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THE NATURE OF EVIDENCE IN EVIDENCE-BASED MEDICINE

guest editors' introduction

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WILLIAM HARVEY, the 17th-century English physician and champion of Enlightenment ideals, captured the intellectual passage from medievalism to modernity with this instructive remark: “It is base to receive instructions from others’ comments without examination of the objects themselves, especially as the book of nature lies so open and is so easy of consultation” (quoted in Rawlins 2008, p. 1). Today, the Harveian appeal to empirical evidence and the critical examination of conventional practices still resonates among health researchers and practitioners; however, the alleged ease of access to the empirical world has proven more constrained than Harvey suggested.

The introduction of evidence-based medicine (EBM) to the medical world initially reflected an anti-authoritarian spirit similar to Harvey’s. In the Evidence Based Medicine Working Group’s programmatic 1992 *JAMA* article, “Evidence Based Medicine: A New Way of Teaching the Practice of Medicine,” EBM was framed as “the way of the future”: a radical new framework for clinical medicine, where junior clinicians would eschew the advice of senior colleagues and instead directly consult the research literature in order to inform

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their clinical decision making (EBMWG 1992). Following the precepts of EBM was supposed to improve clinical practice and, by extension, patient care.

Over the past 17 years, EBM has come to influence all areas of clinical practice. In addition, it has influenced the development of institutional and professional guidelines in areas from nursing to health promotion and moved beyond medicine to other disciplines. But direct examination of “the objects themselves,” or at least the results of empirical research gathered by others, soon proved to be too burdensome a task for busy clinicians. The sheer volume of available medical research made EBM’s initial effort to have the next generation of physicians reading and critically assessing the medical literature seem impractical. Useful time-saving techniques were devised, most notably clinical summaries and protocols, which were created and proliferated by an impressive international consortium of research institutions (for instance, the Cochrane Collaboration). It did not take long, however, before there were so many different hierarchies, summaries, and recommendations in circulation that an official working group—cleverly named “GRADE” (Grading of Recommendations, Assessment, Development and Evaluation)—was convened in order to address this heterogeneity (GRADE 2004).

This shift toward standardized clinical summaries and guidelines indicates that EBM has diverged from its early anti-authoritarian practices. EBM now bypasses the need for critical evaluation at the level of individual physicians and instead relies on specialized experts to do much of the critical work. In addition, proponents of EBM claim that the approach is less rigidly “based” on research evidence, especially the data derived from randomized controlled trials, and is now more open to the integration of different forms of evidence. There appears to have been a slow evolution in the assumptions and practices of EBM. The question facing theoreticians and clinicians today is whether these changes have been significant, and if so whether the newest form of EBM has overcome the critiques levelled against the earlier forms. Even if it has, the newest form of EBM is in need of independent evaluation. We believe the time is right to provide this sort of thoughtful scrutiny.

The latest investigation into the assumptions and limitations of EBM proceeds in several directions and is captured by the scholarly contributions to this special issue. First, EBM’s approach to rating evidence is still open to question. In this new age of EBM, philosophical questions about the nature of evidence and its role in justifying knowledge claims, once solely the intellectual domain of epistemology and philosophy of science, have become the subject of critical discussion in a wide range of health professional journals. Sir Michael Rawlins, Chair of Britain’s National Institute for Health and Clinical Excellence (NICE), recently argued that algorithmic approaches to applying the evidence to therapeutics are misguided, because no one form of evidence will consistently trump others. Hierarchies, he explains, “attempt to replace judgement with an oversimplified, pseudoquantitative assessment of the quality of the available evidence”

(Rawlins 2008, p. 34). Critical debate over the EBM hierarchy has been lively for many years, with critics believing that they have finally done away with the idea and proponents continuing to defend it. This debate continues in this issue, and addresses what remains constant and also what has changed in various formulations of the hierarchy.

In addition to these questions about the nature of evidence, the translation from the results of clinical research to individual patient care has also proven to be difficult. Despite Harvey's belief that "the book of nature lies so open and is so easy of consultation," medical research is both enormously complex and open to damaging forms of bias. Even when experiments are well conducted, the generalizability and applicability of the findings to diverse patient populations can be tenuous. This has been a longstanding concern with EBM, though proponents have argued that further regulation of the research process is the best we can hope for in addressing problems of generalizability. This debate persists today as critics continue to uncover further biases at work in medical research, and proponents gradually recognize the need for pragmatic RCTs and other research methods.

Finally, because evidence-based practice informs patient care, EBM also touches on bioethical issues. The physician's duty to provide the best care to her patients can only be enacted if best evidence is informing the standard of care. Problems in the production and proliferation of evidence therefore have ethical consequences in clinical practice where the safety and well-being of patients is at stake. Patients and providers are only two of the stakeholders in the ethics and evidence dyad, of course, and further stakeholders have been joining the discussion in recent years. There is a potential for compromising bias in light of researchers' financial and personal incentives, as well as a disturbing tendency to withhold negative clinical trial results from the public and from regulatory bodies. Because these regulatory bodies have a role in evaluating the recommendations, and these evaluations in turn influence the contents of insurance baskets and policy directives, "getting the evidence right" has ethical implications for patient care, as does getting all the relevant evidence. Yet even if the evidentiary problems and omissions were corrected, numerous case studies (in this volume and others) have suggested that health-care decision making does not hinge exclusively on the evidence—even *all* of the clinical evidence. What, then, are we to make of evidence "based" medicine?

The articles in this special issue on EBM elaborate on the topics raised in this brief introduction, turning a critical eye on the current state of EBM. Since the publication of the first special issue on EBM in this journal in 2005, evidence-based approaches have become more entrenched and institutionalized in medicine. While the recent editions of authoritative EBM textbooks seem more nuanced in their accounts of knowledge translation, these changes are not an unalloyed sign of progress. Clinical practice still remains largely unchanged, and

many of the problems raised by critics of EBM remain unaddressed by its most vocal proponents. This has been frustrating to many scholars and clinicians wanting to engage in critical discussion over the practice and future of medicine, and may explain why many of the papers in this issue are deeply critical of EBM.

Yet it is a sign of hope that all of the papers in this issue, whether critical or more accepting of the evidence-based platform, strive to go beyond criticism and offer constructive amendments to the evidence-based approach to medicine. Discussions include: how to improve EBM's account of evidence and move beyond the hierarchy of evidence (Giacomini, Borgerson, Bluhm), ethical and epistemological problems with the current "evidence base" (Rogers and Ballantyne, McGoey), the influence of EBM in clinical fields beyond internal medicine (Gupta, Ernst), and the relationship between evidence and both health policy and clinical practice (Goldenberg, Greenhalgh and Russell, Upshur, Tonelli).

We hope that this issue of *Perspectives in Biology and Medicine* prompts further reflection on the most recent developments within EBM, as well as on its enduring aims and assumptions. Given the immense impact of EBM on medical research and practice, we believe this sort of careful discussion is vital to the future of health care.

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