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Evidence-Based Medicine: The Fourth Revolution in American Medicine?

Kevin C. Chung, MD, MS¹ and Ashwin N. Ram, BS²

¹Professor of Surgery, Section of Plastic Surgery, Department of Surgery, The University of Michigan Health System; Ann Arbor, MI

²Medical Student, The University of Michigan Medical School; Ann Arbor, MI

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The U.S. is facing a crisis in healthcare. Decades of healthcare inflation have accrued costs that now total \$2 trillion annually, consuming about 16% of the Gross Domestic Product, and are expected to increase.¹ Concerns about the overall quality and efficiency of healthcare received by Americans are reflected in the statistics: 15–20% of Americans are uninsured² and emergency rooms are overloaded because of lack of affordable preventive services,³ despite the U.S. having the largest health care expenditures in the world.⁴ Experts agree that the existing healthcare system is in a critical state, and in the throes of a historic transition. Currently, experts and legislators are working in tandem to deliberate on resolutions that could potentially produce a transformation of the entire healthcare system. Among the various solutions being proposed to aggressively curb rising costs and help deliver rational care is the implementation of a strict standard of evidence-based medicine (EBM). This response may be akin to the “third revolution in medical care”⁵ proclaimed by Arnold Relman to usher in the outcomes movement (the first two revolutions being the spread of health insurance to expand healthcare and the backlash of payers to curb healthcare costs). Whereas outcomes research has provided some direction for dealing with the imbalances of the current system, the initial enthusiasm and promise of the outcomes movement has not produced tangible results in improving the healthcare environment of this country. EBM, which may be considered the fourth revolution in American medicine, differs from the outcomes movement in that it emphasizes greater accountability, calls for evidence to justify all medical treatment, and may be tied intimately to physician reimbursement.

Studies have exposed the unsettling reality that clinical care is oftentimes limited in its scientific background. This deviation has been linked to broad variations in care, including the “underuse, overuse, and misuse” of diagnostic and therapeutic services.⁶ According to health policy expert Haavi Morreim, “Defensive medicine, patients’ demands for the latest

Corresponding author and reprint requests sent to: Kevin C. Chung, MD, MS, Section of Plastic Surgery, The University of Michigan Health System, 1500 E. Medical Center Drive, 2130 Taubman Center, SPC 5340, Ann Arbor, MI 48109-5340, Phone: 734-936-5885, Fax: 734-763-5354, kechung@med.umich.edu.

technologies, physicians' own fascination with new devices and procedures, and economic pressures can quickly skew physicians' most thoughtful, scientifically well-founded preferences...physicians are neither morally nor financially entitled to do literally whatever they ideally wish to do for their patients. Health care is costly, and the days of handing physicians a blank check to spend unlimited amounts of other people's money are over."⁷ These widely held sentiments have eroded the base of traditional practice and have precipitated a shift in the framework of American medicine. Over the past twenty years, medicine has adjusted to warrant intervention on empirical evidence from reproducible trials; these changes are cumulatively known as EBM.

EBM has been characterized as the movement to evaluate the safety, effectiveness, and cost of medical practices from the approach of best scientific evidence and to establish medical practice on such knowledge.⁸ To some, EBM has been welcomed as the next great "paradigm shift"⁹⁻¹¹ in medicine, sure to deliver uniform care and to diminish the idiosyncrasies of individual treatment plans that are oftentimes ineffective and unsafe. Typically, physicians have used their understanding of pathophysiological processes to practice medicine.¹² For example, until mid-2002, hormone replacement therapy (HRT) had been the standard, sensible treatment for common post-menopausal symptoms such as osteoporosis, vaginal dryness, and hot flashes.¹³ However, in July 2002, the Women's Health Initiative (WHI) conducted a clinical trial that found HRT, in fact, increased the risk of breast cancer, stroke, blood clots, and dementia in treated patients.¹³ The latest research confirms that even three years after discontinuing this trial, women treated with hormones suffered a higher risk for malignancies and experienced a 12% increase in global risk index.¹⁴ To skeptics, this underscores the unintended results of medical interventions not initially supported by good data. Understandably, physicians have come under intense pressure to standardize patient therapy under the strictest scientific measures available.

