that 'invention' or 'discovery' may involve inductive elements, albeit subject to confirmation by testing.
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Response

R Burkhardt, G Kienle

Confirmative significance tests for controlled trials have never led to the discovery of drugs. This is a possible area of agreement with Dr Vere, as he speaks of controlled clinical trials *refining* decisions. It is, however, a fundamental error to make no distinction, as far as the refining of decisions is concerned, between statistical model and medical reality. Because of the practical problems of controlled trials, and also for considerations relating to the philosophy of science in general, such distinction is essential. Identity of model and reality does not exist in medicine, nor in any other empirical science. With respect to decisions on the treatment of further patients statistical decision theory, for instance, calls for random *selection* of experimental units, not random allocation. Significances based on χ^2 or t tests are therefore at most formally correct; they do not, as such, relate to medical reality. As a result it is not acceptable to consider the model result as the final arbiter in decision-making, and clinical judgment on the other hand as speculative. As it would be positivistic nonsense to do away with individual judgment, the putative knowledge would, in Dr Vere's terms, have to be judged by the doctor's subjective belief.

When Dr Vere labels clinical judgment as speculative, this, of course, effectively removes any ethical objections. It would then be impossible to identify statistical experiments in which an effective treatment is withheld from an individual patient. Then there is, of course, also no need for serious consideration of our arguments – to the detriment of trial patients.

Apart from this, practically every argument advanced by Dr Vere has already come up in the discussions in Germany. Dr Vere's paper reveals the kind of positivistic short-sightedness liable to beset anyone who is not prepared to engage in discussions on fundamental questions of human cognition.

Reply to Response

D W Vere

The comments made by Burkhardt and Kienle in response to my response are very helpful, for they reveal with exquisite clarity the nature of the gulf between us. To respond briefly, and seriatim, I would first deny their remark that 'confirmative significance tests for controlled trials have never led to the discovery of drugs'. Of course trials do not discover *drugs*, but they may discover *therapies*. Their statement is untrue for several therapies, hence the one ground of agreement between us which they felt they might have discovered is removed. Effective new remedies against dental extraction pain, and multiple chemotherapies afford some good examples.

The real issue, however, is the relationship between model and reality; they deny it for clinical trials, I accept it. Admittedly, no model is a full representation of that which is modelled, but correspondence between model and reality *within the defined realm of discussion* in a trial is a reasonable postulate. Otherwise no hat ever represented a head, no glove a hand, no rectangle a garden, no map a country, and no science is possible whatsoever. Nor can mathematics help us any more, for numbers model the real world. The fact that I cannot see the real world but only perceive light reflected from it makes it an acceptable aid to reading, but presumably not to those who reject models.

They are not correct to assert that 'statistical decision theory . . . calls for random *selection*'; the point was argued admirably by Geoffrey Rose (1). It is *randomisation* that is needed; random sampling is unattainable in medicine in most situations, but this does not invalidate inference.

My assertion that clinical judgment is speculative rests upon the frequent overturning of clinical dogmas and beliefs by well conducted scientific experiments, nothing more.

That my mind is closed I freely admit; closed by logical inference. If that inference is faulty, or other grounds can be shown to bear more weight, I shall be most happy to change my mind, for what we all long to do is to help our patients.

References

(1) Rose G A. Bias. *British journal of clinical pharmacology* 1982; 13: 157–162.