WHAT IS EVIDENCE-BASED MEDICINE?

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The term *evidence-based medicine* (EBM) first appeared in 1990 in a document for applicants to the internal medicine residency program at McMaster University School of Medicine. EBM was described as "an attitude of 'enlightened skepticism' towards the application of diagnostic, therapeutic, and prognostic technologies." As first described in the medical literature in 1991 [1,2], the EBM approach to practicing medicine relies on an awareness of the evidence upon which a clinician's practice is based and the strength of inference permitted by that evidence. Practicing EBM requires, in turn, a clear delineation of relevant clinical questions, a thorough search of the literature relating to the questions, a critical appraisal of available evidence and its applicability to the clinical situation, and a balanced application of the conclusions to the clinical problem. Balanced application of the evidence involves integrating research data with clinical expertise and judgment and with patient and societal values. This article addresses the need for and nature of EBM and describes principles of evidence-based practice. The authors' comments draw extensively upon a previous publication [3].

The Development of EBM

People have different notions about the nature of EBM. Some critics suggest that EBM equates evidence with results of randomized trials, statistical significance with clinical relevance, evidence (of whatever kind) with decisions, and lack of evidence of efficacy with evidence for the lack of efficacy. Other critics argue that EBM is not a tool for providing optimal patient care, but merely a cost-containment tool [4,5]. However, none of these ideas is consistent with the authors' conceptualization of EBM.

Although use of the term EBM began in 1990, the concepts on which it is based can be traced to clinicians from other eras who rejected commonly accepted practices. For example, in prerevolutionary Paris [6], Pierre-Charles-Alexandre Louis rejected venesection as treatment for fever and tried to determine the "truth" by systematic observation of patients. The first modern step in the development of EBM was the advent in the 1950s of the randomized trial as a methodology for resolving therapeutic dilemmas. Subsequent events in the development of the EBM paradigm include the following:

- Emergence of the term *clinical epidemiology*, which refers to the application of epidemiologic principles to clinical practice
- Publication in 1981 of the first of a series of papers describing principles for assessing the validity of clinical studies (called the "Readers' Guides to the Medical Literature") [7]
- Development of the methodology of systematic reviews and meta-analyses, culminating in the 1990s with emergence of the Cochrane Collaboration [8]
- Introduction of informative abstracts that specify the key components of study design and results [9]
- Publication of secondary journals (eg, *ACP Journal Club, Evidence-Based Medicine*) that contain results of methodologically sound and clinically relevant articles previously published in primary journals

As practitioners realized that the principles of EBM are as applicable to nursing and all other fields of health care as they are to medicine, the term *evidence-based health care* emerged [2]. The interest in and growth of these concepts can be illustrated by looking at results of a simple MEDLINE search: Searching for the phrase "evidence based medicine" yielded 1 citation in 1992, over 1100 in 1997, and over 2500 by 1999. In addition, some internal medicine residency programs in Canada [10] and the United States [11] consider the basic skills needed for EBM practice—formulating a clinical question, computer searching (recommended in Canada [12]), and critical appraisal of the medical literature—to be basic requirements of training.

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Factors Stimulating Interest in EBM

Interest in evidence-based health care has been increasing for several reasons. Chief among these are recognition of problems associated with the use of more subjective forms of evidence (eg, expert opinion unsupported by systematic research, uncontrolled observations), evidence of unexplained differences in medical practice, and increasing emphasis on optimal use of limited health care resources.

Physiologic rationale, historically the foundation for treatment recommendations, has repeatedly failed to predict results of randomized trials, and documented reports of such failures are numerous. Several examples come to mind. Although angiotensin-converting enzyme inhibitors have been proven to reduce mortality in patients with heart failure, other promising vasodilators have had marginal or no effect [13]; and some agents with inotropic properties, despite physiologic promise, actually increase mortality [14]. Similarly, among cerebrovascular surgical procedures initially believed to hold promise, some have been found to have no effect on stroke risk or to increase stroke morbidity [15], whereas others have been proven to dramatically reduce risk of stroke [16]. Finally, some antiarrhythmic agents have been shown to both eliminate noncardiac arrhythmias and increase mortality [17]. In these situations, relying on biologic and physiologic background knowledge led to erroneous predictions. In the midst of such failures, EBM has emerged as an alternative basis for providing patient care.

