Author's response to reviews

Title: What kind of evidence is it that Evidence-Based Medicine advocates want health care providers and consumers to pay attention to?

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PDF covering letter
Responses to Reviewer 1.

1. MS seems wordy. victim of too much passive voice for my taste, so it seems to become a bit boring or pedantic after a while. I encourage more active, lively writing. Also: many paragraphs are so long I lost track of the point. the adage of having a paragraph be about ONLY it's topic sentence remains good advice, and I'd encourage dividing many of these into 2 or even 3. make it easier and less exhausting on readers to follow the argument.

Reply: I've broken up many paragraphs and generally shortened the paper a little (even though adding some material in response to the reviewer's comments) (Background on p. 4 is a case in point!) Do you really permit contractions in work of this sort?

Reply: I hope you will allow EBM – it is in widespread use. Spelling it out each time would be tedious for readers.

2. Didn't understand organization, exactly. Seemed odd to go from "background" to "discussion". why not, if this is intended to be more of an "essay" lay it out a little differently and just use the subheads" within discussion?

Reply: I followed the instructions for organization of Debate articles at the BMC website. I agree with the reviewer that the headings are a bit awkward, especially jumping from Background to Discussion. How about leaving out Discussion as a major heading and making Background and Summary into minor headings? Up to the Editor. (I've included lots of subheadings to guide the reader through the discourse.)

3. All in all, a nice "corrective" to the excesses of EBM advocates of the 1990s. (I, however, would suggest that if the author is making a subtle distinction betw/ evidence-based MEDICINE and evidence-based PRACTICE, it got by me, and I'd have said that, in today's world, practice is the more inclusive, and more relevant, term, and the points made are just as pertinent to EBP as EBM.)

REPLY: I've included some of the many alternative terms for EBM in the text on page 5: Evidence-Based Medicine (EBM), the term and current concepts, originated from clinical epidemiologists at McMaster University. Although the term has been adopted by many disciplines and adapted to their use (eg, as Evidence-Based Nursing, Evidence-Based Clinical Practice, Evidence-Based Pharmacy, and so on), the objectives of these congeners are the same and I will use the generic term in this essay.

p. 4. I think EBM/P also tries to refine methods for coming results of studies on similar topics, to enable folks to reach answers with more precision and certainty. So I think the quoted "activities" of EBM advocates is a little narrow.
REPLY: Point taken. I've made a modification on page 4, underlined below:

To help practitioners meet these challenges, EBM advocates have created procedures to objectively identify and summarize evidence as it accumulates on clinical topics, and resources that allow users to find the current best evidence when and where it is needed for decisions concerning health and health care.

p. 5. Para beginning furthermore: I didn't follow the comparison of accept/live w/ uncertainty versus "reductionist allure of basic science" -- don't believe physicians are always so certain of themselves or medicine as this implies, dealing with new diseases, deciding what to do about new diagnostic procedures, new technologies and therapies, etc. So is this too stark a comparison?

REPLY: I've modified this sentence somewhat to avoid indicating that clinicians always feel certain, and to emphasize the alternative to wishing for certainty, namely actually dealing with uncertainty:

EBM posits that practitioners must be ready to accept and deal with uncertainty (rather than seeking the reductionist allure of basic science)…

p. 6. My reaction to "dedicated to mass destruction." was good grief! That is a gross over-simplification and, seems to me, needless attack on the United States (given that this is coming from Canada). Could even be taken as insulting to the generation (or its family and descendants) that actually did fight WW II.

REPLY: I presume that the reviewer is sensitized to “attacks on America” post-September 11 – but I didn’t mention America, the phenomenon isn’t confined to America, Canada was in the war longer than the US, Canada hasn’t attacked the US since the US attacked Canada in 1812, etc etc. The funds that went into publicly funded health research after WW2 were freed up by ending the war, and a conscious decision was made to spend them on health research in many countries rather than more war machines and armies. So I think the statement is correct and not an excessive exaggeration or oversimplification. Also, the reviewer has indicated elsewhere that he thinks the paper is too boring and passive in places…

p. 6. In my opinion, early advocates DID argue for substituting experimental designs for observational designs, not for adding experimental designs to the research armamentarium, and they did it pretty high-handedly. Believe that’s one of the aspects of the early writings that irritated people in the health services research (effectiveness research) arena so. The sentence top of p. 7 is right. What would be nice is acknowledgment that the “hierarchy” so beloved of EBM advocates isn’t always as neat as they might like to believe. The author returns to this (better, in my view) on p. 17, but at this earlier point in the article, I’m thinking the author is going in a different direction.

REPLY: I’m trying to set the record straight! A particular feature of criticisms of EBM has been that the critics say that EBM advocates said something that the critics disagree with that, in fact, a) is disagreeable BUT b) was never actually advocated by the EBM
founders. The critics then proceed to set up a corrective approach – which generally coincides with the original position actually taken by EBM advocates! I don’t want to get into this whole debate of what we said compared with what critics said we said. Rather, I am simply stating what we originally said – anyone who wants to criticize this will have to come up with specific evidence to the contrary. The reviewer hasn’t done so – because it isn’t true.

p.7 I just lost the train of thought in the para starting Today. the sentence starting "But even though." was just impossible to parse . I tried a couple of times. Got the gist, but this is hard going. (I wouldn't start a sentence with a conjunction anyhow.)

