

Rules versus Standards: What Are the Costs of Epistemic Norms in Drug Regulation?

David Teira (UNED, Madrid)

Over the last decade, philosophers of science have extensively criticized the epistemic superiority of randomized controlled trials (RCTs) for testing safety and effectiveness of new drugs, defending instead various forms of evidential pluralism. We argue that scientific methods in regulatory decision-making cannot be assessed in epistemic terms only: there are costs involved. Drawing on the legal distinction between rules and standards, we show that drug regulation based on evidential pluralism has much higher costs than our current RCT-based system. We analyze these costs and advocate for evaluating any scheme for drug regulatory tests in terms of concrete empirical benchmarks, like the error rates of regulatory decisions.

Some remarks on evidence for external validity

Valeriano Iranzo (Universitat de València)

Standard evidential hierarchies in medicine preserve the top place for statistical evidence—particularly for meta-analyses and systematic reviews of randomized controlled trials (RCTs)—and put evidence about mechanisms at the lowest level. Some authors insist that those evidential rankings neglect the strength of evidence of mechanisms. They point at two main aspects where evidence of mechanisms can be crucial: (i) causal inference; (ii) external validity, that is, inferences from the study to the target population. I will focus on (ii). After discussing the alleged advantages of evidence of mechanisms over statistical evidence concerning (ii), I will argue that external validity is also a problem for those who rely exclusively on evidence about mechanisms. Besides, it is not so clear that

the reliability of target-to-population inferences is automatically enhanced by adding evidence of mechanisms. These conclusions do not rule out that evidence of mechanisms may be a helpful constraint for extrapolation in some particular contexts.

Evidential pluralism and its scope

J. Williamson (University of Kent, UK)

This talk develops Evidential Pluralism as an epistemology of causation. After introducing Evidential Pluralism and its relation to the Russo-Williamson Thesis, I explain how it can be applied to medicine, as advocated by the EBM+ programme. I address two worries about Evidential Pluralism: (i) that it is not feasible, in practice, and (ii) that it is too malleable, i.e., its results depend on subjective choices that need to be made in order to implement the procedure. Finally, I consider whether Evidential Pluralism can be extrapolated from the biomedical sciences to the social sciences.

Evidence of mechanisms and extrapolation of causal claims in social sciences

S. Pérez-González (Universitat de València)

Extrapolation of causal claims from one population to another is a problematic issue. To address it, several approaches have been proposed. One approach that has recently gained relevance is the mechanisms approach to extrapolation. Nevertheless, its adequacy for social sciences has been discussed. In order to address that debate, it is appropriate to distinguish between the positive and the negative side of the assistance of evidence of mechanisms to extrapolation. Evidence of mechanisms can either justify the extrapolation of a causal claim or show its absence of justification. Considering this distinction, it can be

showed that both sides differ in their actual importance in social sciences.

Mechanisms in clinical psychology: limitations, controversies and prospects

A. Fasce (Universitat de València)

Since the seminal paper of Alan Kazdin (2007), mediators and mechanisms have become one of the most important goals of psychotherapy research. Nevertheless, its limitations and prospects are still discussed among clinical psychologists. In this talk, I will address some of the following open questions: Is there something worthy to be called “mechanism” in psychotherapies? If this is the case, is current psychotherapy research capable to achieve evidence of mechanisms? Does psychotherapy research have specific shortcomings and strengths in this regard? Should this evidence be included in evidence-based treatment guidelines? Are explicit mechanisms of change necessary to improve mental health care and to debunk long-established pseudoscientific practices?

Elucidating the role of environmental unpredictability on the evolution of rotifer life history traits

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Bet hedging is a predicted adaptation to environmental unpredictability asking for contrasting evidence. In this contribution, we assess this prediction by reviewing our own results in rotifer research. Rotifers are small (< 1 mm) aquatic animals that produce dormant eggs able to survive adverse conditions, which occur in their habitats after a period of population proliferation of fluctuating length. Because different bet-hedging modalities are possible and these

can trade on different life-history traits, first we used bet-hedging theory to propose specific predictions on rotifer dormant traits in relation to the unpredictability in the length of their habitat growing seasons. Then, we provide observational (i.e. correlational) evidence from field populations of a rotifer model species, after testing that the habitats of these populations are ranked according to their degree of environmental unpredictability. Our results show that these animals adaptively diverge in relation to unpredictability in their local habitats. This conclusion is achieved after considering some confounding factors., which are accounted for by using statistical techniques to dissect the effects concomitant factors. Next, a greater degree of evidence, in this case linked to an adaptive mechanism, was obtained through the study of experimentally-evolving populations under diverging regimes of environmental predictability. Overall, our findings demonstrate empirically the existence of bet-hedging strategies in our species model regarding different dormancy-related traits.