

# Evidence-Based Medicine

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## I. Introduction

Due to an ongoing awareness of the weaknesses in medical decision making as far back as the 1960s the concept of “evidence-based medicine” (EBM) evolved. Many definitions have appeared over time and the description continues to develop through the discourse of those considered expert in this matter. Conceptually established around 1990 (Eddy, Guyatt), EBM has central roles both in global healthcare policy development and the care of an individual patient. Presently, EBM applications are used to guide clinical practice directly and structure the education of healthcare providers. (1,2,3,12)

In 1996, Sackett and colleagues defined EBM as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” (3) Included was the assessment of the strength of evidence related to risks and benefits of treatment or no treatment. Its goal was to create a more systematic approach to patient care by utilizing evidence from well designed and conducted research. (3,10,12) Some editorialists in healthcare, extended the definition to exclude any intervention not scrutinized scientifically.

Since its theoretical establishment, EBM has been both celebrated and demonized. The reality is that there is no “perfect world” and as is often the case, the ideal probably lies somewhere in between the extremes. One’s ability to thoroughly analyze and balance sources of information in order to weight the evidence provided is of the utmost importance. A significant outstanding question remains. Has EBM been made into a comprehensive, useable and reliable method for the clinician in the trenches?

Many issues complicate our goal of a “black and white” system to determine the efficacy and safety of interventions in health care. The “art of medicine” and clinical judgment, once central to practice, are not specifically weighted although clinical expertise is assumed. Consumer choice, cultural and historical perspectives, ethical use, resource availability, research quality and intellectual disagreement are all factors in the selection of treatment approaches in the primary care arena. The challenge of how best to consider these factors with EBM remains significant. Despite ongoing criticism from some respected authorities in healthcare, EBM has survived the test of time and additional refinements could further solidify its position as the “gold standard” for determining quality patient care. Further discussion needs to be undertaken as to the best way to consider interventions not specifically tested scientifically.

## II. Traditional Evidence-Based Medicine (aka Evidence-Based Clinical Practice)

A far cry from the verbal passing of strategies to improve individual health status seen for centuries in some cultures, EBM as defined, seeks to develop a near-exclusive dependence on the scientific method to determine appropriate medical decision making. (1,2) The concepts of faith, cultural tradition, anecdotal patient experience, clinician beliefs and intuition were to have no role. Angell and Kassirer and other outspoken critics of non-scientific ways of knowing, held firm against the existence of two categories of medicine: conventional and alternative. (7) Across “the pond”, EBM was satirized in the classic article, “Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomized controlled trials”. (11) Back on our home turf, skepticism blossomed. David M. Eisenberg, M.D., a Harvard affiliated physician who became the director of the Center for Alternative Medicine Research and Education at Beth Israel Deaconess Medical Center would attempt to both “structure scientific research involving complementary and integrative medicine therapies according to traditional investigative and evaluative techniques, including controlled clinical trials” as well as to “develop criteria in order to responsibly recommend the use or avoidance of herb/supplements and other complementary therapies”. (8,9) The latter served to be a significant breach to the hard line “no exceptions” viewpoint.

Although historically medicine has always sought some empiric support for interventions, EBM formally classifies the strength of the evidence giving higher rank to information obtained from meta-analyses, systematic reviews and randomized controlled studies. Allowance is made for weaker evidence as in case-control studies.

A five step EBM model for clinicians has been widely supported. The first step is to identify information needs and develop answerable questions. Next, the knowledge gap described is addressed by collecting the best relevant evidence available. The accumulated data is critically appraised for its validity and usefulness in the third step. Some variability is found in scales for grading the strength of evidence for this step but a five level system is often used. The highest level of evidence available is attached to carefully designed, conducted and interpreted clinical trials. Randomized, controlled trials are the ideal but often not done. Lower quality (level 4 or 5) evidence is seen with limited studies, case reports, expert opinion, consensus statements, and usual practice. EBM can exist in the presence of low quality evidence however support for the conclusions drawn is considered weak. In the fourth step results of the analysis in step 3 are applied in practice. Lastly, in step five a performance evaluation is completed. (6)

It is quite apparent that this model for EBM poses many challenges for the clinician in a busy primary care practice. The multitude of clinical questions faced in even one day could not be addressed in this manner. Additionally, many questions lack applicable research. Other controversies surrounding EBM's usefulness in determining the care of an individual patient described by Greenhalgh and colleagues include: statistically significant results may turn out to be marginally beneficial in clinical practice, shared decision making is understated, quality differences in novice versus expert clinicians are not addressed, and individualization of care

is not sufficiently considered. (4)

Use of EBM in the development of clinical care guidelines has become commonplace. Expert panel consensus is often combined with the EBM model to develop algorithms to guide practice. The guidelines developed can only appropriately be applied to patient groups whose clinical profile (demographics, comorbidities, etc.) is consistent with those in the group studied. Issues arising with clinical guidelines are numerous. The research agenda is largely produced from big business (pharmaceutical and medical device companies) creating an imbalance in clinical need versus vested interests. Managing the volume and necessary revisions to guidelines as new information becomes available is problematic. Often the guideline does not reflect the most current research. Additionally, the usefulness of guidelines for single conditions in a society overwhelmed with patients with multimorbidities seems simplistic. (4)

Important enhancements to the current EBM model should include attention to; ethically based patient-centered care individualized using available contributions from science, competent clinical judgment and a meaningful clinician-patient relationship. Shared decision making based on consideration of all factors pertinent to the individual patient.

### **III. Evidence-Informed Practice**

There are many therapeutic modalities utilized by healthcare practitioners and sought out by healthcare consumers that are not supported by scientific study enough to be considered in the EBM model. “Complementary and Alternative Medicine” (CAM), as it is often labeled, includes practices that support health but lack scientific validation. The term “evidence-informed practice” (EIP) suggests that the paucity of available research is insufficient to base practice on but can only inform about the intervention. Are the tenets of “do no harm” and “buyer beware” sufficient to support these non-traditional interventions? Traditional Chinese Medicine, Ayurvedic Medicine, and acupuncture are supported by centuries of use within their cultures. Support for the safety and efficacy of these methods when delivered by competent clinicians can be argued given the widespread use over time without evidence of any more harm than occurs with traditionally studied therapies (i.e. adverse reactions to pharmaceuticals, undesired outcomes with invasive treatments). Other more recently (last 100 years) widely used alternative therapies include homeopathy, naturopathy, and chiropractic and “energy medicine” share both minimal level 1 evidence support and lack of significant reported evidence of harm. A number of hospitals in New Hampshire allow practitioners of Reiki, a form of energy medicine, to perform treatments on requesting patients in the institution prior to surgeries and post-operatively. Hospice teams have likewise found Reiki treatments helpful in the global care of cancer patients. It will likely be a long time before these interventions will undergo formal scientific scrutiny. Are hospital administrations irresponsible in allowing such interventions to be administered in their institutions? This is only one of the hundreds of questions that face front line clinicians daily.(8,9)

#### IV. Chronic Inflammatory Response Syndrome as described by Dr. Ritchie Shoemaker

Based on the discussion above, it is clear that the extensive scientific work completed by Dr. Shoemaker provides solid evidence for all steps in the CIRS treatment protocol. All levels of evidentiary support have been utilized from double-blinded placebo controlled studies to case reports. All steps in the treatment protocol are based on the best the EBM model has to offer.

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