

Understanding Evidence-based Medicine

Practicing medicine in today's information-overload world requires an enormous investment of time and energy. Physicians must keep up with the latest developments in their own specialties or areas of interest as well as those in other specialties that may affect their patients or procedures. Evidence-based Medicine (EBM) can streamline this process.

Fast Facts



- ▲ *Physicians have always used the basic concept of EBM as part of daily practice. The formal implementation of EBM takes the process a step further. Page 13*
- ▲ *People often confuse EBM with guidelines, but there is a difference. A prescriptive guideline may be based on evidence; but its purpose is to direct the physician's actions in a given situation. EBM, on the other hand, seeks to discover the outcomes of a particular intervention. Page 16*
- ▲ *EBM may help managed-care practices refine procedures and streamline care for maximum patient benefit. This may help shorten the gap between bench and bedside. Page 19*

Before examining and treating a patient, the physician must be well informed in order to apply the best, latest, and most applicable medical knowledge. That's not easy to do when physicians are deluged by oceans of information that must be read, retained, analyzed, and applied. They must invest significant amounts of time in tracking the latest journals, research, drug developments, clinical trials, policies and procedures, tools and techniques, and more.

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References: 1. IMS National Prescription Audit. May 2005. 2. Sadock BJ, Sadock VA. *Kaplan and Sadock's Synopsis of Psychiatry: Behavioral Sciences/Clinical Psychiatry*. 9th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2003:552. 3. LEXAPRO [package insert]. St Louis, Mo: Forest Pharmaceuticals, Inc.; 2006.

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Evidence-based Medicine (EBM) can streamline the process. EBM is a method of framing clinical questions with sharper focus; searching for the most applicable, valid, relevant, and useful information available; and applying the findings to patient care. Simply put, EBM is the acquisition and application of the best available evidence needed to make the best choices for patient care.

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As David L. Sackett, M.D., founder and director of the Kilgore S. Trout Research & Education Centre at Irish Lake in Ontario, Canada, wrote in his seminal article, "Evidence based medicine: what it is and what it's not" (*British Medical Journal*, 1996): "Evidence-based Medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of indi-

vidual patient. The practice of Evidence-based Medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."

Risa Lavizzo-Mourey, M.D., M.B.A., President and CEO of the Robert Wood Johnson Foundation, says: "I think Evidence-based Medicine is really the backbone of the way we practice medicine. We base our therapies on clinical trials and are constantly refining the comparisons of those clinical trials so that we have the best scientific evidence of what's going to work and what doesn't work. To practice good Evidence-based Medicine just means to use the best available clinical information and to arrange that information in a way that makes it easier, and more accurate, to make clinical decisions that are relative to a particular person. I think that's really the basis of what we do."

But the implications of EBM go beyond diagnosis and treatment. As patient-care facilities and payers (both private and governmental) implement EBM policies and practices, there will be changes in the business of medicine as well. For example, Medicare has announced that starting July 2007 it will reward

physicians who send in data on 16 “evidence-based measures” of quality care. This incentive may push more doctors toward electronic health records, which can facilitate collection of data. It may also leave in the dust some physicians who can’t make the switch from paper. EBM will lead to algorithms and treatment guides that may affect reimbursement patterns and malpractice litigation. It may also feed many physicians’ fears or feelings of losing control over their own practice.

The first workshop sponsored by the Institute of Medicine’s Roundtable on Evidence-based Medicine covered topics ranging from how to generate better evidence to how EBM will affect reimbursement and regulatory issues, and how insurers, government, and health organizations can work around barriers and obstacles to implementing EBM. The stated goal of the Roundtable is for 90 percent of clinical decisions to be supported by accurate, timely, and up-to-date clinical information by the year 2020.

What is EBM?

Although the formal concept of EBM is relatively new (it was developed in the early 1990s), the core concept of basing decisions and practice on evidence is much older and extends beyond medicine.

Most people apply at least some evidence to the process of making everyday choices. Some decisions are relatively simple, such as which loaf of bread to buy or which program to watch on television, and require little supporting evidence beyond personal or family preference. Other decisions, such as which car to buy to meet the family’s needs, are best made after the buyer has considered the available choices and weighed the pros and cons of each.

