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01/24/20

Evidence Based Medicine

Evidence Based Medicine is the foundation of our medical model. At its core it means we correctly interpret well-designed studies, use good clinical judgement and do so in a manner that is agreeable to the patient. It is a tall order. Evidence Based Medicine looks at what is safe, proven and wanted while treating the patient as an individual. I would posit that The Shoemaker Protocol embodies this standard thoroughly and advances the application of Evidence Based Medicine.

The tenth rule in *The House of God* states, “If you don't take a temperature, you can't find a fever.” What if you say you don't know what a thermometer is? What if you can't read the thermometer? If someone tells you about the thermometer and reads it, you say you don't know what a thermometer measures. When you are told the thermometer measures temperature variations, you deny the existence of temperature variations. And when the significance of temperature regulation is explained and the existence of fevers is verified, you simply say you don't believe in fevers: people with fevers are crazy and the thought of fevers is hysteria. This is what so many doctors do in regard to Chronic Inflammatory Response Syndrome (CIRS). James Randi said, “Those who believe without reason cannot be convinced by reason.”¹

Medicine is failing about one quarter of the population, a quarter of the population who could be identified, monitored and educated on the prevention of this chronic fatiguing illness. If you knew your susceptibility, how would you view the stained ceiling tiles at work or the puddles in your basement? It astounds me that so often when I ask, “is there any water in your basement?” the response is a casual, “every time it rains.” Would you regard hiking in the woods differently if you thought Lyme disease to be a permanently debilitating condition as

opposed to an easily treatable infection? Would you avoid going to a Florida beach during a red tide bloom? Would you pass on the local exotic fish on a Caribbean cruise? These are seemingly mundane decisions that can divide your life into *before* and *after*.

It is easier to dismiss patients with CIRS than change the medical paradigm. These patients can be helped. However, doctors need to screen for and understand CIRS. A quick referral, blindly prescribing a medication or dismissing what you refuse to understand is far easier than acquiring the knowledge to treat challenging patients. These patients take far more than the standard 15 minute appointment. Regaining health from CIRS also requires a high degree of compliance from the patient. The first step may mean moving, changing jobs and parting with a lifetime of possessions. Recovery from CIRS also requires meticulous building maintenance. Landlords, employers, insurance companies, homeowners and contractors all have a vested interest in the status quo. Because so many want to plead ignorance and dismiss facts, we must redouble our efforts to reveal the truth with good science in a manner that is overwhelming, sound and transparent.

Evidence Based Medicine was defined in 1996 by Dr. Sackett as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”² It was updated to add, “the integration of best research evidence with clinical expertise and patient values.”³ The five steps are: 1) ask a clinical question, 2) acquire the best evidence, 3) appraise the evidence, 4) apply the evidence, and 5) assess your performance.⁴

The evidence for CIRS is real. A carefully performed history and the Visual Contrast Sensitivity (VCS) test can make an accurate assessment 98.5% of the time. A CIRS history includes exposure and inquiry into the nature of the patient’s symptoms. Correction of proteomics, genomics, VO2 max, pulmonary artery systolic pressure, NeuroQuant MRI and clinical response to treatment all provide further validation. Evidence Based Medicine is the

foundation for this knowledge. The fifth step is “assess your performance.” How many fields of study have this level of evidence for presence of illness and response to treatment?

Evidence Based Medicine demands we have rigorously reviewed data. Peer reviewing is critical to make sure the conclusions are sound and without bias. Are there adequate numbers of cases and controls? Is the sample size large enough? Are we controlling for confounding factors to the best of our ability by designing the studies well and studying one variable at a time? How long was the follow-up? And of utmost importance is the question: who paid for the study and to what end? Evidence Based Medicine calls for our practices to adapt as new data is found. We need to embrace new technologies as the science supports it. Genomics is a wonderful example of that; and the data on CIRS is on the cutting edge. We can prove how genetic expression and regulation change with CIRS and demonstrate correction of genomics with treatment.

The Shoemaker Protocol has been tested in this way. The data shows reproducibility. The work has been peer-reviewed and stands up to scientific scrutiny. Practices that were based on anecdotal observation were tested and incorporated into the protocol. The second Pfiesteria patient received cholestyramine from Dr. Shoemaker in 1997 after an *N of one* improved. This was the art of medicine, and an ingenious move, when many would have just dismissed the improvement in the first patient as a fluke, or written her off as a kook. He implemented a theory after weighing risk against benefit and, consequently, changed medical history. However, it was the resulting peer-reviewed work he did that transformed the theory into a conclusion founded in Evidence Based Medicine. This is why we don't use clay, charcoal, glutathione, or zeolites to bind biotoxins. This is not guessing or application of “green band-aids.”

