primary goals of EBM is to make medicine more objective, it is interesting to discover how few of these criteria have been advanced with the introduction of EBM. The evaluation of EBM as an approach to medical decision-making does not fare well. This is especially true of the first and fourth criteria. While avenues such as medical journals do exist as outlets for physicians’ concerns, the structure of EBM – especially the evidence hierarchy – limits the type of questions that are typically asked. Debate occurs over only the last stage of decision-making in the EBM scheme, and we see numerous publications on ‘how we can best apply the evidence hierarchy in practice’ or ‘how we can make decisions when the evidence isn’t conclusive’ rather than more foundational questions. Physicians critically discuss only the evidence rather than the methods, assumptions, or reasoning behind EBM. The ‘intuitively obvious’ nature of the claim that EBM should be more scientific and more objective ensures that the foundations of EBM are, for the most part, unchallenged.

The fourth criterion raises questions about access to power within the EBM scheme. Certainly physicians all share a certain authority or power as members of their profession, but I doubt that many feel qualified to question the foundational assumptions of EBM. EBM is designed, according to Sackett, as a ‘bottom-up’ approach. It is meant to be accessible to all. But what sort of access do people have if they start from the ‘bottom’? EBM as an approach to medical decision-making has been designed and constructed by a small group of physicians. Longino would suggest that this is acceptable only as long as the community of physicians as a whole are able to engage critically with the assumptions and early foundational decisions of the movement. In order to achieve full objectivity, the members of a scientific community must be engaged in dialogue and debate on all levels of questions and decisions. This is because,

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36 Longino: 76.
“Individual values are held in check not by a methodology but by social values.” \textsuperscript{37} The values of the original designers of EBM need to be balanced out by the values of all members of the community in order for EBM to achieve any sort of objectivity. Longino recognizes that values are likely to permeate all levels of scientific decision-making. We have seen that early designers of EBM made many critical assumptions about medical practice and the role of science in medicine. These are the sorts of questions that must be debated by all members of the medical community if the EBM movement is ever to achieve full (contextual) objectivity.

In order to minimize the subjectivity of the decisions about what is best for the field of medicine, the community of physicians must be engaged with the foundational questions. “If our conception of the methods of knowledge construction in science is broadened to embrace the social activities of evidential and particularly conceptual criticism, we see how individual subjective preferences are minimized in the final products.” \textsuperscript{38} The assumptions made by early EBM advocates may turn out to be acceptable to most physicians, but this can only happen if physicians are invited to engage with those questions. When their voices are added to the discussion, the EBM movement will reflect the strength of their unity. If objectivity is, as Longino suggests, a function of community practices, it is critical that the whole community be involved. “Background assumptions are the means by which contextual values and ideology are incorporated into scientific inquiry.” \textsuperscript{39} Earlier in this essay, I outlined the main assumptions of the EBM movement. With Longino’s assistance, we are now in a position to recognize that these assumptions must be part of a discussion that includes the community of physicians in order to incorporate the values of a wide range of community members. This discussion also must include conceptual criticism and discussion of the philosophical assumptions underlying EBM (a process Longino calls transformative interrogation). Otherwise, EBM reflects the subjective values of only a few individuals, and the practice of EBM suffers from a lack of contextual objectivity.

Though this is by no means high-level evidence for my argument, since it follows only from my own impression in a survey of about two-dozen recent articles, there does appear to be a lack of discussion on the assumptions of EBM in medical literature. While there have been many articles and essays written on the need to recognize other elements of decision-making (the

\textsuperscript{37} Longino: 102.
\textsuperscript{38} Longino: 216.
art of medicine and the value of clinical expertise), it is rare that anyone questions or even engages with the fundamental assumptions of EBM. Ross Upshur suggest that one of the most fundamental questions to be asked with respect to EBM today is, “Who has the authority to create, interpret and judge evidence?” The answer according to Longino’s approach is ‘the community of physicians’. Insofar as EBM presents itself as a scientific practice, the community to which it belongs must shape it on all levels. This is not currently the case.

I have one lingering concern regarding the arguments presented in this essay. I believe that they are likely to evoke a response (especially from defenders of EBM, but perhaps from an even wider group) such as: ‘This is classic philosophical criticism: it fails to grasp the practical utility of basing medical practice on evidence. This belongs in the same category as any other interesting but ultimately unhelpful philosophical work because it is out of touch with the practical value of EBM’, or in shorter terms, ‘But of course you can’t be saying that medicine should not be based on evidence!’ I must defend my claims in anticipation of this criticism.

As I have mentioned repeatedly in this paper, physicians are raising concerns about EBM. In fact, this continuing backlash has been a bit of a mystery to EBM advocates. The problem that I have identified in this paper is that physicians are trying to find room to raise their concerns and criticisms but are only able to do so within the scope of the EBM process. Physicians writing in to medical journals attempt to find a way to fit intuition, patients’ values, or critical perspectives on social values back in to the EBM process – but can only do so as a sort of ‘afterthought’ last step because the hierarchy is assumed to be objective and ideal. The lack of discussion on the fundamental assumptions of EBM not only frustrates physicians but, according to Longino’s account of contextual objectivity, it also diminishes the objectivity of EBM. Community values are not incorporated into the foundational assumptions, so EBM reflects the subjective values of its designers. The (early EBM) assumptions that medicine needs to be ‘more objective’ and ‘more scientific’, even if correct, are actually not achievable in the framework that was designed, because the community of physicians have not been involved in evaluating the foundational decisions. I agree with the authors of a recent article when they

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39 Ibid.
suggest that, “proponents and opponents of EBM should be prepared to defend the normative claims and power effects that are inherently tied to any presentation of evidence.”

