

How do European consumers profit from Evidence Based Medicine (EBM)?

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I was asked to talk about the topic “How do European consumers profit from Evidence Based Medicine?” Maybe I am the least qualified person to talk about that. You wonder why?

It is so

1. because I do not consider patients mere consumers but rather partners in the period of convalescence. I can, however, imagine that there are doctors and scientists alike who think of patients as consumers and who have a different understanding of Evidence Based Medicine.
2. because the principles of effectiveness control concern the innermost core of medical thinking. Thus, we are dealing with far more basic topics than EU consumer protection.
3. as a critic of EBM I am not in the position to tell you how patients profit from EBM. I do, however, want to tell you and I can tell you why I am of the opinion that modern EBM is only of limited importance to medicine in general and even less to naturopathic treatments.

First of all I would like to highlight the fact that the disputes about “EBM and naturopathic treatments” are held on quite low scientific levels. This has changed in recent years on the part of naturopathic treatments, though not completely voluntarily I must admit. But on the orthodox medicine’s side, the scientific level is still unfortunately pretty low. The Lancet-article on homeopathy which presumably you all know has shown this very well (10). This should not hinder advocates and users of naturopathic treatments, and I include you in this group, from further improving their own scientific knowledge. I would like to advise people strongly not to use the complaisance of statistics for economic and other interests as an argument such as “everyone invents a statistic at their convenience”. Of course what I call the “human factor”, the manipulation of results so to speak, is a grave problem in medicine. Particularly the pharmaceutical industry has various means to wield influence which leads to a situation far away from of every evidence based state. Especially supporters of EBM are trying intensely to control this problem. Although the “human factor” is a big problem for the EBM, it is not the essential criterion for criticism when it comes to naturopathic treatments. I would like to show you some examples to highlight my point of view. Each example

illustrates deeper rooted theoretic-scientific difficulties, but due to a lack of time I cannot go into greater details. To a certain degree we are dealing here with an expanded catalogue of theses.

1. Those who cure are not necessarily wrong

Often patients go to us and hand us a huge bag of their evidence proven medication; medication that they had to take for years without their symptoms or illnesses being cured radically. If now after one year of naturopathic treatments patients do not have to take medication anymore and if they are cured, then this is not a proof of the efficiency of naturopathic treatments. It is, however, a proof of the effectiveness control having problems.

2. The impossibility of individual statements

Statisticians report particular difficulties that accompany randomised surveys. Simpson's paradox is probably the funniest of them. It states that the probabilities that are true for two individual populations do not necessarily have to be true for these two individual populations together (7). This means that something that in a study for women and in another study for men has been proven good, can still be bad for the people altogether (1). Another example: if therapy B turns out to be better than therapy A and if another study shows that therapy C is better than therapy B, then it is a logical fallacy to believe that therapy C is better than therapy A (2). One more of the several statistic problems is that statistics can only make statements on defined populations but not on individual cases. In fact, modern medicine has no means to make individual predictions on scientific bases. Those criticising the statistic approach once said, "Big numbers lead to a statistically exact result – but no one knows if it is going to be true. Small numbers lead to a statistically unusable result – but one knows better in this case who this applies to. So it is hard to say which of these forms of ignorance is the more unusable (4)".

3. What might be helpful in the short run, might be harmful in the long run.

I would like to illustrate my next point with some studies.

- when a lateral epicondylitis is treated, it could be shown that an injection with cortisone leads to a significant improvement of the disease pattern in the short run. On a long term basis, though, this therapy is remarkably inferior to a physiotherapy or the simple waiting for convalescence (22).

- A study concerning devices for babies to learn walking shows that so called Baby-Walkers help infants adopt an upright posture, but these infants learn to stand and walk later than infants not using Baby-Walkers (14).
- Babies treated with antibiotics in the first six months of their lives have a greater risk of suffering from allergies later on. This statement is not undisputed, however (5).
- Premies who receive enriched food are more likely to develop an insulin resistance than those who are fed with breast milk or baby formula milk. That means that the quick reaching of a reference level is not healthier (21).

If the principle of “helps in the short run, harms in the long run” was spreaded more widely with the help of existing definit theoretic models, then those studies only spanning a couple of months (most of them) and proving the efficiency of a therapy, were nothing less than a manual to act harmfully.