However, the changes accompanying EBM are at this point ill-defined. Although the logic behind EBM is clear, there is dissent among practitioners and policy-makers about the best implementation of EBM in day-to-day practice. The debates have divided health professionals, especially surgeons, who have felt that EBM has curtailed their autonomy and has neglected patient individuality.^{8,9,15-21} Many aspects of EBM have come under scrutiny including the way it should be implemented at the bedside. As the issue gains more and more prominence and media focus, it will be important to understand what EBM is, why it is being hotly debated, and what EBM will mean for physicians in the near-future.

What is Evidence-Based Medicine?

EBM is the principle of integrating the powerful methods of science into the practice of medicine. The roots of EBM lie in the practice of epistemology, the philosophical discipline that examines the foundations of current knowledge including its limitations and validity. The goal of EBM is to collect and utilize evidence as a guide for the practice of judicious medicine. EBM sets out to rigorously test the value and efficacy of any clinical intervention before it becomes a standard of medical practice to prevent the establishment of "rumor-based medicine."¹⁷ This approach does not discredit or undermine physician autonomy because it stresses the value of the surgeon's clinical expertise and urges the integration of

best evidence with clinical skill.^{15,22} In fact, studies have shown that the marriage of the implicit wisdom of a practicing clinician and the application of the scientific method in the form of data analysis has in many ways validated the “tried and true” practices of the experienced physician.¹² Because the use of any evidence-based algorithm requires an accurate assessment of clinical findings to plug in, EBM is complementary to rather than exclusive of clinical acumen. Hence, EBM involves the combination of clinical expertise and professional wisdom with the best outside evidence to make important decisions about patient care.^{12,18,23–25}

According to the Centre for Evidence-Based Medicine, “Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”¹⁸ In theory, EBM connects five basic ideas of how to practice effective medicine: gathering evidence, integrating evidence with experience to arrive at a clinical decision, implementing this decision at the bedside, assessing performance, and staying current with research. First, EBM makes explicit the need for clinical decisions to be rooted in the best available basic science- and population-based evidence to avoid relying on “hearsay, habits, and standardized protocols.”¹² Second, physicians must combine evidence from these studies with their own acumen and educational background.²⁵ Third, physicians must translate the best reasoned medical plan derived from the integration of evidence and insight to the bedside in a manner that benefits the patient.¹⁸ Fourth, physicians should constantly assess their performance in terms of following these steps and correctly applying these ideas.¹² And fifth, physicians must be proactive about learning and be engaged with up-to-date research.^{11,12,23,26,27}

Much of the ambiguity behind EBM is in dealing with the evidence itself. To provide clarity, the National Guideline Clearinghouse has stratified evidence for physicians based on strength of evidence.²⁸ (Figure 1).

What is the debate surrounding EBM?

The application EBM to the clinical setting has been broken down into a multistep process of creating answerable questions, tracking down the best evidence to answer these questions, evaluating the evidence for its strength, summarizing the evidence, integrating and implementing the evidence into practice, and finally evaluating performance.^{11,27,29} Each step of the process represents a unique challenge in practice that physicians as a whole find difficult to implement.^{12,23,24} For example, Sauerland et al report that only 10–20% of decisions made in the surgical ward are based on Randomized Clinical Trials (RCTs) whereas about 30–50% of decisions in general medicine are based on RCTs.² There may be several reasons why studies are underused in the clinic.

