

Evidence-Based Medicine, The Work of Dr. Shoemaker, and Me by Ming Dooley May 29, 2017

In recent years, evidence-based medicine has become the buzz-word of the times. But there are many flaws in evidence-based medicine's application to the practice of medicine in today's society. Randomized controlled trials have long been the "gold standard" for research, but they have limitations. It's time to move beyond this standard, and look at research methods that provide measurable documentation that they are effective. Evidence-based medicine needs to be patient-centered, looking at the values, needs, and the individuality of the patient, not based on the bottom line for those who profit from keeping people sick.

Evidence-based medicine was originally defined by David Sackett as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research"¹ Its definition has been updated to: "Evidence Based Practice (EBP) is the integration of clinical expertise, patient values, and the best research evidence into the decision making process for patient care. Clinical expertise refers to the clinician's cumulated experience, education and clinical skills. The patient brings to the encounter his or her own personal preferences and unique concerns, expectations, and values. The best research evidence is usually found in clinically relevant research that has been conducted using sound methodology."² I think few would disagree that this is a maxim to uphold. Nevertheless, in practicality, what really happens?

One of my first experiences with evidence-based medicine and relevant research using sound research methods was in 1992, in acupuncture college. What is now the National Institute of Health Office of Complementary and Integrative Medicine, but was then the Institute of Alternative Medicine, offered thirty \$30,000 exploratory grants for research in Alternative Medicine. With no background in research and no experience, I successfully wrote and received one of these pilot studies for a single blind randomized controlled study comparing acupuncture, moxibustion and Chinese herbs with placebo acupuncture, moxibustion and herbs in PMS.

In writing the grant, I came head to head with the difficulties of fitting acupuncture into a single blind randomized controlled study model. And placebo acupuncture? Had studies been done that could assess the impact of non-acupuncture points? No. The study was designed to be carried out in the student clinic. What about the impact of different practitioners on the treatment? What about those practitioners in the student clinic who didn't like the study and doing placebo acupuncture? What if the practitioners told the patients?

It was a 3 month study and involved biweekly treatments and completion of follow-up questionnaires. I was never able to enroll enough participants, and few who enrolled completed the treatment protocol. With no more funding, and the reporting period for the study running out, my study was never completed. But I learned a lot; many beneficial treatments do not lend themselves to the accepted randomized control trial "gold standard" of research methodologies.

In the essay "What is Evidence-Based Medicine" by Dr. Sandeep Gupta³ examines the different forms of bias which can confound randomized controlled trials; I think it is especially relevant when we consider how much pressure there is to practice evidence-based medicine and to base the practice of medicine on what has been "proven" with randomized control trials (RCTs). Dr. Gupta refers to inclusion bias, publication bias and reporting bias.

Inclusion bias refers to the fact that pharmaceutical companies are much more likely to be able afford the expense of RCTs for their patented medicines than non-patented medicines such as nutrients, and lifestyle changes such as exercise and healthy living. Non patented medicine have much lower profitability and many lifestyle changes have no profitability. In fact, there are many who profit from keeping people sick.

Publication bias has to do with what is and what isn't accepted for publication in journals. A study by Dickerson et al⁴ reports that trials with a positive result were three times as likely to be published as studies with a negative result. Sometimes in cases where there is concern about interest or significance of findings, investigators may not submit results for publishing.

Reporting bias, which may be partly related to disclosed or non-disclosed conflict of interest, reflects the tendency to under-report unexpected or undesirable experimental results. A direct correlation between industry funding of trials and a positive outcome of trials was suggested in two highly significant papers by Bekelman et al⁵ and Bhandari et al.⁶ So, if the sponsor had a financial interest in a product or intervention, there was a trend for the findings to be positive. In other words, there was a trend for studies regarding interventions in which the sponsor of the trial had a financial interest in the product or intervention being studied, tending to be positive. Furthermore, these conflicts of interest were not always disclosed. According to a 2011 study, out of 509 randomized controlled trials studied, 219 were industry funded and only 113 of these reported conflict of interest disclosures. Furthermore, these disclosures were rarely discussed in meta-analyses which included their data⁷.

So, while randomized controlled trials have their place, they also have their limitations. Furthermore, who really controls the practice of medicine in this country? Keith Berndtson, in his essay Evidence Based Medicine - The Promise and the Pitfalls, quotes from the writings of Dr. Dr. Brook, Professor of Health Services and Medicine at UCLA's School of Public Health and a member of the Institute of Medicine about the changes in the practice of medicine from the 70s to the present. These writings discuss that in the 70s, health insurance covered any service a physician and patient agreed to without prior authorization or evidence of whether or not it was effective. Now, the Affordable Care Act requires an essential benefit package be defined and brings to light that it is not defined by patients and physicians, but by the powerful special interests who seek to continue to profit.⁸

In truth, although the players have changed, the fundamental principles behind the politics of medicine have not. If we go back in time, in the 1800s Samuel Hahnemann developed the science and practice of homeopathic medicine. He meticulously "proved" all his remedies according to strict guidelines and it was only when they were shown to be effective in clinical practice for the symptoms found in the proving were they included in the materia medica.⁹ If this couldn't be considered evidence-based medicine, what could? Homeopathy was safe and the remedies were inexpensive. Nobody profited from their sale. At the turn of the century there were 22 homeopathic medical colleges in the United States and graduates from traditional medical colleges flunked the medical boards twice as frequently those from homeopathic colleges. It was only through the machinations of George Simmons and Samuel Fishbein, the American Medical Association (AMA) and the Flexner report that allopathy took over.

