

Evidence Based Medicine

February 25, 2013

Does anyone know why the railroad tracks in the United States are set exactly 4 feet, 8 and one half inches apart from each other? A story floats around on the internet stating this gauge came about because of the width of a horse's *derriere*. More specifically, as Rome was building lengthy roads to connect its empire 2000 years ago, rutways from the wheels of wagons, pulled by pairs of horses, were formed in the primitive passageways. Travel was easier if the width between one's wagon's wheels matched the width of the rutways. Traversing these roads was precarious if there was a significant difference. Further, if carriages of significantly different sizes were built, multiple rutway widths could be established in different areas. To standardize matters, Julius Caesar established an edict whereby wheel width must be 4 feet, 8 and one half inches throughout the Empire. This standard was reportedly chosen because the width of the "average" horse pair's haunches approximated this measure. Many of the Roman rutways persisted even through the Dark Ages and into more modern times. As newer wagons were built, the wheelbase was maintained because of the pre-existing rutways. As pre-railroad tunnels were built in England, the same tools and jigs for making wagons were used in tunnel construction. As railroads were built, the same tunnels were used and they accommodated the same gauge. Englishmen immigrated to the United States and helped design and build the American Railroad system. And thus, the American Railroads use a gauge of 4 feet, 8 and one half inches.

The above story may or may not be true in part or in whole. Some details can be confirmed. Others lack any evidence while still other parts have evidence subject to interpretation. For the purposes of this essay, it does not matter if the tale is correct. The story serves as a mental exercise revealing several lessons why Evidence Based Medicine (EBM) is the only future for the practice of good medicine. Much of medicine, as it has been practiced, is tradition passed through the generations. Nobody has proven that many of these traditions are best practices. New advances kick against the goads of tradition.

What is EBM? "Evidence based medicine is 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."ⁱ EBM is a four (or five) step process^{ii,iii,iv,v}. It is intended to

create “an organized framework to facilitate bringing evidence to the point of care”ⁱⁱ.

All referenced texts agree on a simple format which begins with ASK an answerable question, such as, “What is the best treatment for my patient with his specific circumstances and this particular disease?” Next, one must ACQUIRE the needed information, typically through books, journals and online searches through PubMed, the Cochrane Database of Systematic Reviews or other search entities. Thirdly, the clinician must APPRAISE the validity of the information found in each study. For instance, are the methods used to obtain the data valid for the type(s) of data being observed? Is the “n” value large enough to support a change in current practice? Does the study design use controls? Is it prospective or retrospective? Some databases pre-appraise articles and discuss validity. Finally, once validity is insured, one needs to decide if the new information found in the study is appropriate to APPLY to the patient in question. The fifth step, added in some approaches, is to SELF-ASSESS after the process is completed.

EBM is what was taught at this author’s medical school 25 years ago, although the moniker “EBM” was never used. It was taught as the systematic way to stay current. Yet medicine is filled with traditions. For instance, does anyone know why pediatricians, family practitioners and internists treat otitis media (middle ear infections) with amoxicillin for 10 days? It is known that randomized double blinded studies have shown that amoxicillin is more effective than placebo at clearing ear infections. But why 10 days? No one knows. This writer was taught, in 1989, to treat for 10 days. The penalty for failing to prescribe in that manner would have been prohibitive during residency, even though this writer was informed, at that time, that no one knows why 10 days is used. No one knows who started it. No one knows that person’s motivations or data, if any. This author has taught countless medical students and residents to use amoxicillin in the same manner. Treating otitis media for 10 days is a tradition passed from generation to generation of practicing physicians.

Is 10 days of amoxicillin the best regimen for using this antibiotic for this indication? How can one possibly know unless it is tested against other treatment protocols? It simply cannot be proven, and can only be assumed, if evidence is not created through comparative trials. It is impossible to really know.

This is the first lesson to learn from the railroad gauge story. **Without strong, compelling and reproducible evidence, no one can know the truth of any medical matter.** We CANNOT know the optimum way to treat ear infections,

much less cancers, warts, heart disease, diabetes etc. unless there is data to support our suppositions.

Is optimization of care important? Of course it is! Patients want the most effective therapy at the cheapest cost with the least side effects. Physicians also want the same. Third party payers want cost effectiveness and successful treatment. Considering the millions of providers, worldwide, offering all sorts of therapies, how can one know the best course? How can one determine the least expensive therapy, taking into consideration medication costs, time to return to work etc.? How can one determine which therapeutic regimen has the least adverse reactions? Only through the standardized trials which form the foundation of evidence based medicine!