First and foremost, there seems to be a lack of consistent scientific evidence. In the case of surgeons as a whole, Level I evidence is exceedingly difficult to come by.^{23–25,30} Even if there is sufficient evidence, searching the massive database of research available to physicians is a daunting task. Many find it difficult to filter and evaluate studies of sufficient quality that are not only appropriate for their patient, but also amenable to previous research and to pertinent to clinical situations.^{29,31} With the exponential increase in the number of

papers, it is difficult to keep up with current best-evidence.³² The most effective way to circumvent this rapid accumulation of medical literature is to rely on systematic reviews, which are well-planned studies that address the shortcomings of traditional reviews by adhering to strict, reproducible methods and recommended guidelines.³³ When there is a shortage of adequate evidence, many physicians resort to instituting care based on the results of weaker evidence such as cohort and case-control studies and expert committees, which can oftentimes lead to unsuitable treatment regimes because of “overconclusion” (arriving at an incorrect conclusion that is an artifact of the data).^{25,29,34,35} The relative deficiency of sound clinical evidence has spawned the CONSORT criteria. Intended to expand the reporting of RCTs, the CONSORT (Consolidated Standards of Reporting Trials) statement was developed by a group of healthcare experts in 1996 and utilizes organized checklists and flowcharts for physicians to easily follow.^{36, 37} (Figure 2) While these guidelines were anticipated to dramatically increase the amount of RCT reporting, they are surprisingly underutilized. This dearth of relevant evidence accentuates the need to foster clinical research training in all surgical specialties.³⁸

In addition to the lack of relevant evidence, there is also a criticism of the manner in which studies are conducted and presented to physicians by researchers. Because clinical trials focus on outcomes across populations and not on individuals, opponents of EBM argue that RCTs are improperly used to arrive to conclusions.^{10,29} Important questions have been brought up regarding the validity of Level I evidence. Opponents argue that while RCTs can characterize the collective results of a drug or intervention, they are not useful in the context of an individual patient because of the variability in defining disease. Disease is complex and fluctuates substantially among individuals making the findings of an RCT limited and oftentimes inapplicable. Also, RCTs are known to suffer from low inclusion rates and recruitment biases. For example, if the inclusion criteria for a trial are excessively restrictive, then a study may come out underpowered and unsuitable to use across large populations. On the other hand, if the inclusion criteria are very liberal, the chance for false-negative outcomes increases, thereby undermining a trial. Consequently, RCTs are estimated to be invalid sources of evidence by some physicians because they are a “compromise between validity and generalizability.”⁹ Other criticisms of RCTs include that they are complicated to perform, time-consuming, expensive, and biased. For example, industry-funded clinical trials account for nearly half of all clinical studies, contributing to an inherent, systematic bias. With the for-profit motive at heart, the private industry focuses on the newest drugs and devices and tends to underfund older methods. Additionally, for-profit groups have been shown to be more likely to report positive findings than similar trials financed by not-for-profit groups.^{39,40} Another important instance of bias arises when researchers fail to measure relevant endpoints with RCTs.^{9,35,41} Opponents of EBM argue that many researchers base trials on irrelevant data that are relatively easy to collect and freely available instead of concentrating on patient-relevant endpoints such as quality of life measures.⁴² Additionally, not all surgical interventions can be effectively tested in RCTs. Solomon and McLeod performed a search of the surgical literature and found that only 40% of treatment questions involving surgical procedures can be subject to RCTs.⁴³ They cite “patient preferences, uncommon conditions, and lack of surgical community equipoise” as the main factors precluding such analysis.⁴³ However, because EBM advises using the best

available evidence, alternatives to RCT are accepted as laid out by the U.S. Preventive Services Task Force, a government-affiliated expert panel that independently conducts reviews of scientific evidence, and other guiding institutions.