REPLY: I have simplified and shortened this para.

p. 8. I wondered if the author might not want to cite the Eisenberg/Clancy (?) work that lays out a continuum of research (biomedical to health services research) as a clean/clear example of some of these thoughts. I believe it was in Science a couple of years ago.

REPLY: Clancy and Eisenberg had an article in Science in 1998, but it was about outcomes research, at the far “applied” end of the spectrum. I’ve decided to pass on this one, to avoid going off on a tangent.

p. 8. Sentence starting "Because applied research." is incomplete. Idea about applied research as complementary way of knowing is nice . wholly buried in this long para tho.

REPLY: I’ve shortened this para to highlight this thought, and eliminated the offending sentence.

I think somewhere in here, I probably was looking for another subhead or two.

REPLY: I’ve added a subhead:

An example of the interplay between basic and applied clinical research

pp. 9-10 on the example. Was surprised not to see the RAND work cited (e.g., for carotid end.) I thought EC/IC was more commonly used than STA-MCA bypass, but I'm not a clinician. If author is going to describe the STA-MCA bypass so much, tho, I think a similar level of description about carotid endart. might be useful . the comparison doesn't work so well if readers don't know the same amount about both.

REPLY: The RAND work on CE was to create practice guidelines for CE before there was any good evidence for doing so. The RAND report came out in the middle of the CE trial and almost compromised the trial. But that’s another story and there isn’t space in this essay to tell it.

The reviewer appears to think that STA-MCA bypass and EC-IC bypass are different – as noted in the text, they are different names for the same procedure. Because the EC-IC procedure was uncommon to begin with and was then abandoned after the negative trial, I thought a brief description of it would be helpful. CE has been around a lot longer, is a lot more frequent, and is in widespread use these days, so I assumed that fewer
details would be needed. Nevertheless, I’ve tried to clarify the text here by a little wordsmithing.

p. 11. The more pragmatic definition is useful. However, I wasn't entirely sure what "pregraded" or "preassessed" meant. For the uninitiated, this could mean preselected in some biased way, perhaps.

REPLY: I've tried to clarify the pre-assessment of evidence by modifying the sentence to read:

This practical definition reflects the fact that there are now many information resources in which evidence from health care research has been pre-graded for validity by people with expertise in research methods, and, better still, also assessed by experienced practitioners for clinical relevance.

p. 11-12. I take some exception to the way the 'grades' stuff is presented here. I believe there is good reason to distinguish between grading quality of studies/articles and grading/rating strength of bodies of evidence, and this discussion mushes them up. Also helpful might be to make clear that some of the comparison here is between internal validity and external validity/generalizability. Some in the audience may grasp the ideas better with those technical terms (I'm not saying get rid of the more "lay" language, just try to do both). I believe the point that often, for our EBP purposes, internal validity and external validity are in conflict (in terms of selection of studies, grading, weight to put on studies in narrative summarizations, etc.) is not well brought out. However, the last sentence (p. 12) about clinical outcomes important to patients is critical!

REPLY: A valid point. I've added a brief paragraph at the end of this section to address the distinction that the reviewer is drawing:

Once individual studies have been assembled and graded for quality, the collected evidence can be used to make recommendations for practice, preferably with each recommendation being labeled according to the level of evidence that supports it. Various systems for indicating the level of evidence for collected evidence are available, for example from the Centre for Evidence-Based Medicine in Oxford (http://cebm.jr2.ox.ac.uk/docs/levels.html) and in books [1, 13].

pp. 12-13. Have to say I couldn't much make heads or tails of Table 1. A better example walking readers directly through those rows/columns might help. Using a "grid" approach to this table only makes matters worse. Drop the internal (at least the vertical?) lines. The entries in the Table are inconsistently presented. It's virtually impossible to read "cold."

REPLY: I've removed the table and have provided print refs and web links for the curious.

The author might wish to look at an article commissioned by the Institute of Medicine (US: part of the National Academy of Sciences) for a conference about 15-18 months
ago on uses of evidence in medicine and in law. Specifically a piece done by Cindy Mulrow and Kathy Lohr (I think in Health Policy, Politics and Law).

REPLY: I was invited to this conference. It was a largely futile attempt to discuss applying rules of evidence for health research to medicolegal judgments. (The futility came from a 2-day meeting not being long enough to bridge the language and conceptual barriers between lawyers and evidence-based practitioners, let alone come to common ground on how research evidence might be used in medicolegal cases.)

It might be a useful supplement to the party line of Cochrane Collaboration, which doesn't exactly have a monopoly on useful ideas or guidance in this field.

