Author's response to reviews

Title: A Philosophical Analysis of the EBM Debate

Authors:

Prof Scott R Sehon (ssehon@bowdoin.edu)
Dr Donald E Stanley (dstanley@tidewater.net)

Version: 4 Date: 4 Jun 2003

PDF covering letter
June 4, 2003

The Editor
BioMed Central Health Services Research

Dear Editor:

We are submitting a revised version of our manuscript, “A Philosophical Analysis of the EBM Debate” (ID – 1033419046149176). The referees’ comments were very useful, and we have made every effort to respond to their concerns.

Dr. Upshur had seven compulsory revisions. Our responses are as follows:

1. We added many references, and the material has been slightly reorganized. Our listing of some of the criticisms made of EBM has been moved from the discussion section (where it was unduly buried) into the background section.

2. We grant Dr. Upshur’s point that EBM proponents do acknowledge an important role for factors beyond evidence from clinical trials, and we should have said that. We wanted to emphasize that what distinguishes EBM from other approaches is the emphasis placed on RCTs. To handle this, we have inserted the following paragraph:

The heart of EBM is the use of randomized controlled trials (RCTs) to determine the safety and efficacy of interventions, e.g. treatment, diagnosis, and prevention. Of course, EBM advocates have taken care to allow a role for other factors beyond evidence from RCTs. In particular, one must take into account the clinical state and circumstances of the patient, as well as the patient’s own preferences and actions.[1-4] Even for EBM practitioners, the research evidence is but one component of medical decision making. But of course alternative approaches to medical practice will also take into account the patient’s clinical state and values; this is not what separates EBM from the other approaches. What separates EBM from other approaches is the priority it gives to certain forms of evidence, and according to EBM the most highly prized form of evidence comes from RCTs (including systematic reviews) and meta-analyses of RCTs. So, for the purposes of this paper, we will take the term “evidence-based medicine” to refer essentially to the practice of taking RCTs as the strongly preferred form of medical evidence.
3. We have rewritten the first paragraph of the section on paradigm shifts:

Proponents have hailed EBM as a “paradigm shift” or “revolution”, in the sense of those words put forward by historian of science Thomas Kuhn.[5] At the same time, Brian Haynes acknowledges that “most scientists and EBM advocates are ignorant of the philosophy of science and give little or no thought to constructing a philosophical basis for their activities.”[6] Indeed, Haynes goes on to write that “One hopes that the attention of philosophers will be drawn to these questions”[6]. In that spirit, we want to examine more closely the claim that EBM is a Kuhnian paradigm shift. The Kuhnian metaphor is familiar to philosophers, but its implications are presumably less familiar to physicians. We have nothing against a metaphorical characterization of EBM and its alternatives; well-chosen metaphors can do much to illuminate conceptual (i.e., second-order) questions, and thereby can help us answer the normative (i.e., first-order) questions. However, we will suggest that the Kuhnian metaphor is a poor one and serves to obscure more than it illuminates.

4. We’ve added the following paragraph.

The dependence of RCTs on basic science appears not always to have been fully appreciated by some EBM proponents. In some discussions of hierarchies of medical evidence, basic physiology and biochemistry is put at the very bottom or is ignored altogether.[3, 7] Thus, these proponents of EBM seem to say that we should only look at evidence from RCTs (when we have it), and that medical practice is conducted in isolation of our understanding of physiology and biochemistry. We claim that such views are wrong. On the other hand, this is not to say that if a clinical result flies in the face of our physiological understanding that we should just reject it out of hand, as suggested by Couto [8]. In general, given the complexity of the human body and our nascent knowledge of it, if we use basic science alone to judge the safety or efficacy of an intervention, then our judgment will be fraught with a high degree of uncertainty. For example, some laboratory evidence suggests that estrogen might have a positive effect on brain cells, and thus suggesting that hormone therapy might help to ward off dementia. However, a recent controlled trial strongly suggests that
whatever positive effect such hormones have, these
effects are outweighed by negative effects.[9] On the
other hand, in an extreme case like homeopathy, where
the biological plausibility is so low, our background
biological knowledge does and should affect our
interpretation of the evidence from RCTs.

5. We replaced the waffling paragraph with the following:

Returning to the first-order, normative question, we can
now ask to what extent should physicians rely on RCTs
as opposed to clinical experience or observational
studies. Unlike the comparison with basic science, we
cannot simply say that they are complementary and that
we need both. As discussed above, observational
studies essentially are clinical experience made
systematic, and RCTs are observational studies subject
to further controls. The extra time and expense
involved in performing RCTs is justified only if their
answers to intervention questions are more likely to be
ture. For the reasons laid out in the preceding
paragraphs, the proponent of EBM contends that RCTs
are indeed more reliable than the alternatives. We are
inclined to agree. It is clear that for clinical experience
and observational studies, there is a risk of different
sorts of bias; in Quinean terms, the controls imposed by
RCTs give us firmer observational checkpoints and
stronger inferences from observations to conclusions,
particular conclusions about interventions. Experience
confirms that uncontrolled studies can give different
results than RCTs[10, 11]; the Quinean analysis gives a
diagnosis of those differences.

6. We hope that the paragraph just quoted also helps to reply to this point as well. It’s
one thing to say (as Dr. Upshur does) that theory cannot adjudicate evidence, if this
means that a completely a priori or philosophical view cannot tell us what evidence to
accept. But basic science is hardly pure theory, in that sense. Basic science is based on
evidence as well. To the extent that EBM proponents deny that, our claim is that they are
mistaken.

7. We’ve added the following sentence to the third paragraph of the paper: “Our
philosophical analysis will be limited to conceptual and epistemological issues; there are
ethical issues that arise in the practice of evidence-based medicine, but we will not be
addressing those questions.”

We’ve also revised in quite a few minor ways, mostly in response to the discretionary
revisions suggested by Dr. Upshur.
Thank you for your time and consideration.

Sincerely,

Scott R. Sehon
Associate Professor of Philosophy
Bowdoin College
ssehon@bowdoin.edu


6. RB Haynes: What kind of evidence is it that Evidence-Based Medicine advocates want health care providers and consumers to pay attention to? BMC Health Serv Res 2002, 2:3.


