

What is Evidence-Based Medicine Truly

AND WHY YOU SHOULD CARE

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Let's Get Personal

As a narrative therapist, I choose to traffic in stories. To illustrate what Evidence Based Medicine (EBM) is— and maybe even more importantly what it is not— I offer a personal tale. In my mid 30s, I developed pain in my lower foot. It began with a sharp pain experienced one evening after work. I shifted my foot to the right, a move I'd made a thousand times, but this time it was swiftly followed by an unforgettable feeling akin to an electric shock. The shock subsided shortly but the underside of my foot stayed exquisitely tender. The only notable issue on that night prior to my injury was tightness in my calves which I attributed to working several back-to-back 12-hour shifts. The pain in my foot worsened to the point I could not stand at end of day to cook my dinner, so I used a scooter to maneuver around my kitchen as the sun went down. Upon waking, the pain would be improved but by evening it would be back with a vengeance. I saw podiatrists, physical therapists, and orthopedists seeking answers. They could offer nothing substantial. The MRI looks normal they would say and shrug. I was offered many misdiagnoses. After a long wait, I arrived at an esteemed foot surgeon's office with high hopes. When I told him I could no longer stand to work due to the pain, he balked. I was a former marathon runner and knew I could put up with a little pain, but this— whatever it was— was a different animal altogether. I pleaded that even non-weight bearing activity was painful. I was then told I must have "pulled a muscle in my foot" and that swimming should *not* be painful. Deflated, I didn't counter. I wish now I could walk back into the office with the misbelieved woman that I was and say, "But swimming *IS* painful! Maybe you've got the wrong diagnosis." Instead, I limped home and waited on my foot to heal as he said it would. Numbness eventually encompassed my last two toes, and I soon lost the ability to move them entirely.

I would later confirm what I'd long knew- there was in fact something very wrong. Nerve conduction studies showed that my left lateral plantar nerve was entirely entrapped as if by a Chinese finger trap. However, this rarer than rare nerve entrapment laid outside of the playbook of modern medicine's common carpal and tarsal tunnel, and therefore no one with whom I consulted could accurately diagnose the condition much less operate. As a nurse, I understood that the plantar nerve controls movement of the fourth and fifth toes. I also knew that the complete loss of motor function I was experiencing was beyond serious. The nerve was being deprived of oxygen among other things. I was now experiencing random electrical shocks around the clock and doomed to sleeping with toilet paper threaded between my toes, because it hurt immensely when they touched one another. I rightfully feared losing the ability to walk normally. I am privileged by my education to understand how to do a thorough literature search so search I did. I tracked down an orthopedic foot specialist only a three-hour drive away. This was a man who had operated on feet for 40 plus years, trained fellows all around the world, published 27 peer-reviewed journal articles on the intricacies of the foot, and written two textbooks on the matter. One of his discoveries was so extraordinary that it revolutionized the treatment of heel pain. Subsequently, the nerve in the foot prone to entrapment causing heel pain was named after him. I hedged my bets for help on Dr. Donald Baxter.

When I was examined by Dr. Baxter, he was unusually kind. He looked me in the eyes. He told me the pain was not all in my head as had been implied by other doctors. While he studied my nerve conduction velocity and ruled out compression of lumbar vertebrae as a root

cause, he also listened intently to my story. He was hellbent on understanding the exact place I felt the electric shock so many months ago. He drilled down to the specific spot that the pain initially surged through my body, and he marked it with a Sharpie. In essence, he practiced the science *and art* of medicine.

Dr. Baxter explained to me the knowns and unknowns about my unusual nerve entrapment. This was no tarsal tunnel. This was not even a rarer Baxter's nerve entrapment. This was a zebra. He had seen similar cases... maybe only four times in his four decades in practice he confessed. He made no promises. Instead, he explained the consequence of doing nothing after an entrapment so severe that it caused a complete loss of movement for what had now been 7 days. He felt a surgical decompression was my best chance of getting out of severe pain. He was willing to do the surgery. He told me the hope of restoring movement in my toes was less likely, but the chances were not zilch.

I had found the person who I thought could best help me. "One last question," I said while sitting on the exam table feeling especially vulnerable. "You don't take my insurance. How much will this cost? Right now, I can't stand to do my job." "Pay the operating expenses for the surgery as well as the anesthesia," he said, "And I will handle the rest." I took my chances on the surgery which was completed at a quarter of the typical cost. I cried big tears of gratitude three days post-op while sitting on the toilet, when I realized I could once again move my toes.

