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EVIDENCE-BASED MEDICINE AGAIN

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THIS ISSUE OF *Perspectives in Biology and Medicine* presents a group of papers in a symposium entitled “The Nature of Evidence in Evidence-Based Medicine,” which was conceived and edited by Robyn Bluhm, Kirstin Borgerson, and Maya Goldenberg. Two of these editors, Bluhm and Borgerson, also edited a collection of articles on evidence-based medicine (EBM) that we published in 2005 (48:475–584). We appreciate the efforts of the editors and all of the contributors in presenting clearly and succinctly their analyses and critiques of EBM. We believe strongly that EBM has been of major value to medical practice, especially with regard to screening methodologies and therapeutics, and we welcome these critiques as constructive criticism, designed to strengthen, rather than disparage, the practice of EBM.

Because much of the terminology and ardor of this field has developed since several seminal papers were published in the 1980s, EBM is commonly thought to be a new discipline; nonetheless, its antecedents can clearly be traced back at least to several controlled or numeric studies now regarded as epic, such as those of James Lind in the 18th century and John Snow in the 19th. It was not until the mid-20th century, however, that statistical methods, including randomized controlled trials (RCTs) and outcomes research, were sufficiently developed and applied to medical problems to have resulted in approaches to epidemiology and therapeutics that we would recognize as modern in their scientific rigor. About then the pioneering work of several physicians, such as Alvan Feinstein at Yale and Archie Cochrane at Cardiff, led to the creation of the discipline of clinical

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epidemiology and began a more general program of systematically applying these new methods to medicine. It was, however, David Sackett and his colleagues—initially at McMaster University in Canada and then at Oxford—who turned this academic discipline into a “movement,” perhaps largely by giving it the catchy name of evidence-based medicine.

Clearly there was an internationally perceived need for this development, and in the last 15 years EBM has taken off and rapidly expanded, with innumerable articles, monographs, textbooks, and now journals devoted to it. Numerous private, quasi-governmental, and governmental organizations—such as the Cochrane Collective, the U.S. Preventive Services Task Force, and various ad hoc “working groups”—have appeared in order to develop and implement these ideas. These groups, in various countries and some on an international scale, have developed tools such as “guidelines” for medical care, sometimes accompanied by strong organizational or even governmental mandates for their implementation.

Not surprisingly, these developments have precipitated something of a backlash. These negative reactions have ranged from those who argue that informed physicians have always tried to use the best evidence in making clinical decisions to those who are perturbed by the implicit assumption of most EBM models that knowledge of mechanisms of disease is not sufficient for making decisions about medical practice, as compared to evidence from various types of clinical trials. The last assumption unfortunately has been interpreted as calling into question the implicit basis of much funding of biomedical research, the search for molecular and cellular mechanisms, especially when—as now—there is increased competition for research funds.

Other negative reactions have focused on more limited aspects of the EBM paradigm, particularly on the notion of assigning relative values to different types of evidence and the idea that the RCT is indeed the gold standard for judging any intervention. Critics of these and other aspects of the EBM program range from those who approach these issues as philosophers to those who have experienced them as practicing physicians. While we are convinced that evidence-based guidelines and checklists have improved patient care, we agree that there are ways in which the implementation and practice of EBM need to be strengthened. The evidence base of EBM still suffers from a variety of biases, ranging from individual conflicts of interest to unwarranted corporate intrusion into the design and publication of the results of clinical trials; these biases need to be eliminated to the extent possible, and recognized if they cannot be eliminated. Although RCTs are an invaluable source of clinical information, they may not provide the most appropriate information for many situations. For example, criteria used in establishing eligibility for participation in controlled studies may limit the applicability of the results with regard to the general population. Also, as EBM advocates have argued that, because of secular changes in disease, historical controls are not adequate for clinical interventions, it is clear that clinical guidelines need to be reevaluated periodically.

It is interesting that much of the work analyzing EBM in depth comes from Canadian institutions clearly impacted by the concepts that crystallized at McMaster University in the 1980s. The United Kingdom has also been particularly active in these discussions. We suspect that countries with national health plans, in which the methods of EBM are particularly useful in making decisions about the extent of coverage of various care modalities, may have special interest in this field. As the United States again begins an intense discussion of the organization of its health-care system, it too will need to wrestle more fully with the strengths and weaknesses of the current EBM paradigm.

The articles in this issue have a preponderance of critical analyses of EBM, as do several in our previous symposium. We are pleased to present these analyses, as well as other articles more supportive of EBM, to encourage discussion and dialogue as a basis for strengthening and making more useful these new concepts. In addition, *Perspectives* has in recent years received other submissions about EBM, interestingly often also critical. We encourage further manuscripts and letters in response to the current symposium, both in support of EBM as well as arguing for changes, in order to continue this dialogue.