Medicine calls for a combination of scientific rigor and critical thought. I remember the standing orders for pneumonia patients that were derived from Evidence Based Medicine during

my residency. There were pages of standardized orders based on the organisms that caused pneumonia along with their respective resistances. The problem is, as soon as someone mentioned pneumonia, these orders would be implemented and the differential diagnosis would collapse. Some of these patients, for instance, actually had pulmonary emboli which were not caught upon admission. Sure, the patient may have coughed up sputum and been short of breath, but were we identifying the most imminent threat? If we fail to provide an adequate differential diagnosis and make a mistake in the application, that is a user-error and not a failure of Evidence Based Medicine. Evidence Based Medicine calls for *more* critical thinking and innovation, not less. We need to ask the right questions. Use of Evidence Based Medicine is not an excuse to follow a cookbook, but a mandate to develop and refine our theories and processes. We can then reproduce them and prove their validity. It doesn't happen overnight but it is the way to affect a paradigm shift. We must act on what is known to the best of our ability at the time and continue to investigate.

As physicians, we weigh the risks versus benefits. Anecdotal patterns are the foundation for observations which can be verified. If the action is safe but unproven, a *proof-of-concept* study can be performed. Not every action needs to meet Level 1 Criteria. Level 1 Criteria means the data is derived from randomized controlled trials via systematic reviews and meta-analyses.⁴ There is room for a physician's individuality and creativity. The ultimate goal should be to prove the validity of the action, or disprove it, in a null-hypothesis study. To this end we need more cooperation and strength in numbers. Many physicians have limited contact with other doctors and have little interest in research. Most of the criticisms of Evidence Based Medicine are in the domain of implementation, not concept. Funding is certainly an issue.

To do comprehensive research we need more than grass-root funding. When so many parties with deep pockets have a vested interest in the status quo, the evidence must be incontrovertible and communicated relentlessly to professionals and the public. This takes time

and persistence. Medical Education is notoriously slow to catch up with the latest research, however, once the information is out it will no longer be subject to routine, institutional dismissal. Who can refute the role of cigarettes in lung cancer? The Shoemaker Protocol will soon be taught in an American medical school for the first time and I believe that we are approaching a critical threshold.

Who knows what we are missing? The stakes are high and the implications are enormous. This calls for our best effort to further our knowledge. We screen at birth for phenylketonuria (PKU) and the incidence is 1 in 10,000 births. Congenital hypothyroidism has an incidence of 1 in 3000. No one asks if an infant is born in a moldy hospital or heading to a moldy home. Will anyone perform an ERMI in a house or apartment after a case of SIDS? We could easily formulate a study to see if a correlation exists. A VCS screening could be done along with visual acuity and screens for hearing in schools. Will that quarter of children be as healthy as they could be? Will they be able to learn and perform at their peak level? How many exposures are too many? How much potential is being stymied? We know CIRS can cause thrombosis, bleeding via an acquired von Willebrand's disease, pulmonary hypertension and restrictive lung disease, yet how many times is the source of this acknowledged on a death certificate? The scope of this problem demands our best innovation, good science and tenacity. As Fox Mulder of *The X Files* said, "The truth is out there."

We could know the HLA of each infant. We could screen each home before renting or purchasing (and routinely thereafter), especially following an episode of water intrusion. Poorly built buildings could fall by the wayside because human health and mold-specific quantitative PCR have been correlated. The market would favor sound construction and vigilant maintenance. We could follow MSH in susceptible individuals as readily as TSH, for example. Medical costs could fall precipitously as these individuals are being cared for before the

eventual point of crisis. All this would take a substantial, concerted effort but it is all possible with continued study, funding and implementation of peer-reviewed practices.

So much can be known and verified. What cannot be verified is the human cost. How much suffering is occurring from disease that can be prevented, identified and treated if only we prioritize and act on what is known and what can be known?

1. "James Randi." reasonrevolution.org, <http://reasonrevolution.org/secularism-quotes/james-randi>.
2. Sackett, D.L., et al. (1996). Evidence-based Medicine: What is is and what it isn't. *BMJ*,312(7023) 71-72).
3. Sackett, D.L., et al. (2000). Evidence-Based Medicine: How to Practice and Teach EBM. Edinburgh: Churchill Livingstone.
4. University of North Carolina, Health Sciences Library, "Forming focused questions with PICO," University of North Carolina, Health Sciences Library, August 2016. [Online]. Available:<https://guides.lib.unc.edu/pico>.