Assessing evidence plays a key role in many professions and industries. Law enforcement officers do so before bringing charges against a suspect. Attorneys weigh evidence before deciding whether to prosecute or defend a case. Judges and juries consider evidence before issuing a verdict. Retailers look at marketability, price point tolerance, consumer preferences, and overhead or cost of doing business before a line of merchandise appears on store shelves. New evidence adds to the pool of knowl-

edge and may lead to changes in what the company sells, how it sells, how it interacts with customers, what new directions it may take, or even whether it will remain in business.

Physicians, too, have always used the basic concept of EBM as part of daily practice. Each time a patient presents with a set

By using evidence-based rapid assay and treatment guides for routine care, says Dr. Lavizzo-Mourey, it's possible to free the physician to talk with patients about more ambiguous issues. The patient benefits by receiving a rapid and accurate diagnosis followed, if indicated, by faster treatment. The physician benefits by having the diagnostic process made so efficient that it is almost automatic. Both patient and physician benefit from extra time to discuss more complicated issues.

of symptoms, the physician draws on his or her accumulated knowledge and experience to decide what treatment would be best for that individual patient.

But the formal implementation of EBM takes the process a step further to develop protocols and treatment guides that have the potential to streamline some aspects of patient care.

Take the simple sore throat. Although this may seem to be a relatively trivial condition, it is one that causes patients to spend a lot of time visiting physicians, says Dr. Lavizzo-Mourey. “We have a pretty good algorithm on

how to treat a sore throat that is effective 99 percent of the time—how to culture it and examine the patient. You can do a rapid test and know with great accuracy when to treat, how to treat, and how long to treat.”

Using that algorithm doesn't always require a physician, Dr. Lavizzo-Mourey points out. A nurse or other clinician can follow it and get the same result. By using evidence-based rapid assay and treatment guides, she says, it's possible to free the physician to talk with patients about areas that are more ambiguous. The patient benefits by receiving a rapid and accurate diagnosis followed, if indicated, by faster treatment. The physician benefits by having the diagnostic process made so efficient that it is almost automatic. Both patient and physician benefit from extra time to discuss more complicated issues.

“I define the application of Evidence-based Medicine as a four-step approach to patient care,” says Lynne Kirk, M.D., Pres-

ident of the American College of Physicians. She says these steps are the following:

- Define the clinical question in terms of addressing a patient's problem.
- Search the literature for articles that might answer that question in a way that you can apply to take care of your patients or a group of patients.
- Do a critical appraisal of what you find in the literature to determine
 - ◆ if it meets standards of quality scientific evidence; and
 - ◆ if it can be applied to your patient based on the patients who were involved in the study.
- Apply the information in the care of your patient, or at least use it to inform your patients of options they have with this particular intervention or care.

The physician is still in charge. The physician still makes all of his or her own decisions.

What's the difference? Those decisions can be made more efficiently and with greater confidence with the use of EBM.

EBM has the potential to increase the quality of care across the healthcare system. Studies have shown that the patient with the same condition may receive very different care in various areas of the country, including areas that are geographically close to each other. That would suggest that either some patients are getting too much care, or others are not getting enough, whether it be a particular type of treatment or a technology. EBM helps bridge the gap by showing what worked in treating large population samples, what was most cost effective, and what promotes greater quality, and it allows physicians to standardize their approach to care for those patients, says healthcare management and economics expert R. Lawrence Van Horn, Ph.D., M.P.H., M.B.A., associate professor of management; faculty director, health care, The Owen Graduate School of Business at Vanderbilt University in Nashville, Tennessee.

How it works

Although some physicians fear that EBM is a system that forces physicians into formula-driven, cookie-cutter or assembly-line medical practice, proponents paint a different picture.

“Evidence-based Medicine doesn’t tell you what to do. It just tells you what the alternatives are,” says Charles Young, M.R.C.P., a practicing emergency physician in London, England, and editor of the journal *BMJ Clinical Evidence* (www.clinicalevidence.com). EBM supports and informs treatment decisions but does not dictate them, he explains.

People often confuse EBM with guidelines, but there is a difference. A prescriptive guideline may be based on evidence; but its purpose is to direct the physician’s actions in a given situation, Dr. Young says. If a patient presents with Problem A, guidelines might direct the physician’s actions: Do this first. Order that test. Discuss test results. Give this medicine or that intervention. EBM, on the other hand, seeks to discover whether giving a particular intervention, drug, or procedure to a population with the same condition provides beneficial outcomes such as saving lives or prolonging illness-free survival.

