

# Evidence Based Medicine

## The Light and The Chaos

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### INTRO

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### INTRO

I remember as we drew near to the year 2000 that one of the national news magazines did a retrospective piece on the best inventions of the last millennium. Atop the list was Gutenberg's printing press of 1450.

Somehow cars, planes, rockets, computers and phones all seemed to have more razzle dazzle, but I really sensed they were right in giving the blue ribbon to the printing press.

The printing press is what allowed us to share ideas with people who were not in the room, to learn from others worldwide and, as Isaac Newton said, "to stand on the shoulders of giants." (1)

Every day in clinical practice we face questions of how to diagnose, what to expect and what to do. We go back to what we know or what we think we know. But how do we know it? What that just something a resident told us when we were a medical student? Is it just an assumption of something that seems to make sense?

I've told people with diverticulitis "Don't eat nuts and seeds they can get stuck in your colon and give you a flare." Based on my model of the pathology, that made sense.

But where did I get that?

It was just something I was taught. Turns out it was just other doctors' speculation based on their model of the pathology. It had never been tested. In fact in a prospective study of 47,228 men of the Health Professionals Follow up Study followed for 18 years, authors found inverse associations between nut, and popcorn consumption and the risk of diverticulitis. In other words not only did it not support the theory that they were bad, but it suggested an even protective effect (2).

We learn things and we assume they are true. But it would be better to recognize which parts of what we think we know are just assumptions and not to assume that all those assumptions are true rather than being open to new evidence (3).

### HISTORY

The modern origins of the idea of Evidence Based Medicine (EBM) stem from McMaster University in Canada. In a 1992 JAMA paper introducing the concept, (4) the Evidence Based Medicine Working group chaired by Gordon Guyatt from McMaster observed that in the 1960's the randomized clinical trial was an oddity. Our paradigm of medicine was based solely on unsystemic observation from clinical experience, traditional medical training, as well as our basic understanding of disease and pathophysiology. They contended that it was not their intention to demean clinical experience and they acknowledged that some of the things we do will never be tested. That said, if we could test our assumptions it would "markedly increase the confidence one can have in knowledge about patient prognosis, the value of diagnostic tests, and the efficacy of treatment."

David Sackett, also from McMaster and a mentor of Guyatt, offered this definition of Evidence based Medicine: "Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values." (5).

This all sounds quite reasonable but calls to mind the question what is the best research evidence?

Sackett writes that "evidence based medicine is not restricted to randomised trials and meta-analyses." (5) But he goes further to say that "Because the randomised trial (RCT), and especially the systematic review of several randomised trials, is so much more likely to inform us and so much less likely to mislead us, it has become the "gold standard" for judging whether a treatment does more good than harm." (5)

So clearly in evaluating the evidence, EBM places the RCT and meta-analysis of RCTs at the top of the evidence based hierarchy.

## THE LIGHT AND THE CHAOS

As presented by its champions at McMaster, Evidence Based Medicine seems to be a real benefit to the way we do medicine. Who could be against it? The problem as I see it is not with the idea of Evidence based Medicine but with what Sociologist Robert Merton called "the law of unintended consequences" (6)

Unintended consequences of Evidence based Medicine include:

### 1 The delegation of the task.

In his 1996 BMJ paper (5) Sackett acknowledged that time for physicians was a barrier to EBM given the enormous amount of medical papers written every year. Of course, the volume seems exponentially greater now, but doctors may be even more comfortable using search engines like Pub Med as they are increasingly online. Still, it seems most physicians are either not attempting EBM as formally described or leaning on others like the Cochrane Database of Systematic Reviews to do it for them.

This creates all sorts of problems as we do not look at all of the evidence.

#### A The rich get richer

Indeed RCT's can provide a kind of evidence not available from one doctor's experience it but they can be very expensive to do. One study of 28 Phase III RCTs funded by the National Institute of Neurological Disorders and Stroke prior to 2000 found them to have an average cost of \$12 million per RCT (7). Of course those may not be representative of the cost of all RCTs but even if the average were a tenth of that, they would only be done by those with deep pockets.

