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THE CURRENT WORLD OF MEDICAL INFORMATICS

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INTRODUCTION:

Medicine is an ever-evolving field and the views on the best care available are always being updated. The validity of our decisions as clinicians can only be regarded as appropriate if there are scientific studies to back those decisions up. Otherwise, we risk being out of date and taking the chance that the patients we are treating stay stuck in their illnesses and dis-ease. However, the art of medical care is just that, an art. We must therefore be able to take our clinical experience and amalgamate them into the best current evidence that is available, taking everyone's unique set of circumstances into consideration when caring for them. Without this clinical curiosity we risk being out of date and never advancing medicine.

For example, we once believed that Chronic Inflammatory Response Syndrome from Water Damaged Buildings (CIRS-WDB) was due mainly to mycotoxins and their inflammagens as

described in Mold Warriors by Dr Ritchie Shoemaker in 2004. However, recent evidence now illustrates that the immunoreaction is mainly secondary to the inflammagens from actinobacteria and endotoxin exposure. Diagnostic protocols have been updated with transcriptomics and integrative therapies are ever expanding. We need evidence-based studies to be conducted to gain validity of any diagnostic procedure and therapy in the medical community. Therefore, it is our duty as clinicians to be able to find and create the best medical evidence to treat our patients. Only then, can we advance and successfully heal them.

Dr David Sackett was the physician that best defined evidence-based medicine (EBM) in 1996: It is the "conscientious, explicit and judicious use of the best evidence in making decisions about the care of individual patients." Later, Anna Donald and Trish Greenhalgh from the University of Oxford, proposed an alternative definition:

"Evidence-based medicine is the use of mathematical estimates of the risk and harm, derived from high quality research on population samples, to inform clinical decision-making in the diagnosis, investigation or management of individual patients."

Simply put, EBM is an overlap in recognizing the best research evidence while considering the clinician's individual expertise with each patient's unique values. It is described as a 5-step process. First, to **ASK** a clinical question by identifying the patient or problem (P), recognizing the intervention (I), illustrating the comparison intervention (C), and pinpointing the outcome (O). Second is to **AQUIRE** the best evidence. Third is to **APPRAISE** that evidence. Fourth is to **APPLY** that evidence and fifth, is to **ASSESS** the performance.

The quality of evidence is currently based on four levels. **Level 1** is the most reliable and is the gold standard. It includes randomized, double blinded, placebo-controlled trials (RCT) and/or meta-analysis. **Level 2** studies include unrandomized controlled trials, cohort studies, or case

controlled analytic studies and/or multiple time series studies. **Level 3** studies include expert opinions based on clinical experience, case studies, and/or committee consensus reports**.** Usually, these studies have small sample size and no control groups. **Level 4** is of lowest quality and is evidence based solely on personal experience.

It is very difficult for clinicians to keep abreast of the current research. It is extremely time consuming. Once a textbook is published it is already vastly outdated and has been described as "dangerous waste". However, textbooks that have web updates and different web sources are now available. Online clinical content is judged by its timeliness, breadth of subject matter and quality of studies. For instance, *UpToDate*, is evaluated as a 5 for timeliness, 1 for breadth and 2 for quality with 1 being the best score. *Essential Evidence Plus*, is evaluated as a 7 for timeliness, 7 for breadth and 2 for quality and considered "middle of the road" among the texts evaluated. The best option would be an evidence based online service that is regularly updated and pre-appraised. The ideal system proposed was one that could "integrate and concisely summarize all relevant and important research evidence about a clinical problem and automatically link through an electronic medical record, specific patient circumstance to the relevant information."

Unfortunately, there are still shortcomings directing evidence-based clinical care due to the quality of what is being published. It can be difficult to decipher if there is clinical bias in the studies at play. Many companies and individuals have a vested interest in the outcome of the studies and conflicts of interest are sometimes not elucidated. For instance, many of the USDA dietary regulations are based on the consensus of the committee. Ninety-five percent of the members have relationships within the agricultural industry and recommendations have not been based on scientific data.

There is incredible cost to conducting studies and many of them are funded through the pharmaceutical industries themselves. By the time a drug gets to phase 3 of the clinical trial most companies have invested millions of dollars. Therefore, cases of manipulation of the data and safety concerns get overlooked and later these drugs get pulled from the market. Some examples are Merck's drug Vioxx and GlaxoSmithKline's drug Avandia. Both companies were fined billions of dollars for failure to report safety data regarding the increased risk of heart issues. An additional concern is articles accepted for publication in reputable journals, like JAMA, are often printed among pharmaceutical ads. Since they provide funding for the journal, it is hard to believe that inclusion of attacks on the safety of one of their drugs would not be considered.

Another big pharma giant Wyeth paid for 26 papers over a 7-year period backing the use of synthetic hormone replacement therapy (HRT) in women to be written. They contracted with ghostwriters to draft and outline articles that minimized risk versus benefit. In fact, a 1998 study in JAMA, found that 11 percent of the articles in top journals were also ghostwritten. It is important to sift through this publishing game and find the quality research. Otherwise, we are at risk of the "Babel Effect" as described by Dr Dean Black, PhD. This occurs when "frequently undetected scientific fraud in peer -reviewed journals is quoted by other researchers, who are in turn re-quoted by still others and so on."

It is also important to not allow new data to cloud the plethora of information on a topic that has been published prior. One study does not negate all the others when they were reliably conducted. As in the case of the flawed study published in JAMA on testosterone therapy associated with an increased risk of heart disease in men. The largest meta-analysis to date revealed no increase in cardiovascular risk in men and reduced cardiovascular risk among those with metabolic disease.

Of particular importance, is the duration of a study. Many cover only a limited time frame. As in the case of the studies conducted on the safety of silicone breast implants. The studies were concluded after 5 years and many of the patients were lost to follow-up. Yet, safety was claimed. When evaluating/appraising the data we need to look at the sample size and if the patients we are treating are representative of the sample. In general, the larger the sample size, the greater the statistical significance of the findings.

As shown, when studies are conducted, we often look at one outcome and one parameter. It is clear the limitations that can occur when there is a syndrome that involves multiple systems and multiple symptoms, as in Chronic Inflammatory Response Syndrome (CIRS). Level 1 studies with large sample sizes take years and major funding. Thankfully, secondary to the work of Dr. Ritchie Shoemaker and the "Mold Warriors", we now have good quality studies on CIRS. The evidence is plentiful and growing. It has not been easy. The vested interest of building owners and employers have been at play in a multitude of cases. It is very costly to medically remediate a building. As of now, the only evidence-based treatment protocol in CIRS is the Shoemaker Protocol. Unfortunately, acceptance of new therapies and diagnoses take years to reach mainstream medicine and many people will suffer needlessly until then. But, as the body of scientific evidence advances, hope is on the horizon.

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