Discussion: Why may research into homeopathy be practically acceptable?

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ALASTAIR J. CUNNINGHAM:

An objection that is so obvious that you must have considered it is that the application of criteria you proposed prevents any possibility of change in theory. I want to ask you specifically about my own interest; there are now two randomized trials that show that forms of psycho-therapy prolong the life of cancer patients. Is that so improbable as to be dismissed, or does it lead to further investigation of possible mechanisms?

JAN P. VANDENBROUCKE:

Things can be adopted empirically, and, thereafter, theory might change, of course, theory changes all the time. We only live with the *theory of the moment*, I have not expanded that idea, and the people who were surprised by fox-glove had the theory of the moment that the edema was due to the constellation of the stars. That theory changed.

KICHIIRO TSUTANI:

How do you think, to let people and physicians use unproven therapy, is this ethical? To allow the continuation of unproven therapy is one thing, and another to start a randomized controlled trial using patients and physicians and hospitals without a relevant rationale; I don't know what's more ethical.

JAN P. VANDENBROUCKE:

The randomized controlled trial can only be performed by physicians who doubt and who can tell their patients that they doubt, that there is genuine reason to doubt; if you do not doubt you cannot accept randomization, and there are many examples of that in regular medicine. Ten or twenty years ago, there was a randomized trial of laser therapy for diabetic retinopathy and some people were extremely convinced that it worked and they didn't want to

randomize their patients. Only the doubters started a trial, which was ended after the pilot phase, as it worked overwhelmingly. So one part of them had been right, but the doubters were right, as well, given that there was too much uncertainty. When there is surprise and when you doubt, you should do a trial.

ANONYMUS:

Ich verstehe, dass man nicht über alles einfach Studien durchführen kann und man eine Auswahl treffen muss. Dennoch scheint mir die erste Frage von CUNNINGHAM nicht wirklich beantwortet. Es kann ja sein, dass die Homöopathie als Theorie völlig falsch ist. Sie haben aber selbst das Beispiel der *Acetylsalicylsäure* angeführt: Es wurde gegeben, um Fieber zu senken, obwohl die Wirkungstheorie dazu völlig falsch war. Die Theorie kann völlig falsch sein, aber trotzdem kann die Therapie wirksam sein.

JAN P. VANDENBROUCKE:

Now you're asking me to stretch my imagination even further. I am asked to accept not only a principle that has been applied for more than 150 years from a time where no physician was really surprised that it has such tremendous results but also, as you say, I have to discard the theory upon which it is built in order to submit it to proof. This is stretching the whole thing quite far, I think.

JOHANNES G. SCHMIDT:

I really enjoyed your provocative speech very much. However, I don't believe there is a thing such as a *white* or *black box*. I believe that there are only *grey boxes*, light grey boxes and dark grey boxes. How grey a box is, then, has very much to do with the experience and level of expertise which a person has with the theoretical system he uses. And you brilliantly explained it to us that there is a constant interchange with experience and theory, deduction and induction. In some instances, we have an almost black box and yet we dare to go on with it and something good comes out. And then we have a historical period of a certain therapy, where we are much more on the white part until it becomes so dogmatic that we forget the constant need of re-evaluation in practice. Only an interchange of white and black can create and maintain good results.

JAN P. VANDENBROUCKE:

It's a kind of ping-pong game between theory and practice. The practice gives the ball and the theory has to accept and vice versa. I think we agree sufficiently.

RICHARD E. STEELE:

One issue is very difficult to deal with in this context and there's no doubt, I think, that all of us in this room would accept that there are certain aspects of what you are speaking about; established practices that have been shown to have an effect through randomized controlled trials, blind trials, core studies, the kinds of studies that are used for accepting or not accepting on the bases of their internal or external merits. But that's not the issue that we're dealing with in this symposium, and especially within the workshop context tomorrow, which is not going home and doing what we all did before and in the same way we did it before; either on the biomedical or the research side, on the homeopathic side, on the psychotherapeutic side, but trying to find some common ground, trying to move into this sphere of: well, how can we use these things together, (conventional and unconventional) theory and practice? How can we move our understanding of the *gap*, which indeed you address, but do not synthesize. I wonder whether you have some thoughts going further into this question, and would very much hope that everyone keeps this in mind tomorrow during the workshops, so that we come away from this with something more than just going back to what we did before we came here.

ALVAN R. FEINSTEIN:

It seems to me that the main problem with principles here is the infinite dilutions of the homeopathic remedies. With any other substance, whether it be an extract of a flower, or of a tree, there is a substance there, but with the infinited dilutions, it's hard to believe that there is anything there. Are there other forms of complementary or alternative therapies that you would rule out, in the same way as you would rule out homeopathy, if there were substantial *observations* somewhere, that people seem to get better after this treatment? For example, the dance of a witchdoctor, I can't think of how, if you throw darts, or put pins into the image of whatever you're trying to do away with, that principle is somewhat hard to believe also. When I think of all the different alternative medicines, what makes homeopathy so difficult to accept in principle is the idea that there is something there after all the infinite dilutions are done.