In spite of the limitations of RCTs, the prevalent viewpoint seems to be that there is no better, pragmatic alternative. Proponents of EBM state that the unexpected variation in results and recommendations of systematic reviews can and will be corrected when physicians push for steps to improve study methodologies and to standardize reporting.⁴⁴ Additionally, proponents argue, there is a misunderstanding that only RCTs and Level I evidence comprise the “evidence” in EBM when in fact EBM stresses finding the best available evidence.⁴⁵ According to Sackett et al, “...if no randomised trial has been carried out for our patient’s predicament, we follow the trail to the next best external evidence and work from there.”¹⁸ While RCTs are considered the “gold standard” for evaluating the effects of a particular intervention, they may not necessarily be the best resources for conducting diagnoses and prognoses, or evaluating benefits and harms.^{9,29} In fact, proponents of EBM generally accept the difficulties in extrapolating directly from the bench to the bedside.⁴⁶ Therefore, RCTs should not be mistakenly considered a set of instructions when they are simply a collection of guidelines for patient care.

RCTs aside, fervent critics feel that EBM disparages clinical expertise by promoting “mindless algorithm” and hampering physician autonomy by demanding a code of conduct likened to “wearing a straightjacket.”^{16,47,48} Instead of modernizing care, EBM jeopardizes medical progress by introducing a dull environment of uniformity and repetition, derisively coined as “cookbook medicine.”^{47,48} Opponents also maintain that EBM may compromise the skill and competence of practitioners. Instead of reasoning through cases, physicians will be given incentives to follow protocols that treat all patients as basically the same.¹⁰ Consequently, physicians will be ill prepared to cope with the differences between patients they will treat in actual clinical situations.¹⁰ Other arguments against EBM range from characterizing EBM exclusively as a means to cut costs¹⁷ to portraying EBM as an “ivory-tower” concept only feasible in academic institutions.⁴⁵ Guidelines that are incorporated into structured health policy may also carry the stigma of inflexibility, even though this is untrue if EBM is properly implemented.

On the other side of the debate, we find advocates of EBM who believe evidence-based protocols will overcome the many deficiencies of American health care including the soaring costs and inefficiencies.¹⁰ The most cautious proponents have acknowledged the shortcomings of EBM raised by the critics and have countered by encouraging a prudent use of guidelines and standards. According to this group of physicians, EBM incorporates making decisions about treatment plans while keeping in mind both the benefits and harms within the context of a patient’s priorities.⁴⁹ Finding the most favorable balance includes searching the evidence and discussing possible benefits and drawbacks with respect to a variety of outcomes.⁴⁹ By supporting better outcomes as defined by the patient, there would be a subsequent increase in efficiency and would permit practitioners to allocate more resources toward the most effective treatments.^{9,10} Additionally, EBM promises to create better-informed patients and clinicians by offering jointly agreed-upon and publicly available information about treatment options.^{9, 10,23,29} Proponents argue that guidelines

would empower physicians to oversee and manage medical decisions to counter the forces of managed care organizations. Because EBM provides evidence and objective guidelines, physicians could practice medicine with their patients' best interests in mind rather than depending on the approval of insurers and policymakers.¹⁰

In an effort to jumpstart evidence-based practice, innovative formats have recently been developed to enable clinicians to describe evidence to each other and to individual patients. National organizations such as the Agency for Healthcare Research and Quality (AHRQ), field-specific organizations such as the American College of Surgeons (ACS), and specialty-specific organizations such as the American Society of Plastic Surgeons (ASPS), have published data to help communicate up-to-date evidence and guidelines to physicians. Until strict guidelines are made explicit and enacted into policy, these organizations can provide useful information and advice for clinicians.

What will EBM mean to physicians in the near-future?

A push for quality metrics and evidence-based practice will have a significant impact on physician reimbursement and patient care. Policy makers and managed care organizations will begin to rely on the sound science that EBM publicly provides to create national policies such as pay-for-performance. It is crucial for physicians to pay attention to the changes taking place not only in the clinic, but also in politics where the future of health care in the United States will be decided. Perhaps these policy implications are the most overlooked consequences of EBM.

