Author's response to reviews

Title: Sicily Statement on Evidence-Based Practice

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Author's response to reviews: see over
Review: General
The appeal of EBM has been irresistible. In a remarkable short period of time a notion that practice of medicine should be transparent, based on explicit knowledge and that claims of health intervention effects should be founded only on scientifically valid empirical evidence has spread to all corners of the world making an impact not only in medicine but also on lay and policy-makers thinking. In 2001 it was dubbed by the New York Times as one of the “Ideas of the Year”. The movement, which started in early 1990s, has, however, stirred a vigorous debate about principle and the process of EBM (or EBP). Undoubtedly, the EBP movement has required some consolidation and clarification regarding its purpose, process and further integration within framework of education of health care professionals. With this in mind, Martin Dawes and colleagues organized a conference on Evidence-Based Health Care Teachers and Developers from which the Statement on EBP emerged.
This is timely and important exercise, but one has to ask how much it really adds or clarifies the issues that have already been previously debated. The statement predominantly focuses on a five-step process of EBM (or EBP), which was based on appealing normative concepts formulated in early 1990s by the “fathers” of EBM. In the mean time, a lot of debate (and some empirical data) have been published pertaining to each of the “steps” in this 5-step process challenging practicality & feasibility of this “recipe”.

I am surprised that some consolidated reformulation of this five-step process is not offered in the Statement. For example, appealing PICO format is often not suitable for translation of clinical problems (“uncertainties”) into answerable questions. This is because MEDLINE and other databases do not index research papers according to the PICO format.

Response:
One problem is the different interpretations have resulted in emphasis on different aspects. Whereas each has a role, the ‘5-steps’ are a talisman, which formalizes the underlying approach.

Review:
I am not arguing against PICO format- all I am saying that students may spend their time learning how to ask questions in terms of patient-oriented outcomes, only to become frustrated at the second step when they discover that search according to disease-oriented indexing result in better retrieval (at least in my field of oncology)!

Response:
This is a valid point. However the PICO format is taught for several reasons.
1. To determine the type of question one is asking – therapy, diagnosis, prognosis etc. It is often unclear at the beginning of the expression of uncertainty exactly what the question is.

2. To identify clearly separate facets of the question and especially the outcome of interest or relevance to the patient and or health professional

3. To help identify the most likely database where the answer will be found and also to help with the search itself. The use of the structured question helps the searcher identify synonyms and expand increase the sensitivity of the search (Booth A, O'Rourke AJ, Ford NJ: Structuring the pre-search reference interview: a useful technique for handling clinical questions. Bull Med Libr Assoc 2000, 88:239-246.).

However the lack of PICO format in database search engines is an issue that has been raised by the authors with various databases. At the 2004 International Colloquium it was announced that Cochrane is in the process of changing its search engine to more accurately reflect the PICO question format. PICO was designed as the format most likely to be answerable. The five steps as outlined need to be shared more widely at this stage. Although those involved for some time may be aware of these there is still some confusion and some authors miss out, for example, the evaluation of performance. We feel that the 5 steps should perhaps be used more widely before we consider changing or altering them.

Review:
I also believe that steps 4&5 should be modified to reflect better what clinical medicine is all about.

Response:
This is a good point and we realize that many seasoned practitioners will already be doing this. However, we have chosen to keep each step separate for clarity and to make the framework more accessible to novices.

Review:
Clinical medicine is really about decisions and decision-making (under conditions of uncertainty). A lot of is written about “evidence-based decision-making” but a substantial confusion remains here (as the authors of this paper are undoubtedly aware of the fact that evidence is necessary but not sufficient for decision-making).

Response:
Clinical medicine is also about evaluating what care you are giving. Without rational examination of all your processes of care you maybe lured into a false sense of security and only be this last step can you make sure that you are doing the right things to the right people at the right time.
Audit evidence has a role to play in lifelong learning by reinforcing good decisions and offering better alternatives to bad ones.