“People get confused about that quite a lot, and it’s an important difference because if you assume that all Evidence-based Medicine products are all guidelines, then it can make you feel, as a doctor, that you’re being told what to do,” Dr. Young says. “But actually what Evidence-based Medicine and products like *BMJ Clinical Evidence* are designed to do is just facilitate physician options.” They’re not meant to direct, only to assist.

The use of EBM varies by specialty, but it is simply employing evidence that has been clinically derived from results of large population samples, says Dr. Van Horn. It’s a matter of

Why use EBM?

- To refine research. EBM distills research by focusing on the studies that are most applicable and useful.
- To speed information retrieval. Using EBM tools, physicians can search dauntingly vast seas of studies with greater efficiency.
- To make needed data accessible not only when the physician needs it but also where he or she needs it—in the exam room, the clinician’s office, or the hospital.
- To improve patient confidence by demonstrating physicians have current knowledge, speak honestly, and can debunk hokum.

finding the findings from clinical research, published in journals like *New England Journal of Medicine* and *Journal of the American Medical Association*, that demonstrate what works and what is clinically effective, then employing those results in ways that promote efficiency and quality of care for patients. He explains, “It’s not cookbook-based medicine, but it is a quality-improvement strategy approach to consistently treat and care for people.”

For example, a journal like *BMJ Clinical Evidence* may present some information that says a particular drug may be beneficial in melanoma. “What that means is that in the research that’s been conducted in groups of patients, more often than not the patients improve if they’re given that drug,” Dr. Young explains. “What it *doesn’t* mean is that you can guarantee that every patient you gave that drug to would definitely improve, because the research is based on groups of people, not individuals.” It’s important to remember that distinction when you’re discussing treatment with patients who may ask, “How do we know this is going to work?” The physician cannot answer, “Well, it’s almost certainly going to work for you,” Dr. Young cautions. But he adds, “What you can say is, ‘In a lot of people who are similar to you, it worked more often than not.’”

EBM helps physicians clear up confusion, answer questions, and discuss options with patients. When patients are diagnosed with cancer, for instance, they ask what will be done to them, how often that treatment works, whether it will work for them, and what their chances of survival are. Information grounded in EBM allows the physician to answer the patient’s questions with the latest and most applicable information. It also helps the physician explain why a treatment that worked for the patient’s friend may not be suitable for this person with these symptoms at this time. “One never wants to take away the patient’s hope in situations like that,” says Dr. Young, “but it’s also important not to mislead people and falsely raise their expectations.”

Does EBM make the physician’s tasks easier or harder? The answer depends on how the physician views EBM. “If you view Evidence-based Medicine or Evidence-based Medicine products as things that provide you with information that you can use as you see fit, I think it makes things easier because you can be

more confident in what you say,” Dr. Young says. But if a physician thinks of EBM as guidelines that tell him or her what to do, “then that makes it much more difficult” and makes the physician feel pressured and stressed by having to choose without knowing which is right, he says. Instead, Dr. Young recommends viewing EBM this way: “It’s just lots of information that you can use as you see fit.”

Evidence-based reading

In the past few years, there’s been a flood of new evidence-based journals in print. These publications aim to help physicians and other healthcare providers by winnowing out research that may be biased. “We require that manuscripts have the evidence behind the practice, and we make sure the authors are being unbiased in what they are presenting,” says Diana Mason, R.N., Ph.D., editor-in-chief of the *American Journal of Nursing*.

Although this may not sound so different from other scholarly publications, evidence-based journals make an extra point in publishing examinations of the full body of evidence from research—including the size and quality of the studies and any factors that might influence the results—rather than the results of one study. This can help avoid rushing a practice into common use before it is validated, says Dr. Mason.

Applying EBM to journal reading requires taking a step back to consider the big picture. Beyond any single study in the journal or the entire contents of the journal, physicians also need to consider what they’re not seeing in their journals. Studies that find evidence for a certain therapy are more likely to be published than those that show a therapy doesn’t work.