#### B) Inclusion bias

Journals have a tendency to publish new or exciting data, certainly positive data over negative (19) and pharmaceutical companies tend to submit studies that show their drugs work rather than ones that don't. Further, because they have an inherent interest in their products working they may design the study in such a way as to promote the results they want (e.g. short term studies, emphasizing relative risk reduction over absolute risk reduction).

## 2 The denigration of other forms of evidence.

This also was anticipated by Dr. Sackett, but it seems to have happened nonetheless. In our increasingly competitive culture if we deem one player good and another better, the good player becomes "inferior."

#### A The name

In 1915 some doctors formed an alliance called the American College of Physicians who have come to represent internists throughout the country. That's fine. But now with increasing subspecialization of medicine and the advent of Family Practice and Pediatrics boarded specialties, the name implies that Internal Medicine has an exclusive right to the term "physician".

In 1985 some doctors began the "Physicians Committee for Responsible Medicine." That's fine. It turns out that their main theme is that everyone should be a vegan. Now if veganism helps some people, I'm all for that, but if you disagree that it's for everyone, should you join the Physicians Committee for Irresponsible Medicine?

While the idea began as "let's use all the evidence we can especially randomized control trials and meta-analyses," it has become for many the notion that RCT's are the only "real" evidence. If it were renamed "randomized controlled trial and meta-analysis based medicine" then great, but it's not, so if someone ends up on the wrong side of the present day champions of EBM, it looks as if they don't care about evidence at all.

#### B Applicability

By nature a randomized clinical trial wants to weed out any extraneous variables (young people, old people, other diseases etc. ) So a physician may need to be a little creative in deciding if a trial really speaks to his or her patient. If that sort of reason becomes “inferior thinking” then we’ve paid another price for the way we’ve interpreted evidence based medicine.

### 3 Triage

Insurance companies are always going to look for a way to take in more premiums and pay less claims to increase profit. While evidence based medicine was never meant to be another gate for the insurance company gatekeeper that is a real risk of its application.

#### A GOOD TOOL

Again, however, these are not criticisms of the idea of Evidence Based Medicine as proposed by its leaders At McMaster University, but of the way it may be appropriated by those who’ve assume its mantle.

A lot of people with “Chronic Fatigue Syndrome,” fibromyalgia, polyarthropathy, intractable insomnia, migraines, and Irritable Bowel Syndrome bounce from doctor to doctor. Eventually they may make their way to a doctor promising something new or “out of the box”. That doctor may go by various labels like holistic, integrative, alternative and the like. Sometimes these practitioners feel that anything is worth a try as long as it’s not dangerous.

The problem with that approach is that it’s chaos.

If it doesn’t work, the patient may worsen as he searches for the truth that may never come for him. Dr. Ritchie C Shoemaker (11) has provided answers backed by clinical trials that for some of these people may get to an answer quicker.

In this case it’s a great tool that helps you get the job done better.

As a doctor attempting to follow the Shoemaker protocol I’ve had patients say things like “I don’t want to take Cholestyramine. That’s made by a pharmaceutical company. Can’t I just use activated charcoal?” I can say “Cholestyramine has been proven as part of clinical trials to reverse symptoms and biomarkers (9, 10) but to date no natural toxin binder has been shown to do that.”

On the other hand, had Dr. Shoemaker been restricted to only practice using the results of previously published RCTs he would not have discovered and tweaked the biotoxin protocol that was later the focus of study of those successful clinical trials.

All in all if the doctor is a carpenter, then EBM, like a hammer, is a great tool. Sometimes, however, the doctor is viewed not as the carpenter in need of a tool, but as a nail that needs to get in line. In that case EBM as the hammer is no good.

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