

THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW: POINT

Achievements and Limitations of Evidence-Based Medicine



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ABSTRACT

Evidence-based medicine (EBM) has a long history, but was revived in the early 1990s by a campaign mounted by a movement that took its name. The EBM movement focused attention on the need for greater objectivity in medical decision-making and led to the Cochrane Collaboration, which provides reviews of evidence on the basis of comparative research. Important limitations of EBM's effect on medicine have also emerged. Failure to acknowledge the limitations of clinical trials and systematic reviews has limited their applicability to individual patients' circumstances. An almost exclusive focus on drugs and devices has left vast areas of health care in an evidence vacuum. An over-dependence on commissions for its research may have limited its independence in selecting what it investigates. EBM needs to widen its scope beyond drugs and devices to address many areas that often lack evidence at present, notably, health policy, management, and reforms. (J Am Coll Cardiol 2016;68:204-13) © 2016 by the American College of Cardiology Foundation.

The concept of *evidence-based medicine* (EBM), in terms of words and meaning, is relatively straightforward: medicine practiced on the basis of evidence. However, this fails to capture what has come to be understood by evidence-based medicine today, following a campaign launched in the early 1990s by a group known as the EBM movement (1,2). For the purposes of this discussion, we use *EBM* to indicate the specific meaning advocated by this group and to distinguish it from a wider meaning of evidence-based medicine. Motivated to improve outcomes of diagnosis and treatment, the group launched a campaign to enhance the evidence on which medicine is practiced. Coining the phrase *evidence-based medicine* and claiming to have identified a new paradigm of medical practice were brilliant rhetorical devices that successfully captured the attention of the general and medical media (3,4). The group called for greater reliance on up-to-date published research, especially clinical trials, and proposed that the value and reliability of evidence should be considered in a hierarchy, with trial data

trumping other forms of evidence. In particular, it argued that authoritative opinion, clinical judgment, and mechanistic reasoning are less reliable and should be relegated to a lower position. Ironically, these ideas were put forward on the basis of fictional clinical presentations (1,2).

Despite its immediate success, much of what the EBM movement originally proposed has long been discounted. For example, the idea that a new paradigm of medical practice was identified has been widely criticized for ignoring the long history of efforts to improve the evidence base of medicine (e.g., see Tröhler [5]) and is no longer defended. Furthermore, the concept that evidence required for clinical decision-making should be considered in a hierarchy of reliability, with clinical trial data higher than clinical evidence and mechanistic reasoning, has also been widely criticized (6). In practice, mechanistic reasoning plays a crucial role in several areas of medicine; clinicians must often use it when attempting to apply data from large, population-based studies to individual patients. It plays an essential role in



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managing patients for whom no specific trial data is available, and also in formulating hypotheses to justify all original research. For a more detailed discussion of the epistemology of mechanistic reasoning in clinical practice, see Loughlin et al. (7). The notion of a hierarchy of evidence was later abandoned by some members of the EBM movement in a modified definition that described EBM as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (8). This avoided any attempt to categorize evidence or to clarify what is meant by “judicious” and “best evidence,” and seemed to abandon much of the detail of what had been originally proposed. In reality,

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this could be applied to best practice at any time, including before the introduction of EBM or even clinical trials. Indeed, it may well have been in the mind of Sir William Osler when he said, “He who studies medicine without books sails an uncharted sea, but he who studies medicine without patients does not go to sea at all” (9). Despite this clarification, for some, the notion of a hierarchy persists, as exemplified in the Tamiflu case described later in the text. The result has been a lingering confusion about what EBM actually means, depending on the perspective of how health care is viewed, for example, by patients, clinicians, public health workers, or policy makers. EBM has made significant and important contributions to medicine. It has also had some negative consequences, both of which are explored here (Table 1). This review is written from a U.K. perspective, in part reflecting the experience of the authors, but it also seems appropriate because the Cochrane Collaboration, which is the most significant development of EBM, was sponsored and founded from the United Kingdom. In addition, health activism in general seems to have been more prominent in the United Kingdom than elsewhere in recent decades, which may explain why EBM expanded there after its launch from McMaster University in Canada. We welcome the response to this paper commissioned by the editors (10), and we hope it will stimulate further thought and discussion about EBM. For these authors, the “baby in the bath water” is clinical evidence related to individual patients, which is often at risk in an ocean of data of uncertain relevance.

ACHIEVEMENTS OF EBM

The most striking success of the EBM movement has been in capturing the agenda for deciding the future of medicine. Its presence is felt in several

journals devoted to EBM and many others that use “evidence-based” as a prefix in the title. We have a web site for EBM, and academic departments, centers, and professors of EBM. Other activist groups have achieved notable success in capturing the health agenda (e.g., the acquired immune deficiency syndrome campaign and some famine relief campaigns); however, they have focused on single issues over limited time periods. In contrast, EBM has extended its influence over the past 2 decades.

The Cochrane Collaboration is the most prominent result of the EBM movement’s efforts. It currently harnesses the efforts of around 40,000 volunteers to produce over 400 systematic reviews of clinical trials/year related to a wide range of medical treatments (11). The Cochrane library, which makes these available, had almost 4 million downloads in 2010 (12).

The launch of EBM coincided with growing interest in clinical guidelines as a means to improve clinical practice (13), some of which had recently been published (14). Such guidelines seek to bring together the best available evidence on specific topics, and the systematic reviews published by the Cochrane Collaboration and other academic groups were important contributors to this development. Indeed, clinical guidelines are intimately connected to EBM in that they provide a means to disseminate what the EBM movement advocates.

Advocacy has been at the center of the EBM movement from the outset, and this has continued most recently in calls for full disclosure of clinical trial data. The issue arose from concerns that published systematic reviews of the effects of the anti-influenza drugs zanamivir and oseltamivir may have been unreliable due to lack of access to some trial data, and this led to a much wider campaign for full disclosure of all clinical trial data by the pharmaceutical industry, later backed by the World Health Organization (WHO) (15) and the European Union (16).

The EBM movement can also claim some credit for increasing awareness of “overdiagnosis,” not least as an exemplar of how to use campaign language to draw attention to an issue. It had been known for several decades that for some diseases, increased rates of diagnosis did not lead to reduced mortality, for example, thyroid cancer and prostate cancer (17,18). However awareness of overdiagnosis has increased dramatically since the 1990s; the word has appeared in 448 papers in PubMed since 1973, of which 424 have been published since 1990. Overdiagnosis has received the most attention in relation to prostate and breast cancer, but is increasingly seen as a problem facing almost all areas of medicine and

ABBREVIATIONS AND ACRONYMS

AMI = acute myocardial infarction
CCU = coronary care unit
EBM = evidence-based medicine

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