

Evidence Based Medicine and How it Applies to the Treatment of Chronic Inflammatory Response Syndrome (CIRS)

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What is Evidence-based medicine?

Evidence-based medicine (EBM) is the seamless integration of scientific and clinical research, a physician's clinical expertise and judgment, and the patient's values in treatments. EBM was introduced to the medical field by Sackett in the 1970's as a way to advise clinicians on how to use the most up to date research to guide clinical decision making.^{1,2} By 1996, Sackett defined EBM as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."^{1,2}

It is important to note that scientific and clinical research, though extremely valuable in the EBM process, is weighted equally with a physician's clinical judgment and individual patient preference.

How is it used in practice?

Evaluating the implementation and efficacy of medical interventions in EBM is as follows:^{1,2,3}

1. Converting patient information and symptoms into focused clinical questions.
2. Finding the relevant scientific and clinical research
3. Critically evaluating the validity and clinical usefulness of the research
4. Judiciously applying the findings in clinical practice
5. Critical evaluation of performance of the evidence in clinical practice

The Benefits of EBM

EBM enables clinicians to apply the most current research and treatment options to their practice. Historically, research has taken 10 years to get from bench to bedside.^{4,5} Today, however, all research is available electronically upon its publication. Furthermore, there are a number of resources that provide physicians with systematic reviews and meta-analyses that compile large amounts of the latest research into synthesized summaries. These summaries allow physicians easy access to a plethora of information that should be part of their decision making process when treating patients.

What are some challenges with EBM?

As stated before, one of the drawbacks in evidence-based medicine is an over-reliance on scientific data to guide clinical decision-making. This over-reliance often comes at the expense of a patient's own beliefs on treatment and the judgment of the clinician. The main problem with basing treatment solely on scientific data is that research itself can often be flawed, misinterpreted, and be driven by author bias and the conflicts of interest present in a significant portion of clinical based research. These factors will be explored in more depth below.

The sheer volume of currently available research is a major barrier to implementing EBM in clinical practice. To exhaustively examine the available current research, a physician

would have to read between 17-22 journal articles daily to stay up to date on all the research available in their specific field.^{5,6,7} Given the fact that the average physician is able to spend less than one hour per week reading the most recent literature,^{5,6,7} this makes it almost impossible to stay completely up to date.

Another drawback of EBM is that many view the randomized controlled trial (RCT) as the gold standard of reviewing the efficacy of a given treatment. Despite the fact that it has been found that as much as 25% of the RCT research has turned out to be incorrect.⁸

Quality and difficulty in interpretation of the scientific research represents yet another and significant drawback of EBM. Two prime examples of flawed interpretation of scientific research can be found in the American College of Occupational and Environmental Medicine (ACOEM) 2002 Guidelines and the American Academy of Asthma, Allergy, and Immunology (AAAAI) 2006 Guidelines, which both reported that mold and mycotoxins cannot cause human illness.⁹ These conclusions were based on opinion papers, flawed research, and animal research that cannot be extrapolated to humans. Furthermore, it was found that there was bias and multiple conflicts of interest with the authors of the ACOEM guidelines.⁹ Another example of inappropriate interpretation of scientific research and/or blatant disregard for current research can be found in the Infectious Disease Society of America (IDSA) Lyme Guidelines.^{10,11} It was found that only 16% of the IDSA guidelines are supported by quality up to date research.¹¹ The International Lyme and Associated Disease Society (ILADS) currently references over 800 peer-reviewed publications to support their guidelines and dispute the current IDSA Guidelines.¹¹ It should be noted that it is not uncommon for expert panels to have discrepancies in the interpretation of the current body of scientific research.

How can EBM be applied to treating CIRS?

The current body of literature regarding Chronic Inflammatory Response Syndrome (CIRS) is quite vast for the small window of time in which research has been conducted. Dr. Ritchie Shoemaker is oft considered the leader in clinical research on CIRS. He has published many books and scientific research articles in various peer-reviewed journals that chronicle his use of EBM in practice. In regards to the diagnosis and treatment of CIRS, Dr. Shoemaker's approach uses an individualized, patient-centered evidence based medicine model in which the needs of the patient are the forefront of his treatment.

Dr. Shoemaker has collected and analyzed data from patients who have become ill after exposure to biotoxins. His work has resulted in a standardized diagnosis model of CIRS. In this model, known exposure to at least one biotoxin, multiple symptoms in multiple body systems, and abnormal lab tests including at least six of the following: HLA DR DQ, C3a, C4a, MMP-9, ADH, osmolality, MSH, VEGF, TGFB-1, VIP, VCS, MARCoNS Nasal Culture, and NeuroQuant MRI are required for the clinical diagnosis of CIRS. He then has used this baseline data to analyze and rate various treatment protocols which has culminated into the development of the Shoemaker Protocol, which has been scientifically proven to restore abnormal lab values and symptoms to pre-exposure values.¹¹ Furthermore, he and other CIRS practitioners continue to collect and analyze data from patients to improve the current protocol and ensure that the most up to date therapeutic options are available to

aid in the restoration of patient health. For instance, Dr. Shoemaker added the use of Vasoactive Intestinal Polypeptide (VIP) Nasal Spray as the final step in the most recent protocol. VIP has been fundamental in providing a therapeutic agent that could restore lab makers to normal levels. Prior to the use of VIP Spray, some individuals were not able to have complete resolution of symptoms and restoration of normal lab values.¹¹

Dr. Shoemaker is constantly striving to push his research to the next level for the benefit of his patients as well as to expand the knowledge base of biotoxin illness in the context of CIRS. Dr. Shoemaker's research and application in clinical practice embodies the initial premise of evidence-based medicine, "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."^{1,2} Furthermore, his individualized EBM approach follows the five step process outlined by Sackett in his definition of EBM. This is the premise that all medical practitioners should keep in mind to achieve successful patient centered medicine that combines the most up to date research, the physician's clinical experience, and the patient's wishes in regards to treatment.

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