Currently, medical decision making is heavily physician-centric. While health information is freely available to the public, patients rarely gain access to information about treatment options and physician performance. Similarly, payers including managed care organizations and the government, have relatively little information and rely largely on physicians to exercise their best judgment.⁸ In the same vein, there is little in the way of measuring success and assessing treatment quality outside professional self-regulation.⁸ However, EBM will distance physicians from this familiar territory. For example, implementing EBM will allow medical information to be placed into the public arena without the involvement of physicians.⁵⁰ This so-called "evidence-based consumer health information" will result in stripping away physicians' exclusive knowledge of evidence.

Evidence-based guidelines have become highly credible sources of information about what forms of care are effective. These guidelines typically carry the endorsement of expert groups such as the Agency for Healthcare Research and Quality (AHRQ) and the U.S. Preventative Task Force, who have established clear guidelines that are readily adopted as measures for quality of care.⁵¹ Whether the measures used are actually valid indicators of health care quality is up for debate. Additionally, evidence may be a means for institutional control and policy disputes. For example, evidence-based guidelines have served as the basis for initiatives to guarantee certain standards of care. These quality assurance initiatives encourage adherence to evidence-based guidelines for the management of particular diseases and ensure that such adherence is monitored.⁴⁹ These initiatives collect and distribute evidence having to do with a particular condition and provide guidelines for treating patients

with the condition. As it stands, medical decision-making can be established on the grounds of education, experience and insight. However, if EBM gets established at the policy-level, health care managers and patients will likely demand that physicians justify their decisions with evidence. Managed care organizations may find these guidelines helpful in assessing physician performance and quality of care and could possibly gain considerable authority in making medical decisions.⁸

On one hand, EBM has the potential to find newer, more effective treatments for patients. On the other hand, there is concern that EBM may be used as a rationale to deny expensive new procedures and curtail the development of innovative advancements. This contradiction arises because evidence for a procedure is primarily validated by large, time-consuming studies such as RCTs. In the meantime, insurance companies in the US may deny reimbursement for these procedures because even a temporary lack of evidence, to them, is an indication of inefficiency or ineffectiveness. In Germany, for example, reimbursement for cancer care is partly denied because the number of treated patients for a novel therapeutic procedure is too small to reach the standard of Level I evidence, creating a hurdle for the establishment of new helpful technologies.⁵²

Additionally, new treatments and procedures may be at odds with prevailing standards of care. To deal with the medical community's resistance to change, managed care organizations have baited physicians with financial incentives. One of the most effective levers for altering physician behavior is through changes in payment policies.⁵³ Evidence-based guidelines carry the credibility that comes from the impartiality of scientific research, making them attractive as foundations for performance incentives. The most recent data show that health care organizations have already begun to pay physicians for meeting quality standards.^{53,54} In addition, the Medicare Payment Advisory Commission agreed "to recommend Congress enact a pay-for-performance for hospitals and physicians" thus kicking off the first of many payer-induced financial encouragements for complying with evidence-based guidelines.²³ It is believed that this will promptly include bonus pay for providing higher-quality care, however that may be defined.²³

In 2004, the Johns Hopkins-American Healthways Physicians Meeting and Outcomes Summit convened to "bring together physicians and medical managers and provide a consensus statement on how outcomes-based compensation arrangements should be developed in order to align health care toward evidence-based medicine, affordability and public accountability for how resources are used."⁵³ Here, physicians defined the form of compensation referred to as "pay-for-performance" as "the use of incentives to encourage and reinforce the delivery of evidence-based practices and health care system transformation that promote better outcomes as efficiently as possible."⁵³ They reported that while currently 1% to 2% of physicians receive compensation in pay-for-performance programs, the number of physicians and total sum of money implicated in pay-for-performance programs in the near-future will be considerable.^{53,54}

Pay-for-performance is being presently being investigated in several situations. For example, the Centers for Medicare & Medicaid Services (CMS), the federal agency managing Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP),

has issued “report cards” on hospitals to determine the extent of adherence to evidence-based guidelines. The CMS also recently started to catalog quality information reported by thousands of hospitals that is easily available to the public. This data will be used to monitor outcomes of physicians from all specialties and will eventually be condensed into a “report-card” of individual physicians, partially based on compliance with evidence-based guidelines.²³

