The Importance and Impact of Evidence-Based Medicine

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ABSTRACT

OBJECTIVE: To describe the new paradigm of evidence-based medicine (EBM) and the benefits of using EBM in making treatment decisions for individual patients.

SUMMARY: Applying the knowledge gained from large clinical trials to patient care promotes consistency of treatment and optimal outcomes, helps establish national standards of patient care, and sets criteria to measure and reward performance-based medical practice. Implementing the principles of EBM, which rely on the rules of evidence and research, requires a commitment from medical schools, local health and medical licensing departments, physicians, pharmacists, professional associations, and managed care organizations. A review of results from landmark trials in hypertension, diabetic nephropathy, and end-stage renal disease describes the research for evidence-based therapies. A review of studies in the pharmacist's expanding role in implementing evidence-based medicine shows the benefits of collaborative medical practices.

CONCLUSION: Implementation of EBM in the managed care setting provides standards that have the potential to provide the best medical care at the lowest cost.

KEYWORDS: Evidence-based medicine, Managed care organization (MCO), Treatment guidelines, Performance-based medicine, Cost-effective formulary, Clinical trials, Primary care team, Therapy

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Target Audience

Pharmacists, formulary decision makers, physicians, and nurses in a managed care environment

Learning Objectives

Upon completion of this program, participants will be able to

1. outline strategies for the long-term management of hypertension and review American Diabetes Association (ADA) and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) guidelines;
2. discuss the evidence-based JNC 7 guideline recommendations and the application of these findings in patients with type 2 diabetes and kidney disease;
3. summarize the results of the 3 clinical trials that examined the effects of angiotensin II receptor blockers on the progression of renal disease in patients with type 2 diabetes;
4. differentiate the mechanism of action of angiotensin II receptor blockers and angiotensin-converting enzyme inhibitors; and
5. evaluate the cost-effectiveness of angiotensin II receptor blocker therapy for controlling hypertension and diabetic nephropathy.

The Importance of Evidence-Based Medicine

If one needs to describe evidence-based medicine (EBM), David Sackett, a pioneer in the field, defined it succinctly as " . . . the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." It can also be said that EBM uses scientific evidence that is rigorously obtained—and this contrasts with anecdotal experience, which can be biased, since even the most knowledgeable physician can be influenced in the decision-making process by recent experience with patients. Bias, however, can be overcome if the physician is attuned to the results of large, controlled, and objective clinical studies upon which to base treatment strategies. This approach is known as evidence-based medicine.[1]

The advantage of EBM is that the knowledge gained from large clinical trials is applied directly to patient care. Use of EBM promotes consistency in individual patient treatments that assume optimal clinical outcomes and improved quality of life. A main benefit of EBM is its use in the development of evidence-based treatment guidelines. When discussing prescribing patterns, the guidelines make it more efficient to review treatment strategies with physicians, discuss the value of the guidelines for managed care organizations (MCOs), and promote cost-effective formulary decisions. With EBM to support organizational clinical policies, physician agreement on documented clinical evidence can be much more easily achieved.[2]

Considering that the average physician has 7 or 8 MCO affiliations, it becomes apparent that the benefits of EBM can have a far-reaching effect on all of a physician's patients. Using Hibbing Economic Development Authority and National Committee for Quality Assurance criteria for the credentialing of physicians provides a level of consistency that defines a high standard of care for all patients. Using EBM in physician practices maintains regional consistency among MCO members so that national standards can be upheld. Further, excellence in medical practice can be measured with EBM—performance-based medicine can be implemented and physicians can be rewarded

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with either enhanced reimbursement or high capitation that reflects the value of using EBM.[2] The bottom line with EBM is that it provides the best doctors and the best medicine at the lowest cost, which means that consistency of care is maintained.[2]

Evidence-Based Medicine Is a New Paradigm in Treatment Strategies

EBS is, in fact, the new paradigm for medical practice. This new model deemphasizes intuition, unsystematic clinical experience, and the use of pathophysiology as the foundation for making clinical decisions. Instead, EBM emphasizes the importance of the results of large clinical trials in formulating individual treatment strategies. The use of EBM also requires new skills on the part of the physician. These include frequent and efficient literature searches and the critical use of established rules of evidence for evaluating clinical literature.[3]

The older paradigm of medical practice gave physicians a variety of options to sort out clinical problems. Physicians drew on their own clinical experience, reflected on their knowledge of the underlying pathophysiology, researched in a textbook, or referred cases to local experts in the field. Answers to difficult clinical presentations were often pursued through direct contact with local specialists. This particular paradigm puts a high value on the concept of traditional scientific authority and adherence to recognized approaches to treatment. The newer approach, EBM, makes certain assumptions that do not reflect the older ways of clinical thinking.[3]

Certain established teaching methods are still held in high esteem in the new paradigm. Clinical experience and the development of clinical diagnostic instincts are still crucial and important in becoming a competent physician. However, systematic attempts to record reproducible observations in an unbiased manner (the scientific method) strongly increase the confidence that the physician can have in a prognosis, the value of prognostic testing, and the efficacy of treatment strategies. Without systematic and reproducible observation, the clinician must be cautious, as the interpretation of information gleaned from clinical experience and intuition alone may be misleading. Indeed, an understanding of the pathophysiology of any disease state is invaluable, but that understanding is an insufficient guide for formulating treatment strategies and may lead to inaccurate predictions about the performance of diagnostic tests and the effectiveness of treatment modalities. It is therefore important that the rules of evidence be understood in order to correctly interpret the literature on causation of disease, prognosis, diagnostic testing, and therapy planning.[3]