Studies demonstrating wide variations in how physicians manage similar patients have been a second factor influencing the development of evidence-based health care. For example, studies have shown that the frequency with which surgeons perform certain procedures (eg, breast-conserving surgery, coronary artery bypass surgery) varies widely geographically [18–20]. In none of these studies did differences in patient characteristics explain differences in patient management (eg, differences in tumor size and patient age do not explain differences in rates of breast-conserving surgery). These practice variations may lead to additional costs without additional benefit, and their prevalence can be reduced by appropriate application of research evidence. When one considers the inadequate resources available to meet all population health care needs, the need for efficient use of limited resources—the third major stimulus for evidence-based health care—becomes clear.

EBM versus Traditional Patient Care

The differences between EBM and traditional approaches to providing health care can be viewed as evolutionary or fundamental and revolutionary. The latter view contends that EBM represents a shift in the underlying paradigm of health care delivery and notes changes in the underlying assumptions, whereas the former interprets EBM as a refinement of existing and widely used approaches and ideas. Both conceptualizations of EBM imply a number of steps in the development of clinical decisions and policies. These steps include identifying knowledge gaps and information needs, formulating answerable questions, identifying potentially relevant research, accurately assessing the validity of evidence and results, developing clinical policies that align research evidence and clinical circumstances, and appropriately applying research evidence to individual patients in light of their particular experiences, expectations, and values [21].

Traditional Approach

Clinicians who operate under the traditional paradigm evaluate and solve clinical problems based on their own clinical experience or on the underlying biology of the disease, or by consulting a textbook or local expert. For many traditional practitioners, reading the "Introduction" and "Discussion" sections of a research article provides sufficient information for making clinical decisions, and observations from day-to-day clinical experience are a valid means of building and maintaining knowledge about patient prognosis, the value of diagnostic tests, and the efficacy of treatment. Understanding and appreciating basic mechanisms of disease and pathophysiologic principles are thus adequate guides for clinical practice. Because this paradigm places high value on traditional scientific authority and adherence to standard approaches [22], traditional medical training and common sense are sufficient bases for evaluating new tests and treatments, and content expertise and clinical experience are sufficient bases from which to generate guidelines for clinical practice.

EBM Approach

Like the traditional approach to health care, the EBM paradigm also assumes that clinical experience and the development of clinical instincts (particularly with respect to diagnosis) are crucial elements of physician competence. Without these skills, clinicians may not understand how to form clinically relevant questions or how to decide whether additional information is needed. Proponents of evidence-based health care also value the study and understanding of basic mechanisms of disease. Pathophysiology, clinical experience, and intuition are thus necessary but insufficient guides for practice because they may be incorrect and lead to inaccurate predictions about the performance of diagnostic tests and the efficacy of treatments. Instead, advocates of

EBM argue that systematic and unbiased attempts to record observations markedly increase confidence in knowledge of patient prognosis, the value of diagnostic tests, and the efficacy of treatment.

When adducing their recommendations, EBM practitioners (ie, clinicians who work under the EBM paradigm) regularly consult original literature, including the "Methods" and "Results" sections of research articles, and other reliable sources of evidence to help them solve clinical problems. Effectively using the literature requires an ability to independently appraise the credibility of the evidence and expert opinion offered [23]. In turn, correctly interpreting literature on prognosis, diagnostic tests, treatment, and potentially harmful exposures (eg, adverse effects of medication, environmental exposures) requires understanding a hierarchy of evidence. For example, in making treatment decisions, EBM practitioners may conduct an N of 1 randomized trial in which an individual patient is repeatedly treated with active intervention or placebo to determine the optimal treatment for that individual [24], or they may seek a systematic review of randomized trials of treatment alternatives. If a systematic review is not available, they look for individual randomized trials and high-quality observational studies of relevant management strategies. When the literature yields no clinically relevant information, EBM practitioners base patient care decisions on clinical experience and the underlying biology.

Notwithstanding its explicit reliance on evidence, EBM emphasizes that evidence will not dictate clinicians' ultimate decisions [25] and that preference or value judgments about the alternatives will always remain important [26]. Ideally, the values and preferences for patient care decisions should be those of the patients themselves. Some patients prefer the traditional paternal model and will follow their practitioners' instructions and trust them to make decisions on their behalf. Other patients insist on taking a more active role in care decisions and, by seeking clinical information on their own, may even be more knowledgeable about their conditions than are their practitioners. According to the EBM paradigm, however, physicians and patients should strive to share responsibility for evidence-based care decisions.

