(6) Who Needs What? Empiricism And Theory Part 2

Description

We have previously seen that scientific data doesn't easily produce clarity, because we all have our preconceptions based on implicit preferences and experiences. Depending on how firm these preconceptions are, we may need additional information before we grant scientific importance to information provided. We will explore this idea in this and the following chapters by addressing the following questions: Who needs what kind of data and information? And why do different people need different kinds of information? The English have a phrase for this idea: *"Horses for Courses"* – every type of race requires a different kind of horse – one horse for the wild hunt in the open field, one for stylish showing, one for horse racing, and another for the trot.

Patients want safety and effects

Let's start with the patients. When people are ill they want a treatment which has a reasonable probability of alleviating their symptoms and not causing serious side effects. Imagine you are someone suffering from migraine since adolescence. A pharmacological prophylaxis against migraine, which helps many patients, is a possibility. Some people don't tolerate the medication well, or hesitate to use medications regularly. Let's assume you didn't tolerate the prophylaxis well because the drugs curbed your sexual appetite and desire, which you disliked. So you are looking for an alternative. How do you proceed?

Patients are empiricists. You ask around and talk with other patients, friends and acquaintances. Let's say that an acquaintance has told you that not far from your home lives a doctor who owns a new type of machine that will change the energy level of people and successfully treat all types of pain. However, the first few treatments cost $400. Your wellbeing is worth this money to you, so you go to get a diagnostic session and some therapeutic sessions. The machine, so you are told, registers the signature of your electromagnetic radiation and sends back an adjusted ultra-weak electromagnetic pulse. You do not feel this pulse; merely sit connected to this unit a few times for 20 minutes. Lo and behold, you have no more migraines over the next few months. After six months your migraine comes back. You go back to for a refresher session, costing maybe $80, and the migraine disappears for the next six months. You did not feel any side effects. Since the pulses were indeed very weak there is no way for you to feel it. You can eliminate your migraine reliably with the help of this application through treatments of 30 minutes twice a year for approximately $160 total. Did the machine work? Is it "effective" in a scientific sense?

Yes and no. For you as a patient it has obviously worked because it took care of your complaint. It worked at least for a substantial time period with minimum effort and without exorbitant cost. If we surveyed all the patients who came to see this doctor and his machine and documented whether their symptoms were eliminated reliably, you would get a positive view of this treatment. Several such observations and documentation of studies have shown that a so-called bio resonance therapy (that's the name of the therapy briefly described above) usually eliminates or greatly relieves the symptoms of 80-85% of patients [1-4]. Side effects are rarely observed. Such treatment would be considered "effective", or shall we rather say, successful, from the perspective of patients, because the symptoms are gone and no others occurred. Patients want to see the effects and want these effects to be very probable. Patients also want security and certainty.

These kinds of data are relatively easy to obtain by observing a large number of patients, and especially by observing them without making a selection or by not knowing the outcome of their treatment in advance. These are prospective, meaning forward looking, observational studies. Sometimes they are also called single-arm cohort studies (single arm because only one group is observed). Important in such studies is that *all* patients belonging to a particular category are documented, such as all patients with headache or all patients in pain, or even all patients over a certain period of time. It is also important that a measure of the treatment is recorded that is independent of the practitioner, to avoid that his or her preconceptions affect the estimate of treatment success. Therefore, a third party should conduct the surveys and distribute and collect the questionnaires – or one should conduct tests which can't be affected by the therapist. Methodological criteria for such studies have been published [5]. Let's assume that all that has been considered at this physician's location and we have reliable data showing that 80% of patients benefit from such a bio-resonance therapy. Is this enough to say that this treatment is effective? From the perspective of the patient, as stated, yes; perhaps also for the approval authority; however, it is likely a "no" from the scientific perspective.

Will medical insurance companies refund the cost because they recognize the treatment to be effective? Maybe. Will the doctor accept the treatment as effective?

Practitioners want a good theory, sufficient positive experience and some scientific data

Let us turn to the practitioners. Physicians tend to implement new interventions if they learned or saw somewhere that they work. They learn a lot from other practitioners through classes, professional circles, and training courses and also through informal conversations among each other [6]. They mostly want to see studies in support of the new treatment and refer to the scientific information, but these comprise only a fraction of their decision making process. They typically also want to understand why something works. This is why doctors also consider basic science findings that make plausible how the new treatment could work. For example, if one knows that the small blood vessels in a human run to more than 160,000 km, enough to span the earth about three times, that the manner in which the organism regulates the blood flow is still not understood, and if one has seen a short movie showing how the blood flow in such a miniature vessel is changed by the application of a weak, pulsed magnetic field, then one finds the possibility that such treatments are effective plausible. Therefore, when you hear your colleagues talk about their successes, or when you read a few studies, you as a doctor might already feel sufficiently well informed and even try it out for yourself. You will collect your own experiences, kind of like an implicit observational study, and depending on how self-critical you are and how well the method really works, you will form your own opinion. Once that opinion is formed, one or two clinical studies are unlikely to change it. After all, you had your own experience with it, and maybe have already invested ten or twenty thousand dollars in the acquisition of such equipment and have made a lot of patients happy with it.