Of course scientific evidence is an important factor in much medical decision-making. But then, it always has been. What did physicians do about evidence before EBM? They incorporated it into their decisions along with a multiplicity of other important factors. Perhaps some of the conservatism (in responding to new research) expressed by physicians is even a reasonable ‘judicious’ response to the fact that, especially with the outpouring of recent biomedical literature, evidence is ultimately a rhetorical device. It is designed to persuade physicians of the efficacy of particular treatments or drugs. It is possible that physicians are aware of this battle for their attention and their prescriptive power, and that it is prudent for physicians to judge studies on the basis of more than simply good methodology.

IV. Conclusion

The original stated goal of EBM was to “de-emphasize” as much of the subjective element in medical decision-making as possible. This arose because the primary initial motivation for EBM was concern about the unpredictability of medical decisions. Later formulations of EBM, in response to backlash, attempted to soften this intention with talk of the importance of “thoughtful identification and compassionate use of individual patients’ predicaments, rights and preferences in making clinical decisions about their care.” Still, individual considerations come into play only after a thorough analysis of the latest (external) clinical evidence on any issue. No matter how much EBM proponents now reassure physicians that they still see an important role for the subjective and individual elements of medical decision-making, physicians continue to write passionate editorials, essays, and speeches voicing their concerns that the ‘art’ of medicine is being lost.

EBM advocates no doubt grow weary of responding to the same repetitive questions regarding the place and value of individual expertise and intuition in the evidence hierarchy. From their perspective, they have now made it clear that evidence is not sufficient for good

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42 EBM Working Group: 2420.
clinical practice, and that “external clinical evidence can inform, but can never replace, individual clinical expertise.” The frustration mounts on both sides of the debate as physicians continue to raise concerns about EBM long after these concessions have been made. What more do physicians want to hear? Why is there still such a strong reaction to the more inclusive version of EBM? Some theorists have suggested that this response by physicians might be a lingering emotional attachment to tradition or a last grasp for the kind of prestige and status perceived to come only from the ‘mystery’ of good medical practice (and presumed to be diminished under the explicit guidelines of EBM). I have suggested that the negative feedback expressed by physicians is legitimate and grounded in a deep appreciation of the implications, both theoretical and practical, of widespread acceptance of EBM. Many of these concerns arise from the design and authoritative role of the hierarchy of evidence within the EBM approach.

What are the advantages of the EBM approach? Scientific evidence, as we have discovered, is neither necessary nor sufficient for medical decision making. Early assumptions about the need for generalizability and standardization across medical practices are giving way under the weight of patient and physician values, and the recognition of the need for individualized treatment. The desire to make medicine more scientific is questionable given the different values underlying the medical and scientific traditions. The evidence hierarchy was designed to aid physicians in their appraisal of medical studies, in order that they might be able to recognize whether studies were more or less biased. We now recognize that good methodology is no guarantee of objectivity. In fact, the variety of sources of bias make the evidence hierarchy somewhat misleading, in that it may assigned high value to research that has benefited from publication bias and social and economic investments. This can skew the medical decision-making process in favour of corporate or other social interests. Finally, we have seen that if EBM advocates took their own goals seriously, they would be actively engaging physicians in critical examination of the assumptions behind the evidence hierarchy. Without this process, EBM assumptions reflect only the subjective values of its designers rather than the contextually objective values of the community of physicians.

Today, modest EBM advocates might suggest the simple goal of getting more physicians to pay critical attention to recent developments in medical research. I would add that the evidence hierarchy needs to be removed from its prominent position within the approach in order

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44 Ibid.
for this to happen. There needs to be a greater recognition of the fact that the evidence hierarchy is *not* objective and that it reflects the subjective values of its designers (their ideas about what counts as good methodology and the desired relationship between science and medicine).

Physicians today are in a position to assert the legitimacy of the position that “multifaceted medical knowledge is a better basis for patient care than even the most rigorous aggregate outcomes data.” To go a bit further, they are in a position to suggest that the ‘best evidence’ offered by the evidence hierarchy is sometimes not as helpful as the ‘more biased’ case-studies or ‘worse evidence’ and therefore the hierarchy is not suited to their needs as clinicians. This reflects the fundamental philosophical difference between the values underlying science and those foundational to medical practice.

Initial responses to EBM assumed that scientific evidence, achieved through scientific research, is in all cases valuable. The only problem was how and when this evidence was to be applied in practice. I suggest that we need not agree that all evidence is valuable, and we certainly do not need to agree that evidence produced by good methodology is necessarily valuable to medical practice. Evidence is formed in light of background assumptions and takes the form ‘evidence that…’. As such, it is only valuable to physicians if it is evidence *that* meets standards that they have set, and that they see as relevant to their practice. Evidence-based Medicine has survived for a decade because of the seeming neutrality of its goals and a common-sense appreciation of its title. Despite concerns expressed by physicians, EBM proponents have insisted that the new, more inclusive version of EBM is nothing to be feared. As I hope to have established, the dismissal of these lingering concerns is a mistake. Physicians are wary of EBM for good reasons, which I hope to have brought forward in this paper. An EBM that takes these concerns seriously will soon become, if it has not already, indistinguishable from good medical practice as it has been evolving for thousands of years.

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References