Achieving Evidence-Based Practice

Over the last several years, the concepts attributed to and labeled collectively as EBM have become a part of daily clinical life for many practitioners. Clinicians increasingly hear about evidence-based guidelines, evidence-based care paths, and evidence-based questions and solutions. Concern over EBM has shifted from whether to implement the new concepts to how to do so sensibly, efficiently, and without the problems associated with misconceptions about the nature of EBM. EBM-related concepts—such as the hierarchy of evidence, meta-analyses, confidence intervals, and study design—are so widespread that many clinicians willing to use today's medical literature have little choice but to become familiar with EBM principles and methodologies.

Opportunities and Challenges

For policy and decision makers, including regulators and payers, the evolution of EBM provides both opportunities and challenges. When properly used, EBM tools can help generate data to inform and rationalize health care decisions. The challenges, and perhaps dangers, result from superficially using EBM concepts, hijacking EBM labels to support preconceived ideas (eg, selective use of evidence), using EBM labels without completely applying the concepts (eg, relying on economic evidence without realizing its inherent uncertainties [27]), and not recognizing that patient values and clinical experience are intrinsic to the EBM paradigm [5].

Each clinician should decide the extent to which he or she will become an EBM practitioner. Practitioners who understand EBM concepts and can apply EBM skills will be able to more accurately and confidently judge competing recommendations and alternative courses of action. For example, EBM skills allow clinicians to access and apply high-quality information at the point of care (*see Appendix on page 28 for a list of useful EBM resources*). As trainees and practicing clinicians demand greater assessment of the relevant evidence, clinical educators and experts who provide recommendations regarding optimal practice (eg, in reviews, editorials, or practice guidelines) will require advanced skills in EBM. In addition, because evidence is a very powerful and convincing tool, educators without EBM skills will miss an important opportunity for communicating with their learners.

Evidence-based practice comes at the cost of time, effort, and other priorities, and clinicians may wish to seek information from sources that explicitly use EBM tools to select and present evidence. However, even this alternative requires that clinicians possess the skills necessary to apply the available evidence to individual patients. For example, to help patients weigh the risks and benefits of a treatment, clinicians must understand the best estimate of the magnitude of the treatment's effects as well as the precision of that estimate.

Clinicians who do not want to learn the skills necessary to evaluate evidence for themselves may also ensure that the patient care they provide is consistent with best evidence by working in a setting that demands evidence-based practice. Such a milieu may include computer-generated

reminders delivered at the time of a patient's visit, practice audits accompanied by personalized feedback, and academic detailing. Although this strategy may be less attractive to health care providers because it limits the choices available to both clinicians and patients, it will work well if the computer reminders, criteria for audit, and information included in the detail are based on best evidence and are consistent with intended system values.

On the other hand, the practitioner may face an additional challenge if he or she is expected to follow a local "evidence-based guideline" whose authors valued cost containment over the provision of optimal patient care. As found in a recent survey of 279 practice guidelines by Shaneyfelt et al [28], the methodologic quality of guidelines varies widely. The method of identifying evidence was described in only 17% of the guidelines reviewed, the method of grading the evidence was indicated in 15%, the role and use of expert opinion was described in 8%, the role of value judgment in making recommendations was indicated in 6%, and the strength of recommendations according to the quality of supporting evidence was graded in only 13%. Even more surprisingly, the purpose of the guideline was specified in only 75% of the publications, the background and expertise of authors described in only 25%, and the process of external review was revealed in only 32%. The findings of this survey are particularly distressing when one considers that practice guidelines may in some institutions and organizations acquire the status of practice directives. Generation of policies or recommendations intended for wide use requires that authors understand what constitutes "admissible" evidence, how to integrate research evidence with patients' and societal values, and how the strength of a recommendation relates to the quality of underlying evidence and the tradeoffs between risks and benefits.

Conclusion

The skills associated with EBM should allow clinicians to function more rationally. The ability to follow the path from research to application allows for greater autonomy and more satisfaction in daily practice. It allows clinicians to lead rather than to follow directions, to make choices together with patients rather than to accept those made by others, to distinguish valid guidelines from questionable recommendations, to dispute decisions not made on the basis of clinical evidence, and to read the medical literature selectively and efficiently.

In addition, clinicians who do not regularly receive or seek up-to-date information may be unaware of important new findings that should influence management decisions. EBM skills provide solutions to this problem by facilitating the efficient access, appraisal, and application of information from the original medical literature [29]. Thus, EBM is not an end in itself, but a set of principles and tools that help clinicians distinguish ignorance of evidence from real scientific uncertainty, distinguish evidence from unsubstantiated opinions, and ultimately provide better patient care.

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