In summary, practitioners want data covering each category: basic research to contribute to the understanding of the mechanisms, and clinical research to demonstrate that an improvement of the patient's condition was observed – especially when and under what circumstances it is probable. Ideally, there would be also comparative research comparing such a treatment to others already on the market. However, is a treatment effective simply because physicians use it? This is certainly not the case, because doctors have indeed used ineffective or even harmful interventions in the past. They used them because the prevailing theory of that time assumed it to be effective. Think of cases such as the long prevailing idea of denying water to cholera patients because it was thought to dry out the disease. Now we know the opposite to be true and that therapeutic idea came from a false theory. Today's doctors are a little better trained and not only have the theory in mind, but also want to see some data. But usually they do not have the time to systematically go through all the data available. So they rely on reviews, for example in medical journals, or also informally on information from their colleagues and on so-called “mainstream” journals typically read by doctors such as the British Medical Journal, The Lancet, or Neurology, to name a few. In this way, primarily, scientists get to say what is “effective” supported by their science-based concepts.

Scientists want to understand the underlying mechanisms and to discover something new

The primary motivation of real scientists is curiosity. They want to understand how things work and apply this understanding to develop something useful. In order to have the chance to do so they must develop their career by publishing “good” papers in “good” journals. In order to publish in good journals they must either develop very clever ideas and implement them using a clean methodology, or get a lot of money from agencies that support research (ideally both). A good scientist will only investigate a theme such as the effect and mechanism of the bio-resonance apparatus if they assume that there is potential for an interesting finding. Then the scientist will assign the project to one of his or her grad students who will conduct a clean pilot study (basic research or a small clinical study depending of what kind of lab it is). In any case, the scientist will make sure that they are studying a “real” phenomenon and not an illusion or an artifact by performing controlled studies, ideally in the form of experiments. The difference between an experiment and a natural observation is crucial here. Therefore, I will keep on coming back to this point.

Scientists manipulate nature actively, when making an experiment. Through random assignment a scientist can make the control group and experimental group similar in all starting conditions and then run through the experimental manipulation. A basic scientist would perhaps test a system consisting of a tissue or of cells by exposing them to such an ultra-weak, pulsed magnetic field while measuring the control system without any exposure. If they are very clever, they would blind those who carry out the measurement, i.e. conceal which system is treated or untreated. Then after the evaluation of results the scientist will know if the intervention “ultra-weak, pulsed, electromagnetic radiation,” had an effect on such a cell or tissue system. If they are methodically well trained, they will also perform systematic negative controls, i.e. blank measurements of the procedures without making any interventions, in which they act as if they carry out a real measurement of a real intervention. (By the way, such systematic negative controls are rarely performed in conventional research; however, they have become the standard in homeopathy research).

Let’s assume the scientist has seen a change in the test tissue after application of ultraweak electromagnetic impulses: would that be already an indication of clinical effectiveness? This is definitely not the case, because in a complex system such as the human organism there is an abundance of compensatory mechanisms that can balance out and diminish the effects of the intervention. This is why one would want to see clinical effects, i.e. changes that are reliable in the clinical setting and are due to the intervention and not to any casual or other factors. The scientist will, therefore, conduct a controlled study. This can only happen if they split the system. This is also the beginning of the conceptual problems: A really good controlled study costs a lot of money. You need personnel, equipment, money to compensate the time of patients and doctors, etc. Who pays for such a study? Perhaps it comes from a foundation or the device manufacturer? It is difficult to find money for such a study; such studies are often conducted on a minimal budget. The scientist has to limit him or herself pragmatically and, not surprisingly, the obtained results are often obscure. Because the scientist wants to survive, they also publish these results, which then crowd the literature. The reader must then make sense of such results, and that’s not always easy.

In the case of bio-resonance there are now some interesting and positive basic research studies [7-9], clearly positive data from outcome-based research (meaning results of one-armed observational studies) [1-4], and a few unclear studies which were blinded and included sham controls [10-17]. A superficial scientist with no further interest will think: “Not worthwhile, no significant effects”. The inquisitive scientist with a deeper interest will think: “Interesting. This has an obvious effect in practice, but once one looks closely one finds no significant differences between control and real intervention. What exactly is happening here?”

If one were to look for the mechanisms, one would find a vaguely worded statement: ultra-weak pulsed electromagnetic radiation changed the cell systems slightly. But is that enough to make a clinical effect plausible? The answer is probably, once again, dependent on one’s preconceptions. Observational data shows that bio-resonance therapy helps many patients. Taken together with the positive data from basic research, many doctors would combine these two elements into a success story with the headline: “Scientifically proven: bio-resonance therapy is effective.” But is that true? A skeptical scientist will probably see a different story and will want to also see other types of data. Once again we see that everyone needs different information to come to a conclusion. In the next chapter we will discuss what kind of data the skeptical scientist wants to see and whether the existing clinical research data would be sufficient in order to consider the effectiveness of bio-resonance therapy.

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