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An attempt to distinguish science and proven experience

Niklas Vareman

One thing we have learned in this research program is that vetenskap och beprövad erfarenhet (VBE) – “science and proven experience” – is understood in many different ways. Proven experience is seen to range from mere collective accepted practice to the property, belonging to an individual, of being “proven” in their profession. In between, moreover, lies something emanating from practice but severely tested, or something severely tested in the practice (Persson and Wahlberg, 2015). In general terms, we can perhaps characterize proven experience as what you have when you entertain a firmly held belief in the effectiveness of a certain treatment.

Theoretical studies have dug into the relationship between evidence-based medicine (EBM) and VBE, and asked what the “and” in science and proven experience might actually mean (Persson et al., 2018). One thing we have not said much about is how to understand what the distinction between science and proven experience is. This text is an attempt to deal with this question.

The distinction could be one of methodology – that there is a method that is typically scientific, and that proven experience is achieved through means other than this scientific method. Alternatively, it could be one pertaining to the kinds of question that one wants to find an answer to – science perhaps deals in “why”-questions, while proven experience is about establishing *that* something works, that a treatment is effective, and so on. I will in the following try to say something about these ways of understanding the science and proven experience distinction, but I start with an example.

ARDS, TPE, Covid-19 – an example

In an editorial in the journal *Critical Care* earlier this year (Keith et al., 2020), Philip Keith and his colleagues suggested that therapeutic plasma exchange (TPE) could be used in the

treatment of fulminant Covid-19. In early spring 2020 the pandemic was in its infancy with 100 000 people infected and 3300 dead worldwide, but the urgency of finding effective treatments was of course acutely known.

Fulminant Covid-19 can cause several critical states. Keith and his colleagues mention “sepsis, acute respiratory distress syndrome (ARDS), and/or multiple organ failure which are not unique to coronavirus” (Keith et al., 2020).

The case for TPE in fulminant Covid-19 is made in several steps. First, some success in treating patients with plasma from those who had survived the illness had been reported from China, and plasma transfusions are not novel treatments so there is no obstacle to using it in that respect. Second, TPE is known to be effective against the mechanisms in play in many of the states that can obtain in fulminant Covid-19. Third, a randomized controlled study had shown “a tendency toward improved mortality” (Keith et al., 2020) when adult sepsis patients were treated with TPE, and the same tendency had been found in a meta-analysis. Fourth, TPE was used on three children in the 2009 influenza (H1N1) pandemic, all in situations not unlike that created by fulminant Covid-19, where mortality is high. They all recovered “after receiving rescue TPE”.

The authors conducted a single-center retrospective study of the TPE treatment for sepsis where the patients required mechanical ventilator support, and this gave positive results, especially for patients whose sepsis was the result of pneumonia. They write: “Our practice has changed based on our experience, and we now often utilize TPE earlier in the clinical course of septic shock with [the multiple organ dysfunction syndrome] MODS and ARDS rather than as ‘rescue therapy’.” And further: “Anecdotally, the results have been remarkable but have not been reviewed or statistically analyzed.” (Keith et al. 2020).

They conclude the editorial with the observation that TPE “shows promise” and remark that it would be worth doing randomized trials in order to “investigate further”.

There is of course a lot of science here, but also experience and some of it perhaps proven. We learn that TPE has been used as “rescue therapy” (because of results from a few studies

that are not exactly relevant to the situation at hand); that it was then systematically evaluated in a small retrospective study; that the practice was modified on this basis (if I read them correctly), with TPE then being applied earlier in the sepsis process; and that, in order to be sure, randomized trials ought to be conducted.

So, is the experience proven, and if so, when did it become proven? And what in this example is science, and what is proven experience?

Scientific methodology as distinguishing feature

In the TPE case, the authors use the treatment in their practice and test its effectiveness in a single- retrospective study. So, they have the experience, and they have tested it by analyzing previous cases in their own hospital. It seems they have proven experience, then. They also see the need for randomized studies. It is not all that far-fetched, if this was in a Swedish setting, to see the need for randomized trials as that which is needed to arrive at VBE – to add science to the proven experience. The reason would in that case seem to be that a single- retrospective study is not science, while a randomized controlled study is. Both kinds of study try to answer the same question. Each evaluates a hypothesis that is present as a rather firm belief. Their methodologies differ, however. The randomized trial, which will handle problems with bias better than the retrospective study, is more scientific. Perhaps it can even be said to be science while the other is not.

Or we could accept that the retrospective study is actually science too, and that the proven experience was present already when it was conducted, so that the study issued in VBE. (Would we then say that the randomized study issued in even better VBE?) Perhaps it was some combination of the results from the H1N1 study on three children together with the practical application that made the experience proven? But even that small case series involved systematic handling of a set of observations, the comparison of outcomes with a baseline, proper handling of data, etc. All these are marks of a scientific methodology, albeit more vulnerable to bias than the retrospective study.

