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# HUMAN VARIABILITY AND THE CONTROLLED CLINICAL TRIAL

ABSTRACT. The author points out that the so called Controlled Clinical Trial (CCT) is not sufficient to demonstrate the validity of a drug because of the impossibility to utilize a really homogenous group of persons to test it. Besides, he stresses the difficulty for homeopathy and chiropractic to be accepted without reserves by the allopathic medical science.

During my undergrad days at the University of Miami I had a girlfriend who, to make extra money, decided to sell her body. Actually she was going to rent her body. It's not what you think. It was to science, to test a new drug. I didn't think it was such a bad idea since at the time I was pre-med and naive (but then, I repeat myself). She had to stay in a group home with about 30 other women, ages 18-30, for a week. I spoke to her when she got back:

> "How did it go?" I asked.
> "Ugh! It was so weird, I don't think I'll ever take another medicine again," she said.
> "What happened?"
> "Well, it was a mix of black, Latino, and white women. Most of us followed the rules but some put the pill under their tongue and spit it out when no one was looking. Others got real sick and stopped taking them. Others took some, but not all of them. I think I got a placebo because I didn't feel anything. The food wasn't so good so people would sneak stuff in. It was so boring. Some smoked dope to kill the time. It was a joke."

Based on that controlled clinical trial or CCT conclusions were drawn regarding a drug's safety and efficacy. Conclusions, which were, to put it mildly, worthless.

But forget about the dope, the poor compliance and the food that was snuck in. Let's say you got 30 or 100 or 1,000 people together to test a drug who were all cooperative and would follow the rules and be good. The conclusions would still be worthless.

Why? Because for a CCT to be valid you have to have a homogenous group of subjects: people that are similar. That's impossible to find as the famous nutritionist Roger Williams writes:

> While healthy young men of the same height and weight may resemble one another in their overall oxygen consumption, specific chemical reactions may take place, under basal conditions, five or ten times as fast in one individual as in another ... Each individual would, if subjected to the same stress and given the same food, exhibit a highly distinctive metabolic pattern. In our experience with control young men we have never found one who exhibited a pattern which was free from distinctive variations from the average. Roger J. Williams, cited in *Controlled Clinical Trial* by Harris Coulter, Ph.D., p. 216.[1]

Williams claims that less than 3% of persons in "normal" health need to consume the "minimum daily requirements" or "recommended dietary

[1] I am indebted to Harris Coulter, Ph.D., and his two wonderful books, which every D.C. should have: *The Controlled Clinical Trial* and *Divided Legacy*, Vol. 4.

allowances" of vitamins and minerals. There is no normal for the five major vitamins and minerals. Why? Because we are just too different. As Harris Coulter in his little gem *Controlled Clinical Trial* states: "If every individual has a different set of fingerprints, would should everyone have the same riboflavin requirements?" And we may add, why should everyone metabolize drugs the same way, react to their environment the same way or get sick the same way? Look at some of the things that make us chemically different:

- Sex - men and women have different body chemistry, different blood composition.
- Age - different ages have different chemistry and nutritional needs.
- Ethnic background - will affect how drugs are metabolized.
- Time of the year - metabolism undergoes variation from season to season.
- Time of the day - metabolism undergoes variation from day to night.
- Time in menstrual cycle changes body temperature.
- Place - body temperature is different in different latitudes.
- Past immunologic history. As Coulter writes: "Each individual possesses a unique set of antibodies, representing the *history* of his or her lifetime exposure to the environment." *Divided Legacy*, Vol. 4, p. 218.
- Emotional Stress - metabolism is affected by emotional stress.
- Genes - are never the same in two people, so proteins are different.

Other variables include height, weight, diet, past drug use etc. But lets say you could somehow test a drug on 25 fifty year old white Polish women of similar height, weight, personality and body-type from the same place, who menstruate at the same time and have similar immunologic histories (don't ask me how). Question: Do the drug findings from this CCT relate to you, me and the man or woman down the street? Answer: No.

The basis of medical testing today the "Controlled Clinical Trial" sounds very impressive: you get a group of homogenous people suffering from the same condition or with no condition at all, you give them a drug and you see what happens. This information is then printed on drug inserts, in drug ads, in the Physicians Desk Reference (PDR) and other publications as Side Effects, Contraindications, Adverse Reactions, Indications and so on. The implication is that the physician will know what will happen when he/she gives the stuff to patients. The reality however is that there is no way of knowing.

These tests are *very* expensive. The Food and Drug Administration (FDA) makes drug companies spend over $300 million to get a drug to market and yet you still cannot predict how the next person will react:

> More than half the prescription drugs approved by the Food and Drug Administration (FDA) between 1976 and 1985 caused serious side effects that later caused the drugs to be either relabeled or removed from the market. M. Caldwell, «Serious Side Effects linked to many drugs», *Washington Post,* May 28, 1990.