When I was later seen at the Mayo Clinic and relayed this tale of triumph to the doctor assigned to my case, I was told that Dr. Baxter was a "cowboy" and that this was dangerous medicine that he was practicing. "He could have hurt you," the confident doctor said sternly while adjusting the lapels of his fancy suit. Was Dr. Donald Baxter truly a dangerous cowboy poised to hurt me or was he practicing Evidence-Based Medicine grounded in practice-based research while holding near the value I placed on the ability to walk?

It's Complicated

The word "science" can be used as a prop. We've seen this buzz word used repeatedly in the COVID age. Differing political factions each purport that science is on their side. What I've sadly learned is that when profit is the bottom line, "science" can be twisted to support almost any narrative. Scientific proof is a concept much more complicated and nuanced than many would like to admit. EBM operates in much the same way.

What officially is EBM anyway? Many posit that EBM is simply using the best current evidence to make decisions about patient care [1]. While this is a good start, I prefer an earlier and more nuanced definition. "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." This definition appropriately elevates clinical experience and patient preferences, lesser appreciated components of EBM. For instance, when considering my personal story, Dr. Baxter's 40 years of clinical experience and depth of research knowledge certainly played into his willingness to

perform an experimental surgery in an attempt to save my ability to ambulate. EBM would be unlikely to support a resident with little experience and a small but growing understanding of the foot if they offered to perform the surgery. In addition, I was aware that there was a risk I would endure the pain of a surgery that may produce no benefit. This was thoroughly discussed, and my preference was to take this risk. Had I feared the discomfort of a failed surgery more than the ability to walk normally, EBM would take into account my personal preferences. While we may wish that EBM could be adequately encompassed in a simple definition and tied up tightly with a pretty bow, EBM must be applied in the real world which is multifaceted and often messy.

When research is conflicting, how do we know what research to trust? During our expensive educations, we learn that EBM aims to formally classify the strength of evidence in research studies. Higher ranks are given to meta-analyses, systematic reviews, and randomized controlled trials and are associated with higher quality research, while lower ranking is given to case reports, expert opinions, and consensus statements. While this can be a helpful tool, we must be wary of those that take this hierarchy of evidence as gospel. In addition, we must always consider individuality. We mustn't forget that a highly ranked meta-analysis's statistically significant results may range in clinical practice from unbeneficial to only marginally beneficial to highly efficacious for each unique individual [2]. Next, we must acknowledge the role that businesses with deep pockets such as pharmaceutical companies play in producing current research agendas. Billion-dollar companies can fund higher ranking research, but how can we be sure it is of high quality and not compromised due to vested interests. Pharmaceutical superpowers have proven repeatedly that they will choose profit over people. This is demonstrated in the role pharmaceutical companies played in the heartbreaking opioid epidemic and the subsequent settlements paid which are now public knowledge. If Dr. Baxter was practicing "dangerous medicine" on me in an attempt to preserve my mobility, what might the doctor at Mayo Clinic term the corruption demonstrated within the pharmaceutical industry? We must dare to ask hard questions like- Is a smaller study completed by a curious and committed medicine man less valuable than much of the pharma driven dribble? Lastly, doctors and scientists that were once ridiculed and mocked- even sent to asylums- are often vindicated. What were some of these madmen purporting? William Harvey asserted that blood circulated with the help of the heart. Gregor Mendel posited that there were recessive and dominant genes. Ignaz Semmelweis's crime was circulating the idea that handwashing could decrease infection. His exoneration came a mere 28 years after his death! We must guard against letting tradition interfere with the open mind require to thoughtfully consider new knowledge in a timely manner. Change is hard, and yet we must "trust no tradition, challenge everything, prove all beliefs or discard them" [3]. Otherwise, we are not practicing EBM.

While EBM has its challenges, it shouldn't be given a bad rap. After all, true EBM pushes scientific discovery forward. EBM respects the idea that the human body is complex, and strive as we may, we may never understand it fully. Taking that idea a step further, EBM also understands that you can't find what you aren't looking for. So, how can you differentiate real scientific discovery from junk science, true EBM from disingenuous EBM masquerading as the real deal? EBM demands rigorously reviewed data that stands up to scientific scrutiny [4]. Peer review is a solid example of appropriate critique. In addition, EBM presents data that stands up to reproducibility. EBM also requires curiosity and critical thinking. In other words, true EBM is

not for the faint of heart or the physician on autopilot. EBM requires individualization. It is not blindly following an algorithm but instead considering risk versus benefit while weighing the very things a patient holds most dear. Lastly, EBM requires flexibility as a provider's practices need to be adapted quickly as new data is discovered and deemed appropriate for implementation in practice [4]. If done well, the EBM quest never ends resulting in practice that is ever evolving and therefore exciting!