REPLY: I'm going to pass on responding to this comment! This is the only reference to the Cochrane Collaboration in the paper, and it simply isn't possible to name all the contributors to the success of EBM, and the paper is not intended to be a comprehensive description of all the players involved in EBM.

pp. 13-14. Not clear why follow-up is made to be such an important criterion. The CC 80% rule seems arbitrary, and it's irrelevant for many clinical questions (desirable, maybe, but unattainable). I didn't find this segment an especially persuasive defense of the 80% rule. Moreover, the bigger issue may be differential attrition (from various arms or groups of a given study), not 80% (or whatever) per se. Finally, other elements about follow-up (loss to) may be quite important and are not mentioned here. Generally "reasons" for loss to follow-up, whether the follow-up is short-term or long-term (and with or without multiple observations). All in all, I thought this a poor example to single out.

REPLY: I've taken out the example along with the table.

p. 14. Pro CC bias. or anti-Americanism. slipping in. It's questionable not to mention the AHRQ EPC program (and see article in Lancet last year sometime quoting John Eisenberg??) along with CC.

REPLY: I don't see how the reviewer can possibly interpret what I've said as anti-American!!!!! AHRQ isn't a competitor of Cochrane, but rather brokers systematic reviews that respond to issues of concern to the organizations that sponsor the reviews. Three Cochrane Centres, including the one I started in Canada, are involved in AHRQ Evidence-Based Practice Centers. I am a co-leader of the McMaster EPC. I know John Eisenberg well and admire him greatly – and he would be the first to indicate that AHRQ's EPC program was a response to help with the mission begun by the Cochrane Collaboration, in a way that would be relevant to research transfer in America. The reviewer is simply imagining bias where it does not exist.

p. 14. The Institute of Medicine's work in early 1990s on clinical practice guidelines made a pretty strong point of how guidelines ought to factor in attention to patients' preferences and values (recalling the IOM's definition of clinical practice guidelines as being about clinical conditions). To the extent CPGs are based on systematic reviews of the EBM sort, in theory ways do exist to try to combine these elements (research evidence, clinical circumstances, and patients wishes). There's a history to a lot of this thinking that goes back beyond 2000 or so!
REPLY: No claim is made here that EBM invented the notion that patients' preferences should be including in applying evidence, merely that EBM always included this notion.

pp. 16 and thereafter. Maybe was lay perspective, but again extremely hard to read/follow because is so dense on the page. Please, could much of this be cut into smaller, bite-sized pieces?

REPLY: I've broken this up into mono-point paragraphs for the most part.

I was a little surprised not to see some citations to the articles that have come out periodically (in theme issues) of the Journal of Evaluation in Clinical Practice (do not have it handy, but that's close. Comes from Britain. Edited by Andrews Miles). They have done significant pieces on this philosophy of science as applied to EBM more than once. One of the thematic issues was spring 2000, for example.

REPLY: My paper isn't an attempt to respond to the critiques of the likes of Andrew Miles! See my reply to the comment about p. 6 above.

p. 17-18. Para beginning. Furthermore,.... believe this is a v. important point. Again, to some extent this is taken up in work relating to CPGs (see note re IOM work, above, from 1990-1992). However: the para beginning. Finally.. struck me as rather nihilistic. Moreover, there are many things about EBM/EBP (broadly defined) that might be studied in trials or other well-designed studies, short of the RCT the author posits (which then becomes a tiny red herring): one could study reliability of systematic reviews themselves, g'line development activities, CPG implementation, etc., and contribute to the overall knowledge base in many ways.

REPLY: I've toned down the nihilism by adding this sentence and a reference.

Nevertheless, we do have limited evidence that the concepts of EBM are teachable [26].

pp. 18-19. These are important things for an EBM/EBP leader to say! (Please, tho, cut these paragraphs into smaller chunks!)

REPLY: I've broken this up a bit. The editor is welcome to do some more breaking.

Critique at the bottom of page 18 may be a little extreme: good systematic reviews DO take harms. into account of this sort (chiefly clinical, but also costs and cost-effectiveness). Moreover, believe this discussion misses the point that, more often than perhaps typically understood, EBM/EBP products will lead to recommendations against provision of services, which certainly undermines the argument about EBM indirectly leading to prolonging life unnecessarily and unhappily.

REPLY: I've rephrased this passage to read as follows:

For one, full implementation would cost much more than the resources currently available for health care, even accounting for some cost effective innovations and
deletion of existing but ineffective practices. The increased costs of care would lead to unaddressed (let alone resolved) dilemmas in distributive justice.

Response to reviewer 2.

One area that might usefully be covered that is avoided is the role that EBM plays in health care rationing. This is not explicitly covered but the fundamentalist view that only truly scientifically funded treatments etc should be paid for is increasingly prominent. Is this valid? If so why? If not why not?

REPLY: I agree that this is an interesting issue. However, I don't know enough about how rationing works in my own jurisdiction, let along others, to make accurate and useful statement on this. Also, the paper is already lengthy.