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Wellness enABELLed

Evidence-Based Medicine

The term evidence-based medicine was first used in 1990 by GH Guyatt McMasters University internal medicine residency coordinator. He initially called this "scientific medicine". It was built on the groundwork laid by his mentor, Dr. David Sackett, using a critical appraisal technique applicable at the bedside. The response from his fellow staff was not warm and inviting. Dr. Guyatte then returned with a new title called "evidence-based medicine".

A broader description of evidence-based medicine appeared in 1992 with the publishing of the evidence-based working group in JAMA. (1) This article states A new Paradigm for medical practice is emerging. Evidence-based medicine deemphasizes intuition, on systemic clinical experience, and pathophysiologic rationale as sufficient ground for clinical decision making and stresses the examination of evidence from clinical research. It was stressed that "evidence-based medicine requires new skills of the physician including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature."

This was further defined by Dr. David Sackett, et al in 1996.

"The conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients." (2)

It is based on the premise that the guidelines for the most effective clinical treatment of any condition should be based on the best scientific research possible instead of relying only on clinical judgment and experience.

There are 3 evidence-based medicine principles that are used to make decisions about care of patients.

1. Evaluation of valid current research
2. Incorporating patient values and expectations into decision-making
3. Evaluating likely treatment benefits versus risk.

There are different hierarchies of evidence as a core principle of evidence-based medicine. Please see diagram below. Obtained from Icahn School of Medicine at Mount Sinai. (3)

Level 1 evidence comes from randomized, double-blind, placebo-controlled trials and/or meta-analyses that combined at the evidence from these trials.

Level 2 evidence comes from controlled trials without randomization, prospective cohort or retrospective case-controlled studies in multiple times series studies.

Level 3 evidence comes from expert opinion and case studies

Level 4 evidence comes from personal experience.

The first decision point recommended in this process is the PICO framework:

Patient and problem: The patient is a member of a population as well as a person with or at risk for a health problem. In addition to age and sex, you may have to consider as well other variables such as ethnicity, socioeconomic status or other demographic variables when you look for and evaluate the evidence.

Intervention or exposure: Evidence-based medicine seeks to compare interventions in the framework of an individual's preferences and resources to identify the best choices.

Comparing proposed interventions to other strategies, using the research as a guide.

Outcome: Assess whether this approach is helping and assisting the patient achieve his or her anticipated and expected health goals.

As noted in the upper outer circle on the left, one of the principal components of evidence-based medicine is individual clinical expertise. I do believe that we need to follow the findings of the higher-level studies as much as we can. However, as physicians, we must rely on basic science as well as our clinical expertise including outcomes of patients that we had treated through the years. I remember, in 2005, asking an endocrinologist who was rounding with a drug representative how he would predict one of my patients was doing. I shared his creatinine level from 1995 of 2.5, urine protein of 5000 mg per 24 hours, background of hypertension and long-standing type 1 diabetes already with ophthalmic complications in 1995. The doctor looked at the numbers, stated that he was either on dialysis or dead. My answer was, actually, the patient is a retired executive playing golf with a creatinine of 1.5, 10 years later with minimal proteinuria. Had I followed strictly evidence-based medicine without researching the science as well as applying this knowledge without random placebo-controlled studies, the endocrinologist would have been right.

Insurance companies also pay attention to evidence-based medicine in order to cut their cost. With this, they develop clinical guidelines and place these to the responsibility of the treating physician. This means the person is a diagnosis code, not an individual. In any large placebo-controlled trial, there are going to be non-responders, but in this case the "majority wins"

I do believe in evidence-based medicine is a very important part of patient care. However, evidence-based medicine is going to be practicing years behind the science. I have seen clinically that some patients do better as I watch the science directing their care.

And with respect to the published data, can we always believe that? In a review in PLOS, Ioannidis suggested that it can be proven that most claimed research findings are false. Please see the excellent review as referenced below. (4)

And then, another example, in 2009, court documents showed that ghost writer's paid by a pharmaceutical company played a major role in producing 26 scientific papers backing the use of hormone replacement therapy in women, suggesting that the level of hidden industry influence on medical literature is broader than previously known. I am purposely not mentioning the pharmaceutical company.

Publications have suggested that in recent years, a number of studies have shown that clinical drug trials financed by pharmaceutical companies yield favorable results for company products more often than independent trials do. (5)

And so, in summary, I do believe in evidence-based medicine. I remember a research cardiologist from Harvard came to give us results of a clinical trial he was doing on mice with heart failure using ACE inhibitors. At that time, the one-year mortality for a patient with an ejection fraction of 20% was about 50%. After introduction of ACE inhibitors that number went to 10%. We rapidly instituted the use of ACE inhibitors in patients with heart failure.

Evidence-based medicine is not just about the trials and the evidence. A huge component is incorporating one's clinical knowledge and experience. And, medicine needs to be individualized, not just based on what happens to the overall numbers in a 1000 patient placebo-controlled study.

Randomized placebo-controlled trials typically look at one parameter. With the multiple parameters that are abnormal over multiple systems, think about how long it would take for CIRS to be teased out in "traditional" medicine.

I have been practicing medicine for 29 years now. In medical school, we were told that 50% of everything we were taught would be proven wrong, but the problem is they did not know what 50% that was. In 2006 I read a book, *The Life Extension Revolution* by Philip Lee Miller. Having read that, I knew I needed to investigate further and went shortly afterwards to the annual American Academy of Antiaging Medicine conference. This was a whole new world to me. Everything they spoke of was documented in the literature. I eventually went on to Fellowship status with A4M, and then found the Institute for Functional Medicine. Certified in 2016. I believe my patients do better clinically utilizing this knowledge, however many of my colleagues refuse to accept any of this. That was not taught to them in medical school or residency, nor at any continuing education experience. This becomes one of the major obstacles that we come against. CIRS will take many years, if ever, I think for the general physician population to understand or accept.

And now, moving on, incorporating evidence-based medicine with Chronic Inflammatory Response Syndrome. (CIRS)

It started with Pfiesteria, as the saying goes. In 1997 CSM given for the diarrhea resulting from this toxin resolved multiple symptoms throughout multiple systems in most patients. What the heck was going on. Well, an astute physician took this information and began researching it from multiple angles. And, in a span of 20 years, we now have the Shoemaker Protocol which is backed by two randomized controlled trials showing resolution of symptoms.

Based on Dr. Shoemakers studies it is clear that the extensive scientific work completed by Dr. Shoemaker provides solid evidence for all steps in the CIRS treatment protocol.



1. **Evidence-Based Medicine** A New Approach to Teaching the Practice of Medicine
JAMA. 1992;268(17):2420-2425
2. **Evidence based medicine: what it is and what it isn't** *BMJ* 1996; 312:71
3. **Icahn School of Medicine at Mount Sinai**. Evidence-Based Medicine Guide.
4. **Ioannidis, J.P.A. (2005)** Why most published research findings are false. *PLoS Med* 2(8): e124
5. **The Financing of Drug Trials by Pharmaceutical Companies and Its Consequences** [Dtsch Arztebl Int.](#) 2010 Apr; 107(17): 295–301.