The medical world is filled with traditions. Most practitioners cannot distinguish between what they know as proven fact and what they were taught as tradition. Yet providers will believe both with equal vigor and practice both with equal (dis)regard. This allows anecdote and personal experience to rise to the same level as well constructed, high powered, prospective, placebo controlled, double blinded, multi-centered, reproducible trials.

Indeed, we already see the fruit of this spawning from the internet. Patients, in an effort to become more informed, scan the web looking for useful information. Yet most don't have the tools to discern the difference between good science and scare tactics. To many, $n=1$ and $n=10,000$ are the same. As such, they will believe almost anything. They neither know the individual authors nor said authors' agendas in writing. These persons are unable to use the differential diagnosis process and are ill equipped to employ critical thinking skills. Just one effect of this is the shrinking rates of childhood immunization in Europe. American parents are following the same trend. As herd immunity is diminished, subtle but real increases in some childhood illnesses are occurring. Epidemics of previously well controlled disease may be the next step. Only through systematic evaluation of procured data can optimum therapies be determined.

The second railway story lesson follows: **the traditions physicians use may be valid or may be invalid**. Parts may be true, parts may be false. No one can ask the men who built the first American railways why they used the gauge they did. Those men are all dead. The best one can do is speculate and review the evidence that is extant. With EBM however, prospective trials, cost analyses, head to head comparisons, and the like, can show beyond a shadow of a doubt what is useful, what is wasteful and what is dangerous. Rating the value or "strength of evidence" of individual studies, based on design, methods, numbers

etc. provides the medical community a valuable service, because nobody can keep up with the thousands of articles published monthly around the world. Compiling a body of strong studies supporting or refuting a particular hypothesis helps clarify for all what the truth of a matter is.

Every practitioner has sacred cows, beliefs that are unsupported, traditions. Some of these may be distilled from thousands of years of medical wisdom. Others may be wasteful and useless. Still others may endanger lives. Scrutiny, testing, data collection and comparison are the only measures which can discriminate between these outcomes. Using evidence is the only way to destroy the sacred cows (if the providers are willing). Trust no tradition, challenge everything, prove all beliefs or discard them.

The third lesson we learn from the railroad rendition is that **tradition interferes with the application of new knowledge**. If indeed any truth exists in the story above, there is a link, to some degree, between Roman roads and modern technology nearly 2000 years later. The modes of modern transportation are faster, more powerful and usually more dependable, but their foundation is roughly the same. Change from the rutway standard would have been inconvenient, possibly difficult and likely expensive. Even if one produced a far more efficient wheelbase for carriages, the road width had already been determined by the rutways before. Multiple governing bodies would be involved. Changing all the road widths would be a daunting task and so, apparently, it was never done. Inertia at its best! The same is true in medicine.

Look at Ignaz Semmelweis... He published his seminal work on hand washing in 1847. Introduction of hand washing, with a substance analogous to Clorox, between handling autopsy materials and delivering babies, reduced the rate of developing fatal puerperal fever by 90%! Hundreds of lives were saved just at his clinics! Semmelweis' data, however, was rejected, and he was reviled, humiliated and lost his position. Fellow physicians thought he was crazy. He wrote angry letters to obstetricians and called them murderers because they wouldn't wash their hands. As such, he was institutionalized and died in an asylum. It was another 28 years before hand washing was widely accepted, and then, only because germs had been discovered microscopically and a prominent surgeon also recommended sterile operating room procedures, including hand washing. Semmelweis' data was published 28 years earlier! Countless women died from post-partum childbirth infection while many, many others succumbed to post-operative infections due to iatrogenically induced organisms living on the surgeons' own hands. Above all else, DO NO HARM!

Today, we see the same recalcitrance toward accepting new knowledge. Dr. Atkins was ridiculed for his metabolic syndrome. Not anymore! For some conditions, acupuncture, biofeedback and chiropractic medicine have gained acceptance in Western Medicine thought, though they were thoroughly reviled in the 1980's. Only through EBM did these disciplines gain any credibility with allopathic doctors. The key to understand here is that acupuncture, biofeedback and chiropractic medicine didn't change; rather the perceptions of Western trained physicians were altered by data. Still, quackery and foolishness in medicine do exist. How does one decipher what is effective and what is dangerous? It is only by EBM that such differentiations can occur.