Dr. Mason describes a paper published in the journal *Cancer* (August, 2005) that reported that approximately a third of the 275 Phase I clinical trials presented at the 1997 meeting of the American Society of Clinical Oncology had not been published as of 2001. “Four years out,” she says, “a third of the papers that were presented at that meeting didn’t make their way into publication.”

Funding is another factor. With the current system for clinical trials, it is easier to get grants to test a pharmaceutical intervention than to test a special diet or even physical therapy. There

may be other interventions that work equally well if not better, she adds, but there is less money available to investigate those therapies.

Bench to bedside

One reason EBM is gaining greater acceptance among physicians, hospitals, and other care providers is the speed it brings to information retrieval and application. EBM saves time for physicians by sharpening the focus of research to provide the best and most applicable information.

Hospitalist Mary Jo Gorman, M.D., M.B.A., CEO of Advanced ICU Care in St. Louis, Missouri, explains that after new research is published, “It takes a long time to bring that knowledge and practice to the bedside.” Sometimes a new development is implemented on the basis of a single definitive study; sometimes an accumulation of studies is needed before change can

“It takes 17 years for a new finding to percolate down to the clinical office and the patient’s bedside,” Dr. Britto says. “The trick is not just to generate Evidence-based Medicine but to find out how to get it quickly to the clinics and hospitals, so it can start making a difference.”

occur. In either case, research has shown it takes 15 to 20 years to put study findings into practice, Dr. Gorman says.

Joseph Britto, M.D., pediatric intensivist, Co-founder and CEO of Isabel Healthcare Inc., USA., agrees: “It takes 17 years for a new finding, such as a recommendation about the advisability of using antibiotics to treat chronic otitis media in children, to percolate down to the clinical office and the patient’s bedside,” he says. “The trick is not just to generate Evidence-based Medicine but to find out how to get it quickly down to the foot soldiers, to the clinics and hospitals, so it can start making a difference.” We can’t wait until the next generation gets trained in this, he says. Physicians need to learn how to use evidence to improve practice.

Specialists often jump-start new evidence-based practice. A cardiologist who focuses on that specialty incorporates into his practice the latest findings sooner than physicians who see fewer cardiology patients, Dr. Gorman says. Similarly, hospi-

talists and intensivists (physicians who specialize in intensive-care patients) can bring new developments in their fields to patients sooner.

Managed care may have a similar effect of shortening the gap between bench and bedside. With large patient populations on which they can collect and evaluate data, managed-care companies can accelerate implementation of therapies that the data reveals as effective.

Ideally, this process will permit physicians to shorten the 15-to-20-year gap between research and practice. Dr. Gorman's hope is "that by leveraging the concentration of patients, you reduce variability and bring more patients into Best Practices."

As hospitals, emergency departments, nursing homes, and payers implement EBM policies and practices, physicians already in the habit of using EBM will be ahead of the game—and their patients may benefit sooner.

Busy physicians like Scott Luria, M.D., associate professor at the University of Vermont College of Medicine in Burlington, use EBM every day. "I have a very active, full-time primary practice of Internal Medicine," Dr. Luria says. "I use the principles of Evidence-based Medicine all the time, at least in theory, and try to put them in practice as much as is practical." He teaches medical students and residents in the office and in the hospital wards about evidence-based care in general. He also uses it in patient care. "Day to day, I see patients every 15 min-

What an EBM approach can do for physicians

- Resource centers devoted to EBM can significantly shorten the time it takes a physician to locate, read, evaluate, and compare new research.
- CME EBM courses can improve physicians' understanding of and ability to interpret research.
- Tools such as evidence-based risk calculators can help physicians make rapid evaluations and treatment recommendations for best patient outcomes.
- Treatment guided by EBM is less likely to be challenged or rejected by patient insurance providers and provides supporting documentation for physician records in the event of legal action.

utes to half-hour. Much of our interaction has to do with modification of risk factors for disease,” Dr. Luria says.

For example, Dr. Luria often finds himself trying to convince patients that their elevated cholesterol and elevated blood pressure really do indicate an increased risk for heart disease. To the patient, he says, those statistics are only numbers; their importance is hard to grasp when the patient may feel fine. But to the physician, those numbers are key factors that guide decisions such as whether lifestyle changes may be sufficient or the patient should go on medications.