JAN P. VANDENBROUCKE:

Well, I have two criteria to say no. One is when the principle cannot be right, and there homeopathy is a prime example, but the other is when there is no surprise improvement. If there is something that I do not understand, but which does not go against established principles, but there is also no physician telling me that he is surprised, then I walk past as if nothing happened.

GEORGE DAVEY SMITH:

It seemed that you were not just talking about homeopathy when introducing the criteria. Maybe what you are saying starts with a notion that people who are going to organise trials are actually the people who determine how therapy is going to be introduced. Yet, the situation might be different. If you are actually faced with existing use of therapy - therapies are obviously going to be introduced. In the US, in the mid 80's when HIV disease became prevalent, a large number of alternative treatments, megadoses of vitamins etc. got introduced and whole networks arose of lay people who started to educate themselves in science, and yet the people involved in setting up trials refused to start the trials. All their interests were in AZT and other anti-retrovirals which have not been proved to be too effective. It would have been much better in that situation to study the many treatments which were in fact introduced by the patients. Even if there is no great theory behind these many unorthodox treatments, one could identify important elements to allow another more specific trial. Something could have been learnt, it was a huge opportunity. Now, in 1993, the result is that there is no really useful therapy for people with HIV disease. The surprise is not the only thing, if treatments are in fact applied we should be pragmatic and do trials.

JAN P. VANDENBROUCKE:

The argument is often forwarded that as a service to society, these studies of treatments which are practiced should be done. But where is the beginning and where is the end? How many candidate substances should be put to trial? There are perhaps thousands, where should you direct your resources? What you in fact suggest are quick phase I trials, and this is close to looking for the element of surprise.

Andrew Herxheimer:

The question about the legitimacy of randomized controlled trials, in the context of our discussion I think, does involve civil liberty and self-determination. If homeopaths want to be accepted scientifically they have to do randomized trials, and the trials have to demonstrate an effect. If they want to do it then nobody should stay in their way. No-one else is obliged to do the trials for them. In order to prevent the situation of a sheer game of chance, however, they must register all trials at the start. If not only the positive ones get published the chance effect will become a non-problem. But the records of the studies must be accessible so that they can be analysed collectively, combined, and the correct conclusions drawn from the whole collection. If these requirements are met, any group with a particular therapy can do studies which are founded on truth.

C. Willem Kramers:

I want to ask Prof. Vandenbroucke if he really thinks that alternative physicians cannot be surprised, but only regular ones.

Jan P. Vandenbroucke:

The surprise of an alternative physician often is found only if treatment did not work.

Johannes G. Schmidt:

Dr. Vandenbroucke very nicely described the interaction between theory and practice and how practice evolves from that. And I said, a black box has not the same darkness to everybody. Myself, I was often quite surprised about the effects when I started to use acupuncture in my own practice. That is why I feel it is worth doing randomized controlled trials. My suspicion is that Dr. Vandenbroucke was overly provocative on purpose, and I thank him for that. It helps to reduce the complacency and the over-enthusiastic beliefs often found among unconventional practitioners. It helps to go back to the facts, away from too many dreams which will not bring us any further, and to a calm kind of discussion. In the workshop tomorrow, we will of course allow ourselves to discuss the value of randomized trials in unconventional medicine [see the contribution: *Measuring the efficacy of acupuncture medicine* on p. 203»].

Now about the dilution: If John Snow had not dared to go on with his black box idea of an invisible «germ» in the water he would not have succeeded – Jan

VANDENBROUCKE might say that it was not a black box, but for the establishment at that time it was a black box. It may also have occurred that his ideas had turned out to be wrong, but he dared and eventually was proven right. You never know beforehand, that is the funny thing about life, you only can dare.

JAN P. VANDENBROUCKE:

The account on JOHN SNOW you have just given is that of the «black box epidemiologists». They say that 30 years before the discovery of the cholera germ, by mere observation, he developed his succesful prevention. However, the truth is different. The truth is that JOHN SNOW was a believer in the germ theory. By conceptualizing the mechanism of transmission he concluded that the disease had to be transmitted by something in the water. He acted according to a pure theory, and his first observations initially rather seemed to refute his theoretical asssumption, but he went on until he collected the right sort of observations.

JOHANNES G. SCHMIDT:

You are of course right, DR. VANDENBROUCKE, except perhaps for the interpretation whose black box it was and whose not. It was not a black box for JOHN SNOW, but it was a black box for many of his colleagues and for much of the established theory. Acupuncture, for example, is not a black box for me, but perhaps for you and the established theory. We cannot resolve this by a majority vote or consensus, because only adequate trials, only the future, will prove who is right and who is wrong. Your persistent scepticism, however, prevents us from being over-enthusiastic and from doing biased research. Thank you for that.

Further reading

BRUCKMAN R, LEWITH G. What does homeopathy do - and how? *British Medical Journal* 1994; 309: 103 - 106