George Simmons and Samuel Fishbein dictatorially lead the AMA for the first half of the 20th century. At the time when George Simmons took over, the AMA was a weak organization with little money and little respect from the general public. However, he transformed into a big business by granting the AMA "Seal of Approval" to certain drug companies that placed large and frequent ads in it's journal and affiliate publications.

By divulging the constituents of their drug and it's beneficial use in addition to advertising in every local, regional and national AMA publication, drugs were given the AMA "Seal-of-Approval". There was no testing done by the AMA and no requirements for any

evidence of safety. Consequently, from 1899 to 1909 the AMA's advertising revenues grew from \$34,000 to \$150,000 and membership increased 8000 to more than 70,000 from 1900 to 1910. The AMA, with its financial power, established its own guidelines for giving homeopathic medical colleges lower gradings than allopathic medical colleges. In conjunction with the 1910 Flexner report funded in part by John Rockefeller and Andrew Carnegie, which attempted to align medical education under a set of norms that emphasized laboratory research and the patenting of medicine, it was the beginning of the end for homeopathic medicine.¹⁰

Nevertheless, according to W.A. Dewey, M.D., in the 1918 flu epidemic prior to the advent of antibiotics, Dean W.A. Pearson of Philadelphia collected 26,792 cases of influenza treated by homeopathic physicians with a mortality rate of 1.05%, while the average old-school mortality rate was 30%.¹¹ Once again, how can we ignore this evidence, even if it is not in the form of a randomized controlled double blind study?

To bring it down to the personal level, there is evidence from my own experience. I have worked with my husband, a homeopathic physician, for over 25 years. Many of his patients came to him because they do not want to take allopathic medicine with side effects or they want to get off the allopathic medicines. And certainly his success rates are comparable to others. When I started my acupuncture practice 2 years ago, I started with some of his patients with chronic conditions that hadn't improved. While they felt better with my treatments, they were still suffering. So I started looking for something more. In the course of treating a patient involved in a mold lawsuit, I started looking into Dr. Shoemaker's Surviving Mold protocol.

In Dr. Shoemaker's work, I found the answers I was looking for. Dr. Shoemaker takes a disciplined approach to collecting and analyzing patient outcomes data. He has clearly defined guidelines for diagnosis and treatment. This is a true evidence-based approach through rigorous data collection. His findings have been published in peer reviewed journals, and his results have been being replicated by other physicians.

Coming from a different perspective, it was his rigorous data collection and documentation of his methodologies that convinced me to integrate a treatment that used primarily allopathic medicine into my practice and my personal life. Following my discovery I started testing my patients who weren't improving, and found that all of them had the genetic susceptibility; and so, like many others, began my path to certification.

A study in 2000, published by Benson and Hartz, in the *New England Journal of Medicine*, concluded that there was "little evidence that estimates of treatment effects in observational studies reported after 1984 are either consistently larger than or qualitatively different from those obtained in randomized, controlled trials."¹² I think true evidence-based medicine lies in practice-based research like Dr. Shoemaker's, centered on patient's values and the clinicians who treat them, not based on decisions made by health insurance executives, lobbyists, policy wonks, and politicians who never see the patients they make decisions about.

¹Sackett, D. L., Rosenberg, W. M., Gray, J. A., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't. *Bmj*, 312(7023), 71-72. doi:10.1136/bmj.312.7023.71

²Sackett, D. L. (2002) *Evidence-based Medicine: How to Practise and Teach EBM*, 2nd edn. London: Churchill Livingstone.

³Gupta, S. (2015). What is Evidence Based Medicine? Retrieved May 29, 2017, from www.survivingmold.com/EVIDENCE-BASED_MEDICINE_ESSAY_V0.4.PDF

⁴ Dickersin, K.; Chan, S.; Chalmers, T. C.; et al. (1987). "Publication bias and clinical trials". *Controlled Clinical Trials*. 8 (4): 343-353

⁵ Bekelman JE, Li Y, Gross CP (2003) "Scope and impact of financial conflicts of interest in biomedical research: A systematic review." JAMA 289: 454–465

⁶Bhandari M, Busse JW, Jackowski D, Montori VM, Schünemann H, Sprague S, et al (2004)

⁷Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials." CMAJ 170(4):477-80

⁸K., Berndtson. (n.d.). Evidence Based Medicine - The Promise and the Pitfalls . Retrieved May 29, 2017, from http://www.survivingmold.com/docs/Berndtson_essay_1_EVIDENCE-BASED_MEDICINE.pdf

⁹ Dooley, T. R. (2002). Homeopathy: beyond flat earth medicine: an introduction for students and patients. San Diego, CA: Timing Publications.

¹⁰Ullman, D. (2014, November 10). How the AMA Got Rich and Powerful. Retrieved May 30, 2017, from http://www.huffingtonpost.com/dana-ullman/how-the-ama-got-rich-powe_b_6103720.html

¹¹ Dewey, W.A. (1921) "Homeopathy in Influenza- A Chorus of Fifty in Harmony". Journal of the American Institute of Homeopathy, (5):1028-1043

¹² Benson K, Hartz AJ (2000). "A comparison of observational studies and randomized, controlled trials." NEJM 342(25):1878-86.