Cowboys Can Use Evidence Too

Quite frankly, I am happy to have happened on an expert "cowboy" who was willing to use his knowledge to take a chance toward restoring the functioning of my feet. Cowboys can be dangerous no doubt if they employ foolishness and quackery. There is no room for this in Evidence Based Medicine. However, those who use EBM to push scientific discovery forward are cowboys of a different stripe. Change is threatening. EBM cowboys may threaten medical providers who are unwilling to destroy— as Dr. Scott McMahon calls them— their sacred cows [2]. More dangerous yet, EBM cowboys may enrage those with competing interests, especially those with high financial stakes in the game.

Enter Dr. Ritchie Shoemaker- an EBM cowboy in every sense of the word. In 1997, a doctor in a rural practice in Maryland was soon to find himself at the epicenter of a public health crisis. An algae-like dinoflagellate came from out of the dark water of the Chesapeake Bay and was wreaking havoc on both people and fish within his community. Dr. Shoemaker didn't shrug his shoulders and leave his sick patients to suffer- or worse yet- offer them an erroneous psychiatric diagnosis. Instead, he used common sense, curiosity, and Evidence Based Medicine to effectively treat the illness menacing his community. He discovered that cholestyramine not only resolved the unpleasant *pfisteria*-induced diarrhea but also seemed to resolve the chronic inflammatory innate immune response plaguing many of his patients with multiple symptoms. With one formidable discovery under his belt, he did not retire to a life of leisure for which I am very grateful. Instead, he found ways to fan the flames of his curiosity leading to further monumental breakthroughs. As time would tell, there were many different biotoxin that could cause illness in humans via a dysregulated innate immune system. This disease caused by dysregulation would in time be coined Chronic Inflammatory Response Syndrome (CIRS). Dr. Shoemaker used rigorous EBM to develop what would come to be called The Shoemaker Protocol. I have seen few take such a disciplined and rigorous approach to collecting and analyzing data. Dr. Shoemaker is quick to call out opinions masquerading as facts. He has developed clearly defined guidelines for diagnosis and treatment of CIRS. Dr. Shoemaker's work has been and continues to be published in peer-reviewed journals. His results are replicated repeatedly by other medical providers. As colleague Ming Dooley has eloquently said, Dr. Shoemaker's research was "not based on decisions made by health insurance executives, lobbyists, policy wonks, or politicians who never see the patients they make decisions about [3]." Dr. Shoemaker's practice-based body of patient-centered work is an example of exemplary EBM at its finest.

I am forever grateful for pioneering EBM cowboys (and girls)! While they may not receive well deserved recognition such as a Nobel Prize, they did summit mountains that made many colleagues cower. They did not go to sleep. They stayed forever curious. They questioned

the religious devotion to the medical playbook and dared to think outside the box. They elicited the respect of fellow EBM committed practitioners who began to study at their feet. They engendered the thanks of patients who were given an entry back into life despite being told by others that they were broken beyond repair. And probably most importantly, they fulfilled their sacred oath. They respected the hard-won scientific gains of those in whose steps they walked. They remembered that there was an art to medicine as well as a science. They were not ashamed to say, "I don't know". In fact, I believe this stoked their curiosity. They did not treat a chart but instead a suffering human being. They took joy in healing those who sought their help. They are respected by EBM practitioners while they live and will be "remembered with affection thereafter [6]."

- [1] D. Sackett, W. Rosenberg, J. Gray, R. Haynes and W. Richardson, "Evidence Based Medicine: What It Is and What It Isn't," *BMJ*, vol. 13, no. 312, pp. 71-72, 1996.
- [2] T. Greenhaigh, J. Howick and N. Maskrey, "Evidence Based Medicine: A Movement in Crisis?," *BMJ*, vol. 348, no. 3725, pp. 1-7, 2014.
- [3] S. McMahon, "Surviving Mold Shoemaker Protocol Certified Physicians," 25 February 2013. [Online]. Available: https://www.survivingmold.com/docs/McMahon_Evidence_Based_Medicine_3_25_2013.pdf.
- [4] A. Vukelic, "Surviving Mold Shoemaker Protocol Certified Physicians," 24 2020 January. [Online]. Available: https://www.survivingmold.com/docs/April_V_EBM_2_11_20.pdf. [Accessed 7 October 2021].
- [5] M. Dooley, "Surviving Mold Shoemaker Protocol Certified Physicians," 29 May 2017. [Online]. Available: <https://www.survivingmold.com/docs/MingDooleyEBM4.pdf>. [Accessed 7 October 2021].
- [6] PBS NOVA, "Doctor's Oath Modern," [Online]. Available: https://www.pbs.org/wgbh/nova/doctors/oath_modern.html. [Accessed 7 October 2021].