4. The more affecting the context or surroundings, the more specific the efficiency

Another phenomenon is supposed to be exemplified by balneology. Those of you who have already been at old spas and got some treatments know the healing effect of a beautiful architecture und its corresponding ambience. It conveys the feeling of internal dignity. Unfortunately, however, nowadays balneological treatments are given in merely functional buildings that have no charme at all. In such settings specific parts of aspects are examined in an evidence-based manner. One example is which effect certain exercises have on the mortality of patients suffering from a left-ventricular systolic dysfunction (12). What is the use of these studies? Are they indeed independent from external frameworks? And what is more, what should we think of a medicine that considers beauty and dignity at best a placebo effect? What you hear is not the sigh of an aesthete. We are rather dealing with a significant scientific problem. In an experiment with hamsters it could be proven that wounds heal quicker if the hamsters were left in their normal social surroundings. When put into a glas tube, their wounds initially got worse (11). If thus in such a setting the efficiency of a healing substance were examined, it could in the first instance be manifested a placebo, but in the second instance a specific effective medication. This means that a substance will seem the more effective, the more harmful the therapeutic framework is. The contradiction of hospital-based research (glas tube) and a general practitioner’s treatments has unquestionably been discussed in medicine already, but the thinkings in this context were not thought through to the end. Since most of these

treatments result in a positive therapeutical ambience, this problem is of even higher importance to naturopathic treatments.

5. Adaptability versus rigidity

Ever changing contexts play a role in a different respect as well. Beta blockers are good for several illnesses (evidence based), ranging from hypertension to glaucomas and states of agitation. A side effect is the lower ability to adapt to heat. A heat stroke is more likely to happen (8). If climate change leads to hotter summers, then the positive effect found in studies would be gone instantaneously. This implies that a well measurable effect leading to an improved adaptability could be devastating if circumstances changed. A hardly measurable effect, on the contrary, leading to an improvement of one's adaptability could be of great use under certain circumstances. So, what might be helpful in one context might be harmful in a different context. This means that randomised studies cannot differentiate between rigidity and adaptability.

6. Learning in higher order

I would like to present a logical instrument to you that is apt for illustrating this process more accurately, that is the different orders of learning as introduced by Bateson (3).

- Learning of the order 0 exists if a unity shows only little change or none at all in its reaction pattern after having been exposed to repeating stimuli. This form of learning can be found in simple automatic regulatory circuits or if an organism is overstimulated or if a stimulus answer is determined structurally.
- Learning of the 1st order is what we typically consider learning. It is Pawlow's learning theory that can be examined under laboratory conditions. Learning a language belongs to this category as well.
- Learning of the 2nd order is learning to learn. When learning a foreign language, one learns to learn other languages more easily. Learning of this category can be found everywhere, but it is not necessarily more positive. If for example a person has a bad experience when learning a language, he or she might be reluctant to learn another one, so that learning another language results more difficult or even impossible. The problem is that learning of the 2nd order cannot be discovered through simple measurements. Rather a row of measurements are needed and needless to say a corresponding theory.

- Learning of the 3rd order is characterised by basic changes that go beyond what is actually supposed to be learned. A change from a linear solution-oriented thinking towards a systemic thinking aimed at problem solving is learning of the 3rd order. It is not about contents anymore but rather about a basic evaluation of contents.
- Learning of the 4th order would be a change of the learning structure and includes morphological and genetic influences.

In the medical context for example, the acquisition of a specific immunity is learning of the 1st order. If resistance against other infections in- or decreases due to an infection at the same time, then we are dealing with learning of the 2nd order. If a chronic disease deteriorates or ameliorates through such an infection, then it is learning of the 3rd order. The last category would imply the epigenetic consequences of such an infection. The basic problem is that current medicine only knows learning of the order 0 and the 1st order. The learning of higher orders will be eliminated from the observation framework as an unspecific effect although it surely is absolutely specific.

Randomized studies concerning naturopathic treatment

Randomized studies are designed in a way to examine the effectiveness of a specific intervention on a sham intervention in a defined setting. This setting, though, does not coincide with the setting of the naturopathic treatment. The keyword is individualization. I would like to illustrate that by the following example.