Teaching Evidence-Based Medicine

More timely adoption of EBM by physicians may require 2 dramatic steps. First, all medical schools in the United States should be required to teach EBM to their students. Currently, only 9% (11 of 125) of medical schools offer a separate course on EBM. As a follow-up, when students graduate and enter residency programs, continuing medical education throughout their careers should reinforce the EBM training.[4]

Acting as role models, attending physicians should be enthusiastic and effective in conveying the importance of EBM, especially to residents and other attending doctors. Role models impart attitudes that help learners develop skills in critical appraisal. The physician role model is important insofar as the mentoring involves focus on the importance of the strength of evidence supporting clinical decisions that are derived from the findings of large, randomized, controlled clinical trials. The mentor can also cite large, randomized studies that have been rigorously reviewed and included in a focused meta-analysis. In other instances, the best evidence may still come from accepted practice or a physician's clinical experience and instincts. The clinical mentor should always clearly identify the basis on which treatment decisions are being made in a particular case.[3]

Second, the EBM training should be enforced. State health departments or professional associations could monitor physicians' adherence to guidelines to ensure compliance. This would be especially applicable for illnesses such as diabetes, heart disease, hypertension, asthma, and chronic obstructive pulmonary disease. The MCOs may also participate by monitoring the doctors within their networks. Suspension of licensing might be a final measure with nonadhering practitioners.[4]

The Effectiveness of Evidence-Based Medicine

Measuring physician treatment practices and patient outcomes can, however, be a challenge. Patients vary in complexity and degree of illness, as they do in their individual responses to medication and other treatment modalities, so statistical data must be gathered properly and then corrected to reflect variations in patient complexity. Ultimately, though, EBM will help physicians provide more rational care with better outcomes. The guidelines based on large, randomized, controlled studies are not inflexible, and they do provide the best first step. Patients are still treated on an individual basis, especially in cases of serious illness or when issues requiring treatments are not specifically covered by guidelines. That is when the physician's judgment and years of medical training become invaluable assets.[3]

The proof of EBM rests on whether patients who are treated in this mode enjoy better health. Of course, this proof is no more available for the new paradigm than for the old—simply because at this time, there have not been any long-term comparative studies. What do exist are data from short-term trials confirming that the skills of EBM can be taught to students in medical schools and to residents.[3]

The Future of Evidence-Based Medicine

EBM is concerned directly with the uncertainties of clinical medicine but has the potential to transform the next generation of

clinicians.[3] These new physicians will join their established colleagues in facing a profusion of scientific literature, the continuous introduction of highly complex technologies, concern about the escalating costs of medical care, and an increased awareness of both the quality of positive outcomes and treatment strategies. All indicators point to EBM as a paradigm that will help deal with many of those issues. Because EBM will require new skills and outlooks for clinicians, incorporating the principles of EBM into postgraduate medical training and residency education should promote the dissemination of this new way of developing treatment strategies. The ultimate objective is that EBM will become totally integrated into the daily practice of medicine.[3]

The Impact of Evidence-Based Medicine on Outcomes and Costs

The articles that follow present data from important research: the Collaborative Study Group (CSG) early trial, the Irbesartan Diabetic Nephropathy Trial (IDNT), the Reduction of Endpoints in NIDDM With the Angiotensin II Antagonist Losartan (RENAAL) trial, and the Irbesartan in Patients with Type II Diabetes and Microalbuminuria (IRMA II) trial. These clinical trials are examples of large, randomized, controlled studies that produced data that can be used to develop evidence-based treatment strategies for patients with type 1 or type 2 diabetes who are progressing to end-stage renal disease.

The landmark studies cited in these articles were conducted using angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) in the treatment of hypertension, end-stage renal disease, and diabetic nephropathy. The resulting data show that blockade within the renin-angiotensin-aldosterone system axis and adherence to the guidelines of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) and the American Diabetes Association in the management of hypertension and microalbuminuria in type 2 diabetes and overt diabetic nephropathy produced excellent patient outcomes. These data also show that treatments with ACE inhibitors and ARBs were cost effective, improved quality of life for many patients, and, in some cases, prolonged lives from months to years.

From a managed care point of view, these trial data indicate that the health of these patients can be improved and the costs of treatment can be reduced through implementation of EBM in their treatment plans. Now that the effectiveness of ACE inhibitors and ARBs has been studied and the evidence examined with the goal of devising the best strategies for this difficult-to-treat patient population, the critical challenge becomes the development of EBM guidelines and application of those guidelines in clinical practice.

The expanding collaborative role of pharmacists in implementing evidence-based treatment strategies is also discussed in the following articles. Results from several programs and studies involving patients with hypertension document the effectiveness of pharmacists as academic detailers, clinical advisors, and patient comanagers with physicians and primary care teams that utilize the EBM paradigm for treating patients with hypertension.

Development of evidence-based treatment strategies, education and training of physicians who are adept at evaluating the literature with an EBM perspective, and acceptance of and adherence to EBM policies by physicians and pharmacists in a collaborative mode are critical to attaining better outcomes for patients with diabetes, hypertension, and other complex, chronic diseases. The EBM paradigm is poised to have a positive impact in the managed care setting—providing the best medical care at the lowest cost and achieving optimal outcomes.

DISCLOSURES

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