While EBM has many anticipated benefits, physicians should approach this trend with a sense of guarded optimism. Many experts have warned that not only are “unintended consequences” to be expected, but that there is currently no means of spreading accountability among policy makers.^{55–57} Also, some have described pay-for-performance and the policy-making approach “an unproven and potentially risky intervention”⁵⁵ and a form of “social experimentation”^{58,59} because it increases physician accountability. This is complicated by the fact that accountability is already difficult to define in clinical situations where patients may be treated by many physicians. Some worry that policy changes in healthcare may be espoused based on funding circumstances or political sentiment rather than evidence of benefit or harm. Additionally, pay-for-performance has been called into question; according to Fisher, it could diminish patient trust and physician professionalism, and reduce access for at-risk populations.⁵⁷ In other words, if physicians’ salaries are tied to their performance, they could decide that it would be more profitable to neglect the sickest patients thereby bankrupting providers serving the disadvantaged. If the medical community is not conscious of the political entanglements that will certainly accompany EBM-based legislation, the health care system could suffer greatly. As guidelines become the criterion for practice, it will be important to be able to challenge the power and oversight that will be handed over to managed care organizations and policy makers.

Summary

There are some very critical issues that must be addressed with regards to EBM’s proper implementation in the wards. Issues such as “medical necessity” will soon be debated among policy-makers and lawyers and interest groups who may have no significant, lasting interest in patients but rather to questionable principles and economic-rationales. As pointed out by Arnold Rosoff, JD at the Wharton School of Business, “Evidence-based medicine is often used to create clinical paths, or practice guidelines. But the courts have yet to figure out what to do with these guidelines - and if the courts are unsure or confused, the benefits may be compromised.”⁶⁰ In the face of rising accountability, physicians must be ready to define quality-standards and to formulate agreeable policies regarding what constitutes evidence. These definitions must clearly outline and support medical-decision making when physicians are brought to the courtroom. As the dialogue surrounding EBM continues, it is important for the medical community to take a proactive role in dictating its terms.

EBM is the platform from which evidence is consolidated into medical management. However, while society has largely found comfort with professing evidence as truth, for individual patients it can be far from the truth. Well-trained physicians can oftentimes be misled into believing that studies are the be-all and end-all of medicine. But while studies can confer a central logic that can help steer clinicians in many situations, evidence must be

treated as just that – a pool of observations weighted toward levels of confidence. Clearly, no randomized clinical trial or evidence-based guideline can fully dictate a surgeon's move in the OR. Evidence-based guidelines have their limitations and must be interpreted on a case-by-case basis when dealing with patients. As it stands, guidelines based on evidence are finding their way into health policy. As this process evolves, the medical community must act in its self-interest to make light of the possible oversimplifications of enacting evidence-based generalizations into law. Medicine is far from an exact science. It is a blend of technical proficiency, intuition, and human interaction. It is important to acknowledge that evidence-based medicine, along with the broad changes that will follow imminent reforms in healthcare legislation, while relevant, can in no significant way change these core values.

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Level Ia
Evidence obtained from meta-analysis of randomized controlled trials
Level Ib
Evidence obtained from at least one randomized controlled trial
Level IIa
Evidence obtained from at least one well-designed controlled study without randomization
Level IIb
Evidence obtained from at least one other type of well-designed quasi-experimental study
Level III
Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
Level IV
Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

Figure 1. National Guideline Clearinghouse Stratification of Evidence. The rating schemes for the strength of clinical evidence compiled by the National Guideline Clearinghouse.

Figure 2.

CONSORT flow chart. The flow chart shows the passage of patients through a randomized clinical trial. The image presents information from four stages of a trial (enrollment, allocation, follow-up, and analysis).

Source: <http://www.consort-statement.org/index.aspx?o=1077>