Even a simple massage has to be individual for every patient and every patient needs his/her individual dose, otherwise the massage can not be successful. What is good for one person can be harmful to another. So how to evaluate a study which compares the effect of a standardized physiotherapy (massage, warmth, cold, etc.) with the simple, standardized instruction to stay active? The result that a physiotherapy is not superior to a simple advice, might not be of great relevance. What is important, however, is, that both treatments, standardized therapy and standardized advice, are bad medicine. Considering this form of effectiveness control for naturopathic treatments, one could set the following rule-of-thumb: The worse the practiced medicine, the better a study in its methodology. Basically the common studies measure a form of naturopathic therapy which does not comply with real conditions. The concept of a specific causative factor in a specific situation is, in most cases,

not suitable for procedures which most of the time are aiming at an unspecific activation of self-regulation. Of formal logic, studies can only lead to statements about things they examine. The above described physiotherapy study thus only proves, that this form of standardized therapy is not superior to a simple advice. Even if a potentiated house dust mite does not show a better result than a placebo, concerning a house-dust allergy (17), this does not prove anything about potentiated substances, nor about homeopathy. In the same way, a study which does not show a positive effect of acetylsalicylic acid on breast cancer (9), cannot evaluate the effectiveness of acetylsalicylic acid in general, and a fortiori it cannot give any information about the effectiveness of pharmacotherapy in general. Nevertheless wrong conclusions like that are the order of the day. In logics we call that “violation of the logical typecast” (19). If one class (therapy) is put into the same category with an element of the class (specific intervention), then a paradox situation is created, which is no longer able to give a reliable statement. The idea of examining a whole procedure with only one study therefore is a significant problem.

Of course, there were attempts to adapt studies to the naturopathic treatment setting.

The Munich headache-study (23), for example, fulfilled the preconditions of statisticians and homeopaths a priori.

Patients with long-term headaches, (average duration of illness 23 years), were treated in an individualized way. The result was that the individually designed homeopathic remedy did not show a better effect than the placebo. With the wisdom of hindsight, the homeopathic side of course, like always when a study does not show the desired results, raised a number of objections. The study was too short; the cases were too difficult for the simple scheme of the study, etc. In this context it does not matter if those arguments are valid or not. What is important is the fact that the homeopathic treatment in principle (remedy and placebo), was effective for almost a fourth of the patients. This is really interesting, because a number of studies on acupuncture came to a similar result (6, 18, 20): Both therapies, remedy and placebo, are effective, but the real therapy with the remedy is not or only slightly superior to the placebo therapy. That means, homeopathy and acupuncture are effective forms of therapy, which are able to control long-term pain in a cost-efficient way and with little side effects. But they don't do that in a specific way.

According to the common logic, the medical standard treatment should be deleted from the catalogue of benefits of the statutory health insurance companies because its results are worse than those of an unspecified placebo therapy! Of course nobody would take such a demand seriously. And it is absurd. That is because it is based on wrong conclusions, for example the

Simpson paradox. But also the reversed conclusion, that naturopathic treatment is ineffective, is impermissible in the same way. Therapies can be effective although they are ineffective – this is a phenomenon that occurs if the logical typecast is violated, that means if the class (procedure) is mixed up with the element of the class (specific therapy). In general that means that the results of these studies neither prove the effectiveness nor the ineffectiveness of naturopathic treatments. At best they prove that this type of effectiveness measurement, due to logical reasons, is not appropriate to reach a solid result.

Conclusion

Randomized studies are known as the gold standard of EBM. But in spite of the enormous triumphal procession of EBM, there are a huge number of second thoughts pointing to the limitedness of this approach. With this type of effectiveness measurement, basic topics like adaptation, individual transferability, and evaluation of complex and/or long-term processes can only be evaluated inappropriately.

Randomized studies are the appropriate means for a medicine mainly aiming at the eradication of symptoms.

For regulative processes in which the appropriate stimulus for an individual is chosen, the main procedure of EBM is not very useful; this is because in so called network pathologies the same stimulus can cause either amelioration or deterioration. The question which remedy or procedure is more effective concerning headaches is not so important in this context. This completely different understanding of health and illness can not only be found with naturopathic treatment. The more recent research studies about immunology at least point at the fact that the conventional understanding of illness based on simple path physiological descriptions or even on the counting of criteria, is an end-of-range model. What kind of design the effectiveness control in such a regulative health model, in contrast to a path physiological illness model, might have is quite hard to say. In my opinion it should be a dynamic procedure that can shape transformation processes. If one is to continue to call such a type of effectiveness control, which completely differs from today's type of control, EBM, depends on one's personal taste. I personally rather tend to not burden a modern understanding of medicine with old terms.

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