In order to know how a drug will work on every single person, every single person would have to be tested. That would really increase costs and the drug companies could collectively afford to put out a new drug say, once every 500 years. Come to think of it, that may not be a bad idea.

A. B. Hill the British statistician who developed the controlled clinical trial wrote:

> The controlled clinical trial ... does not tell the doctor what he wants to know. It may be so constituted as to show without any doubt that treatment A is on the average better than treatment B. On the other hand, that result does not answer the practicing doctor's question what is he most likely outcome when this drug is given to a particular patient. Is there indeed any way of answering that? (A. B. Hill, *Principles of Medical Statistics*, 8th ed., 1966) in *Controlled Clinical Trial* by Harris Coulter, Ph.D.[2]

What's the moral of this story? Human variability in health and disease cannot be controlled for. Therefore the controlled clinical trial is seriously

[2] Coulter also brings up the salient point that Homoeopathy, as well as Chiropractic, is not suited to be judged by the Controlled Clinical Trial since a purely homogenous group of individuals (with or without the exact same disease, another impossibility) is needed in order to perform a proper CCT. Such a group does not exist since human variability is so great. But homeopaths and chiropractors do not treat diseases, and homeopathic philosophy, along with acupuncture and other vitalistic schools of healing, do not even recognize individual diseases.

flawed in testing a drug, a chiropractic adjustment, an herbal remedy, a exercise regime – that is to say, *any* intervention.

Heath care is a unique occurrence and must be individualized. What works for one person will not work in the same way for another. That is one difference between chiropractic and medicine. Each person must be analyzed for their unique subluxation pattern and their adjustment will be unique for their needs. No two spines are alike, no two people have identical joints, nervous systems or structural systems. No two people have identical subluxations.[3]

Also, homoeopathic M.D.s began CCTs in the 1960s so the medical monolith would change their opinions of homoeopathy. After over 100 CCTs it did not change. The very idea that chiropractic and chiropractors (who have no M.D.) can earn acceptance by kowtowing to or mimicking the medical model is the height of foolishness. DCs should stop saying that if chiropractors will only do more CCTs we'll get "accepted." That attitude destroyed all but destroyed Osteopathy and Homoeopathy earlier in this century.

There has been the false belief that if we do enough studies the medical profession, the government and the people who make drugs and have influence

[3] To read more about chiropractic techniques and, in particular, about the Koren Specific Technique, you can visit the website http://www.teddkorenseminars.com/articles.asp.

will accept us. That is fantasy. That approach has been tried, and has been discredited in the laboratory of life. Controlled clinical trials will not get us accepted!

Homeopaths are M.D.s. They graduate medical school, take the same courses, get the same degrees. They are in the club. Not like us D.C.s. But homeopaths have a different medical philosophy than their allopathic brethren – a philosophy that is more aligned with chiropractic in their respect for the wisdom of the body, the dangers of suppressing symptoms, the enhancement of natural resistance to disease.

So although M.D.s they were attacked, ridiculed, rejected and ostracized. They were labeled as quacks and frauds, phonies and unscientific charlatans. (That fact that they got their patients better, often after allopathic medicine failed, was irrelevant to the allopaths).

To disarm their opponents and gain acceptance, they decided to do enough research studies to prove their theories so that any prudent person would have to accept homeopathy's validity. After the data was on the table, and published in respected journals, it was assumed then homeopaths would be accepted.

Sound familiar? We find the same lament from many chiropractors. “If only we do the right scientific studies, then the medical profession will accept us,” they cry. Well, let’s see what happened when that was tried.

In Harris Coulter’s *Divided Legacy* (Vol. 4) we find the following:

> “Introduction of the allopathic ‘controlled clinic trial’ in the 1950s placed on the agenda the task of using this technique to test homoeopathic remedies. It was even suggested that barriers to general acceptance of homoeopathy would fall if only their therapeutic value could be demonstrated as “rigorously” as this is done in allopathy.”
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> “In the 1970s and 1980s, with the rapidly growing public acceptance and popularity of homoeopathy, these physicians decided to take up the challenge of the ‘controlled clinical trial,’ and by 1991 more than a hundred such trials had been reported not only in the homoeopathic literature but in such publications as Lancet, British Medical Journal, Journal of Clinical Pharmacology, Arzneimittelforschung, Presse Medicale, Therapiewoche, and Deutsche medizinische Woochenschrift.”

But all to no avail. Homeopathy is laughed at and derided in the medical literature and by individual MDs. Why would anyone think that chiropractic would have a better chance?