Rules, norms, evidence and proven experience

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Introduction

What place does proven experience have in evidence-based medicine (EBM), and is there a relevant difference between EBM and Science and Proven Experience (VBE)? These are questions that Johannes and other participants in the VBE-programme have recently delved into (Persson et al., 2017). The suggestion in this paper, which touches on the interesting historical development of the VBE concept, is that in a rather natural conception of EBM, proven experience is disqualified as a source of evidence. Of course, what proven experience actually consists in is debatable. I will make it easy for myself here and construe it as a firmly held belief which, although it has undergone some kind of testing, is encircled by epistemic support we describe using terms such as "grounded in practice" and "not subjected to scientific testing". It is not research evidence, and as such it is not evidence of the kind prioritized in some formulations of EBM. Proven experience can be information or expertise, but evidence is what comes from proper research and nothing else. Emphasis on the idea that an activity should be based on science and proven experience can be interpreted as showing that both science and proven experience are important sources of evidence, and in this way VBE is different from EBM, it is argued in the paper. However, it may perhaps seem somewhat pernickety to say that proven experience is excluded from the evidence focused on in EBM when in fact the practitioner can use his or her proven experience in the actual implementation phase. Is this not using evidence in some sense too?

Maybe we can make it a little clearer what this difference amounts to with the help of Carl Hempel's conception of two set of rules governing scientific reasoning and Ilkka Niiniluoto's account of the notion of a technical norm.

Rules of confirmation and acceptance

In "Science and Human Values" (Hempel, 1965) Hempel discusses two sets of rules: *rules of confirmation* and *rules of acceptance*. Rules of confirmation govern what is to be counted as confirmatory and disconfirmatory evidence of a certain hypothesis under investigation. Rules of acceptance state what has to be in place in order to accept or reject a hypothesis, i.e. how much evidence, and of what quality, is needed if we are to accept or reject a hypothesis. The question when to accept or reject a hypothesis rests on the risk that a false hypothesis will be accepted, or the risk that a true hypothesis will be rejected. Hempel calls these risks "inductive". The rules of acceptance then decide what level of inductive risk we can accept. So, then, what is meant by "acceptance" ? Here we will settle for the idea that acceptance is the decision to use a hypothesis as a basis for a decision. So, for instance, if as a doctor you decide to treat your patient, suffering from a headache, with Aspirin, you have accepted the hypothesis that Aspirin is effective in treating headache.

The rules of confirmation in EBM are quite clearly formulated both by way of evidence hierarchies that have for some time been the basis of systematic reviews of medical

literature (CEBM, 2009) and by the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework for evidence assessment. The latter describes how we are to rate evidence, up or down, by assessing factors including: study design (inherently, randomized controlled studies are of higher quality than observational studies and case studies, etc.), study limitations, inconsistency, indirectness, imprecision, publication bias, magnitude of effect, dose-response gradient and whether confounding factors would lessen an effect, or suggest a spurious effect if no effect was found. These are rules of confirmation; they decide what is to be regarded as confirmatory or disconfirmatory evidence, and to what degree. The rules exclude proven experience. Expert opinion, a species of proven experience one might argue, is at the absolute bottom of the evidence hierarchy set out by the Centre for Evidence-Based Medicine (CEBM, 2009) and is not even mentioned in GRADE.

On the other hand, clinical expertise is mentioned in EBM as an important part of implementing evidence-based methods in practice. It plays a significant role, then, in the acceptance of a method. In EBM, then, proven experience, or clinical expertise, is allowed in by the rules of acceptance, it seems. To what degree this is actually the case can perhaps be debated. In GRADE there are rules of acceptance as well as rules of confirmation, and the former are based on risk-benefit analyses where one decides – on the basis of thresholds describing how many patients need to be treated in order to achieve one successful effect – whether the benefits outweigh the risks. A strength of recommendation is set using this measure. If this recommendation becomes, at the policy level, a guideline for use, then proven experience of practitioners is not part of the rules of acceptance. But the values of the people making GRADE recommendations do inform those rules. So a rigid use of GRADE could exclude proven experience from the medical decision making altogether. We will however follow the intent of EBM to let the rules of acceptance allow clinical expertise in the decision making.

The rules of confirmation relating to VBE do, one may argue, allow proven experience to provide evidence confirming or disconfirming hypotheses – together, of course, with evidence from EBM.

Evidence and technical norms

Hempel notes that the question whether a hypothesis should be accepted or rejected depends on the degree to which it reaches a goal of some sort. This goal can, in practical circumstances, be economic, or technological, or – as in our case here – related to health. In pure science things are, perhaps, less clear, but Hempel argues “that the standards governing the inductive procedures of pure science reflect the objective of obtaining a certain goal, which might be described somewhat vaguely as the attainment of an increasingly reliable, extensive, and theoretically systematized body of information about the world” (Hempel, 1965). These standards could be different. Presumably, the goal could be aesthetic in character, and then the rules of confirmation and acceptance would be different too, certainly. Hempel continues: “the standards of procedure must in each case be formed in consideration of the goals to be attained; their justification must be relative to those goals and must, in this sense, presuppose them” (ibid).

So, one may ask, what are the goals, or values, that are presupposed by the exclusion of proven experience from the realm of evidence?

The rules of acceptance in GRADE, as described above, suggest that the goal of EBM is to provide *technical norms* (see Niiniluoto, 1993, for description of G. H. von Wright's notion). These are statements of the form "If you want A, and you believe that you are in situation B, then you ought to do X". In the case of medicine they take a form such as "If you want to make a certain proportion of patients, P, suffering from disease D, healthy, you ought to treat these using method M".

The technical norm might be true if method M actually is effective in treating disease D and consequently restores health in P – that is, if M causes P to be healthy if P has disease D. This can be established either "from above" (Niiniluoto, 1993) by derivation from general causal statements, laws, established from (pure) science. Or it can be done "'from below' by building up a simplified model of the situation, using trial-and-error procedures and experimental tests to investigate the dependences between the most important variables, and trying to find the optimal methods of producing the desired effects. When the result is expressed as a general rule, a technical norm with some empirical support is obtained" (Niiniluoto, 1993). Simplifying, and adapting the suggestion to the present context, we can say, then, that research evidence supports from above and proven experience supports from below. EBM is only satisfied with evidence from above, while VBE accepts support from both above and below.

All this may seem quite as it should be, since EBM is about deciding how to treat patients on the basis of what the science says is effective treatment. But a technical norm can get adequate support also from below, so why not accept this way of confirming the norm if it is the validity of the norm we are after rather than the truth of a causal claim? The rules of acceptability suggest that the goal of EBM is promoting health; it is not about truth or a "theoretically systematized body of information". With a large enough effect, highly uncertain methods can be accepted if the effect, expressed with its uncertainty, is above a set clinical threshold. So, why should the rules of confirmation aim at the (possibly) higher goal of truth when the rules of acceptance settle for the goal of promoting health?

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