Unusual Claims, Normative Process: On the Use and Stringency of the Scientific Method

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'... The use of hypotheses lies not in the display of ingenuity, but in the labor of verification'

T.C. Allbutt [1]

Do unusual claims require extraordinary proof? A scientific claim is evaluated through application of the scientific method. This involves experimentation (most rigorously in comparison to some form of control) and/or observation. Analyses and descriptions can be quantitative or qualitative, but adherence to stringent criteria to ensure validity of method and outcomes is essential. Claims that have been evaluated by this method are then disseminated through publication and/or presentation so as to be independently tested by other scientists. If such tests support the original claim, then, following a sufficient but indeterminate number of successful replications, the claim and any accompanying hypotheses and theories may be added to the scientific lexicon. If such tests fail to support the original claim, it is questioned and rejected (usually following a lesser number of replication attempts than is required to accept or sustain such claims). These results are commonly considered as 'proof' among the non-scientific, lay public. However, this is a misnomer. The process of discarding and/or accepting scientific claims is one of convergence upon 'a truth' that is subject to change as a consequence of scientific knowledge itself. Therefore, scientific claims and the truths they seek are always tangential. Unlike a mathematical proof, scientific claims and accompanying hypotheses and theoretical bases are always subject to scrutiny, challenge and revision, based upon both ongoing evaluation of the claim, and intellectual understanding of science and nature, at large.

This is true for unusual claims as well as the more mundane. To suggest that something further needs to be applied to scrutinize an unusual claim is to misunderstand the principles of the scientific process, and scientific philosophy. It is of course a truism that all important or groundbreaking claims are by definition 'unusual'. The elegance of the scientific process is

that it addresses and evaluates all claims and discoveries identically. The process itself is progressive as Joshua Roebke claims '... science is ... an unending courtship, flirting ever closer with the absolute truth it desires though may never attain' [2]. The scientific method, though rigorous, is not perfect. But, as Roebke notes, may be '... the best tool humans have for discerning facts of the world ...' and 'its utility, *despite* its limitations, earns it our trust'. The process of peer review is only a first step toward solidifying such trust and participating in that courtship.

In this issue, such attention may be directed to somewhat 'unusual' scientific claims regarding outcomes and mechanisms of homeopathic treatments in which it is claimed that medicinal value may be found in solutions that do not contain the active ingredient. This seems contrary to the established theoretical understanding of pharmacobiology. However, the scientific approach is not to reject a claim simply because it seems implausible or unorthodox. Rather, the scientific approach is to test the claim. Historically, there have been numerous examples of scientific claims that were considered implausible, unorthodox, if not impossible based upon the epistemology of the time and/or culture, but were subsequently validated (e.g. heliocentrism, germ theory, etc.). In hindsight, we recognize that it was our understanding of both the claim and the natural world that was flawed.

In this issue of FORSCHENDE KOMPLEMENTÄRMEDIZIN, Pathak and colleagues seem to have made an implausible claim – that an oral solution with none of the putatively active molecule present can significantly impact the course of hepatic neoplastic disease in a mouse model [3]. They have tested this hypothesis in their laboratories and maintain that there is evidence to support their claim. They have described the conditions under which tests of this hypothesis were performed and have submitted their findings to peer review pursuant to publication in this journal. This is the scientific process.

To be sure, the scientific model is one of inherent trust. We must trust 1) that the authors are truthful, not intentionally deceptive, and actually did what they claim; 2) that reviewers were selected based upon their experience and expertise; 3) that these reviewers were objective and unbiased and 4) that the scientific community is able to rely on published methods and results as a pediment to further analysis, scrutiny, replication, and ultimately consideration of the value of the authors' reported findings. This process of trust is the basis for the larger fiduciary relationship between science and society which upholds science's value as a public good.

At this point, there is nothing more we can ask of the authors as scientists. It is now up to the scientific community to test their claims. Deriding their claim simply because it seems implausible is not part of the scientific process. Such derision may reflect vested interests, and may lead to deterministic thinking. This is dogmatic and contrary to scientific philosophy and method. If, in fact, independent replications fail to support the authors' claims, it is their responsibility to respond and engage any and all refutations with evidentiary facts to support and sustain their claim, or revise or rescind their hypothesis. This journal is committed to publishing these developments. The resulting debate among scientists, with time, will lead to the truth, or at least some construct of 'truth' as defined by and reflective of current, changing epistemic capital. The study reported in this issue by Pathak et al. addresses the genetic and biochemical consequences associated with a homeopathic remedy. It is somewhat surprising that every measure employed responded to homeopathic treatment. In our experience there are usually some effects that are not what one expects. The authors appear to be fortuitous in that each measure supports a genetic mechanism as the basis for the anti-tumor effects observed. Also, anti-tumor effects are quite potent. Be that as it may, biology is often seemingly paradoxical, difficult to interpret, and only independent replication, and framing these results within those of other studies – and approaches – will adequately test these claims, and allow realistic insight to outcomes and mechanisms.

But this may speak to a secondary problem that may be near(er) to the heart of the matter. There is a pervasive tendency against publishing negative results. Given that there is a paucity of mechanistic explanations for many of complementary and alternative (CAM) therapeutics (and particularly the claims made by homeopaths and homeopathic researchers) it may be difficult to develop insights to physiologic mechanisms upon which further studies may be conducted [4]. As well, in light of the fact that mechanistic understanding of several CAM therapies remain unknown, and the adversity to publishing inconclusive or negative findings (as well as the relative impact that such publications might be considered to incur

upon professional standing), many scientists are unwilling to engage in such research for fear of stigmatization. Additionally, it may be that there are too few scientists that are sufficiently trained in CAM approaches to allow thorough understanding of conditions necessary to accurately reproduce particular experiments and findings [5].

A recent issue of *Nature* (March 22) highlights the possibilities of placebo effects in homeopathic practices, stating that: '... for advocates of evidence-based medicine, [the claim by some homeopaths that double-blind, placebo-controlled, randomized trials undermine the homeopathic process] are equivalent to admitting that homeopathy is nothing more than a strong placebo effect ...' [6, pp 352–353]. The work of Pathak et al. prompts this question; as they openly admit, the animal handlers were not blinded to the treatment conditions of the animals. These same individuals provided the daily oral gavages used for administering the remedies. In a clinical trial this would establish what is widely accepted as the perfect conditions for a placebo effect. Could this be an operative mechanism in these (animal) studies as well? We must consider that placebo effects reflect conditioned physiologic responses by several factors including genetic predisposition(s) and environmental (experimental or clinical) interactions. There is evidence in the literature for a placebo effect in animal studies. However, the authors do not consider this as one of the possible mechanisms ...

Perhaps one of the 'best' results of unusual findings is that they may stimulate not only scrutiny but new ways of looking at the problem, outcome(s), and/or mechanism(s). Philosophically, science, while doctrinal, is inherently anti-dogmatic in that it affirms the obligations of self-criticism and self-revision. The beauty of the scientific method is not simply that it is dialogical but that it is designed to compel true dialectic, and as such is encouraging of discovery and progress. Let this stand as an invitation; let the dialectic begin.

References

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