Review:
The Statement like this should provide a paragraph or two about the role of evidence and EBP in enabling rational decision-making (including a definition of rational decision-making and the need to link EBM to other methods of decision-making). Furthermore, the explicit linkage to the purpose of education would be highly desirable. (As a suggestion, one may link EBP goals to Stanford’s Douglas Hurd reflection on the purpose of education, which is to learn how:
- distinguish evidence from propaganda (advertisement)
- probability from certainty
- data from assertions
- rational belief from superstitions
- science from folklore
- theory from dogma
I cannot think of any better way to link EBP with medical education.

Response: We agree with this and have added this to the text. Thank you.

Review:
Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached) The Statement should clearly separate principles, process and evidence-based outcomes. As it currently reads, this is a bit conflated.

Response:
Thank you – we have tried to separate more clearly process and outcomes for the reader in the revised draft.

Review:
Also, as indicated above the Statement can be better linked to the purpose of education and the role of evidence (and EBP) in decision-making.

Response:
We have introduced new text on p10 to address this.

Review:
Regarding some assertions made in the paper, I do want to comment on two: a) practice of medicine and decision-making should be informed by the “tacit and explicit knowledge”.

This may be so, but if one acknowledges equal importance of “tacit” (expert) knowledge with the explicit knowledge then a line between EBP and traditional
medicine becomes completely blurred. EBP is about explicitness and transparency, and if the Statement implies that care can be equally effectively delivered by those who rely on their tacit knowledge (as opposed to explicit knowledge), then this will lead EBP to a slippery slope and the authors may actually see a demise of EBP instead its further growth. I suggest deleting importance of tacit knowledge in EBP (or very carefully explaining its relationship to “explicit” knowledge).

Response:
It is useful that you have pointed out this potential confusion and changes have been made to the text to address this. In this statement we define information as data that has been sorted, analysed, & displayed and communicated through spoken language, graphic displays, or numeric tables. Explicit knowledge is then the meaningful link people make in their minds, between information and its application in action in a specific setting. An example of this might be the need to evaluate quickly the patient with chest pain to take advantage of the proven window of opportunity for treatment of acute coronary syndrome. Implicit or Tacit knowledge is that knowledge which is harder to share and may be developed through experience. For instance, the recognition of a sick child: there is a long list of clinical features that when present denote severe illness. In contrast to the resident who may know the list the experienced clinician has a tacit knowledge of “sickness” in a child that comes from knowledge of the list and assimilation with experience speeding up the recognition of “sickness”.

We have added substantial text and new references on page 6 to address this.

Review:
b) on page 8, the authors make a remarkable, thought-provoking statement: “What has also became evident was the exaggerated impact that weak research methodology and publication bias have on putative effectiveness”. If there are no typographical errors here, this is a truly important statement, and in fact if it is believed to be correct, then it will lead to the death of EBM education as we now know it. This is because the major impetus in EBM courses, as also noted by the authors, has been on critical appraisal. If, however, learning skills of critical appraisal will not affect our conclusions about intervention effectiveness, then a step #3 of the 5-step EBP process will end up being significantly de-emphasized. Personally, I believe that empirical evidence is not strong enough to make this statement (yet). The authors cite the paper, which indicated that worries about allocation concealment may indeed have been exaggerated. Our own work indicates similar findings (see BMJ 2004;328:22-5; Accountability in Research 2003;10:302-317). However, some other work (e.g. Cochrane review on mammography) indicated that poor methodological quality may have been associated with inflated treatment effects. In my opinion, it is too early to de-emphasize the role of critical appraisal.

Response:
Thank you for pointing out this serious error in drafting and we have changed the sentence construction to the following: “What also became evident was that weak research methodology and publication bias may cause a dramatic overestimation of therapeutic effectiveness”

Review:
Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)
Unable to decide on acceptance or rejection until the authors have responded to the What next?:
major compulsory revisions
An article of importance in its field Level of interest:
Acceptable Quality of written English:
No Statistical review:
Declaration of competing interests:
Although I have interacted over the years with some of the authors of this paper, I believe that my evaluation is fair and impartial. Consequently, I declare that I have no competing interests in relation to this paper.

Response:
Professor Jackson suggests we consider mentioning the types of evidence most relevant to EBP. The authors have discussed this. But as the paper was designed to provide a theoretical framework, we felt that additional details would make it too long and risked distracting the reader from the central elements of our message. However, we are prepared to reconsider this if the editors feel strongly about this option.