It is difficult to see how a clear distinction between science and proven experience can be drawn in terms of methodology if it is part of the concept of proven experience that something has been properly tested, since testing will typically involve systematic study of a phenomenon of some sort. (I realize it is possible that no such distinction is to be found.) And what is more, such a distinction, cast in terms of methodology, is not adding anything useful in comparison with the situation where we have only well-proven experience. The question is only whether the experience has been tested enough. Is a case study of three patients enough? Is a single- retrospective study adequate? Or do we require an RCT in addition? What kind of study suffices will depend on what it is possible to do, as well as on how obvious the effects at issue are.

The questions needing answers

In a loose sense, every systematic study of phenomena, every systematic search for new knowledge, can be called science. What the knowledge consists in can differ. It can be to know *that* there is a causal relation between two phenomena, on any given level of complexity, or it can be the search to say what that causal relation is (by screening off certain aspects of the phenomena in order to isolate the cause). In other words, to explain *why* the phenomena are related the way they are. Let us for now entertain the idea that what science is ultimately after is understanding – in conducting science we want to know *why*.

I take it that our interest in proven experience is an interest solely in knowing *that* some treatment is effective, or that the treatment causes the patient to be healthier than she would have been without it. Why the treatment causes the patient's health to improve is not the important thing here. To know that it works is enough.

The experience is a practical experience. Proven experience is learning, coming to know, by doing. But not only by doing – that would only be to pile up experiences, one on top of the other. Somehow this pile of experiences becomes a *proven* experience, a conclusion as to what these experiences, taken together, as a whole, tell us. How does that happen? In more

than one way, presumably: From an unconsciously formed conviction, a firmly held belief, that the treatment is effective, or through conscious observation that a satisfactory proportion of patients do not come to see the doctor again (or perhaps something like the “remarkable” results reported in Keith et al. (2020)). Or the experience of the effects of the treatment can be systematically tested through a single-center retrospective study, or even a randomized trial. The result, in any of these cases, is proven experience in the sense that the those with the experience have used the treatment and, for some reason or other, come to form a strong belief that it is effective, become convinced that it works. How this belief is formed depends on how severe one requires the test to be (and on how obvious the effects are). One practitioner may settle for the look on the patients’ faces when they leave the hospital. Others may challenge this and claim that experience of that kind is not proven after all. It takes a more rigorous kind of testing, they will argue, for it to be *proven* experience. Perhaps setting up a registry would work, or designing and running an observational study on one’s patients, or even performing a randomized trial. Perhaps the way alternative medicine is viewed, in Sweden at least, could serve as an example here.

But then, one might ask, what happened to science? Clinical research seems to have been all but disqualified. And, yes, so it has. In this picture science has retracted to the kind of activity that involves trying to sort out the inner(most) workings of things: Basic science, bench research. Perhaps, again, the whole meaning of VBE has been lost? Hospital legal teams will not need the “V”, the science, to sort out whether or not there was malpractice, surely? What they will want to know is whether the treatment was safe enough, effective enough. Why it works and the way it works is not of much concern to the court. Well this is true I suppose. Nonetheless, in an indirect way science does enter the picture in here. Consider a new treatment that has not yet been introduced/accepted in ordinary practice. Here the basic science on which the treatment is founded can be an argument in favor of the reasonableness of using it.

It is even better, of course, if some randomized trial has been conducted with promising results. This trial will not perform the same function as it did in the proving of experience. Here, it is instead a test of the implementation of a scientific hypothesis, from micro level to macro level, cell to whole human. The study is a tool that can be used to test the experience

of an intervention/treatment/action – to show whether it is as effective as we believe it to be (or not to be). Or it can be used to test whether a mechanism found through science can be expected to do the same work in a whole human body as it has been found to do in individual cells. Same kind of test, but for different purposes.

These are cases where there is either science or proven experience. What is the value of having both? With a treatment that is already in use, having a firm belief that it has shown to be effective, and a justification of that belief, seems to be all that is needed. But if this belief is certainly given substance when it is backed up with an argument as to why the treatment may actually work, as opposed to an argument showing that the treatment's effectiveness is robust. And the science here has another use: Having a grasp of the basic mechanisms at work makes it possible to extend the treatment to other areas of use. As Keith et al. (2020) report: The knowledge that TPE "uniquely offer[s] benefit on multiple levels by removing inflammatory cytokines, stabilizing endothelial membranes, and resetting the hypercoagulable state" is an argument in favor of using TPE on patients with Covid-19. The rather weak proven experience gleaned from the successful treatment of the three H1N1 patients further strengthens this belief, as does the added proven experience the authors themselves have of treating sepsis caused by pneumonia. But an important part of the justification for using TPE comes from the conviction that it works on the (many) mechanisms that are in play in fulminant Covid-19.

Conclusion

Methodology offers a poor basis on which to draw a meaningful distinction between science and proven experience – partly perhaps because it is difficult to pin down what a scientific methodology actually is, but mostly because such methods are methods of obtaining or attaining *something*. It is that something – at least, to my mind – that could be different things in the two cases. In a court of law, the evaluation of evidence will look rather different depending on the issue being adjudicated: Is it a question of establishing whether a treatment that is actually used, and where there is practical experience, *should* be used, or is the question instead whether a treatment of which nobody has any real practical experience was used in an acceptable way in the case at hand?

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