Traditions are unproven beliefs held by persons unwilling to change, unwilling to challenge their sacred cows and unwilling to know the truth, especially if new knowledge contradicts their unfounded beliefs. These persons are like ostriches with their heads in the sand. They are insecure in their knowledge. Their identities are falsely built on the knowledge they believe they have. As such, they cannot question their beliefs, nor allow anyone else to, for the internal and unrealized fear that their entire belief structure will crumble. Change cannot be tolerated, even if it is the truth.

Tradition is personal and unique. It is a possession held by each person. No one wants to lose their belongings!

This, along with ignorance, explains why Chronic Inflammatory Response Syndrome (CIRS) has not already been widely accepted, why it is not taught as primary instruction in medical schools and residencies and why hundreds of millions of research dollars, or more, are not being allocated toward its study each year. Most persons don't know about CIRS. Most patients eagerly accept teachings about CIRS because it is the first diagnosis that explains all their symptoms. CIRS is the end of their personal search! However, when practitioners learn of it, each must make a decision. Some embrace the truth, the 50,000 patients in the literature, the hundreds of peer reviewed articles in journals etc. Others stick their heads in the sand, state it can't be true and forget about it. They lose respect for the physicians who champion the cause. They tell their own patients, "It's all in your head," and send them to a psychiatrist. This writer sees and successfully treats these physicians' enigmatic patients! Still others, in their arrogance, ignorance and denial, vilify those who pioneer. The arrogance comes from failing to appreciate how truly little we understand about the workings of the human body but still considering what we have been taught as sufficient to exclude any new ideas. The last, and most despicable group, profits financially in

courts, spewing unfounded, untested, illogical traditions to deprive persons who were wrongfully harmed by CIRS.

EBM is also necessary to standardize the treatment in disease. Standardization could be a two edged sword used to stifle innovation. However, with CIRS, there are a number of practitioners using a number of different homespun protocols. These therapeutic endeavors may be sound, but have they been tested? Have they been compared to other protocols to see which is the most efficacious? The answer is no. To date, only Dr. Ritchie Shoemaker's treatment protocol has undergone prospective, placebo controlled trials and been published in the peer reviewed literature. That is why this author uses Dr. Shoemaker's protocols and sees similar results in his own data. Reproducibility is key!

If tradition is a roadblock to the implementation of new knowledge, EBM is a bulldozer. Given enough time and enough evidence, tradition will fall away and truth will be accepted. Just ask Dr. Atkins... And yet, some will STILL cling to their traditions.

Every practitioner holds on to some traditions. Most are unaware of this concept. Every doctor's practice has some elements of unsubstantiated and speculative medicine hidden deep within the proven knowledge. Physicians continue in their traditions whether they are valid or not. Traditions further impair the acquisition of new knowledge. A standard is needed to differentiate what is true knowledge and what is sacred cow. What is the best therapy? Will a screening test save money? Or lives? Only EBM, proven and tested medical facts, can answer these types of questions and cause physicians to release their traditions. As this happens, care can be standardized and improved to what has been established, scientifically, as best. Costs will come down, waste will be minimized and side effects will be reduced. New understandings will be assimilated as the data and the evidence show the way. Taking the guesswork out of medicine and training new providers with the best information is optimal! EBM has always been the best medicine and is the only future for the practice of good medicine.

ⁱ Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71.

ⁱⁱ Robbins BW, Evidence-Based Medicine. American Academy of Pediatrics Textbook of Pediatric Care. The Donohue Group, Inc. 2009. Chapter 5. p38-42.

ⁱⁱⁱ Shaneyfelt T, Baum KD, Bell D, Feldstein D, Houston TK, Kaatz S, Whelan C, Green M. Instruments for Evaluating Education in Evidence-Based Practice. A Systematic Review. *Jama* 9/6/2006; 296:9.

^{iv} Mark DB, Wong JB. Decision Making in Clinical Medicine. Harrison's Online. Part 1. Chapter 3. Found at: <http://www.accessmedicine.com/content.aspx?aID=9091080>. Retrieved 3/23/2013.

^v Center for Evidence Based Medicine. Found at: <http://www.cebm.net/?o=1014>. Retrieved 3/22/2013.