“It’s a tough sell” to convince a patient who feels well that he or she needs to take medication, Dr. Luria says. The patients listen as the physician explains that they should control their blood pressure and cholesterol. But the key point is, what does this mean to the patients? “It means that they are taking a medicine that is expensive and has side effects,” says Dr. Luria. It also changes the patient’s self-image from “healthy” to a person who takes medicine every day.

“That’s where I find the evidence-based tools are particularly effective,” Dr. Luria says. He uses the Framingham Heart Study Risk Assessment Tool 10 to 15 times a day and says, “It is a classic evidence-based study where it is not just saying you should treat high cholesterol or high blood pressure, but [explains] what the numbers actually mean.” It takes only seconds to type in the patient’s total cholesterol, HDL, systolic blood pressure, and four other factors to get the patient’s 10-year risk. The patient has a clearer picture of what influences his or her risk and the physician has an evidence-supported reason to enforce his or her recommendation to the patient.

EBM tools and procedures also help managed-care practices refine procedures and streamline care for maximum patient benefit with the most efficiently used resources. As electronic medical records become more widely used, the information will broaden the applications where EBM can be used.

Charles Young, M.R.C.P., editor of *BMJ Clinical Evidence*, points out that United Health Foundation—a nonprofit organization formed by United Health Group, the managed-care and benefits giant, to support health decisions—distributes his publication to more than 500,000 U.S. physicians nationwide.

“Increasingly they [United Health Group] say they use it to base guideline management on,” he says.

According to R. Lawrence Van Horn, Ph.D., of the Owen Graduate School of Business, Vanderbilt University, the focus of EBM in managed care is fourfold:

- to develop population-based guidelines that improve the quality of care;
- to reduce inappropriate variation;
- to increase clinicians’ adherence to guidelines that benefit patients; and
- to increase patients’ adherence to guidelines that benefit them.

Pros and cons

Although EBM is spreading, it is not universally supported.

Some physicians say it’s nothing new. Clinicians have used EBM for ages. After all, at its core, it is the textbook scientific method that is taught in high school biology classes.

Some oppose it because it sounds like “cookbook medicine,” a one-size-fits-all recipe that minimizes the physician’s role from caregiver to conduit, a mere vehicle through which EBM is delivered to patients.

When a patient enters a physician’s office and presents with a certain problem or complaint, says Steve Singer, Ph.D., director of educational services at PeerPoint Medical Education Institute, LLC, in Evanston, Illinois, “You have to figure out what to do,” says Dr. Singer.

EBM essentially takes the good old scientific method by which research is structured: you have a hypothesis, collect data, make observations, test your hypothesis, and see what you have learned, says Dr. Singer. “Evidence-based Medicine is taking that scientific method and essentially making it a requirement for clinical decision making.”

But others fear that EBM will be used to force decisions on physicians even when they don’t fit. In defense, supporters point out that a key element of EBM is assessing whether a decision is the right choice for each individual.

Some are concerned that extensive searches in gigantic databases will overwhelm physicians with more information than they have time to slog through. Supporters say this concern is

eliminated when physicians learn more efficient search practices and use better data-retrieval tools.

“I think Evidence-based Medicine is wonderful as far as it goes,” says Clifford Dacso, M.D., professor of medicine, chief of general medicine, and vice-chair for clinical affairs in the Department of Medicine at Baylor College of Medicine in Houston, Texas. “It is a huge advance from where we were, which was anecdotal-based medicine.”

He stresses he is not opposed to using evidence to inform clinical judgment but says the problem with EBM is “that the evidence we use to inform clinical judgment is population-based evidence, and the gold standard is a randomized control trial.” The patient in Dr. Dacso’s waiting room may bear only the slightest resemblance to the population tested in a randomized clinical trial; therefore, the conclusions that study reached may not be applicable for his patient.

He’s not saying we should abandon EBM. Instead, he contends that we need to tweak it to make it even more applicable. “My concept is, we have to find a way to expand the power of the evidence in such a way that an individual can use that information to inform his or her own clinical decision making,” Dr. Dacso explains.

His research program is dedicated to finding a way to extend that evidence so that it informs individual decision making and allows physicians to decide how much they expect to get from a particular intervention.

“I don’t hate Evidence-based Medicine,” Dr. Dasco says. “I think it is wonderful. It is just inadequate.”

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