Reviewer's report

Title: Designing concept maps for a precise and objective description of pharmaceutical innovations

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Reviewer: G. Caleb Alexander

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General comment
The authors attempt to develop a model to serve as a standard for presenting the main features of new pharmaceuticals. They identify an important gap in knowledge created by the fact that at the time a drug reaches the market, the summaries of evidence about the drug are monographs (produced by industry and thus with implicit bias) and evaluation reports published by national drug agencies (which are lengthy, may vary country to country and tend to provide little information on safety or ease of use). They argue that a model such as the one they propose may serve an important purpose. Although I was quite excited to read this and found their abstract quite compelling, the data presented with respect to how their model was developed and validated raise a number of concerns that I believe limit its utility.

Main specific comments
1. The authors report they “tested” the adequacy of their model, but provided very little information in the way of any formal validation process or result. For example, why did they not use a Kappa statistic or some other measure in order to assess the inter-operator reliability of their methods? Overall, the validation process seemed quite inadequate for this type of scientific manuscript.

2. I was surprised that the authors didn’t present any quantitative results of these analyses. Are they planning to do so in additional manuscripts? Given that they have concept maps for each therapy, it would be of interest to know at least basic descriptive statistics regarding the therapies examined and how they measured on the domains assessed. Of course, more sophisticated bivariate and multivariate analyses might also be performed.

3. Introduction, general comment. The discussions of the reports produced by the regulatory agencies in the United States, France and Austria seemed a bit ad hoc and also didn’t really add much. Perhaps the authors could condense these paragraphs and also better emphasize the discussion of the main limitations of these summaries. Also, it seemed to beg the question as to whether others have conducted analyses comparing the results of the drug summaries produced by different country’s regulatory agencies? This might be of interest to discuss in the Introduction or Discussion.

4. Methods. There is a lot of tacit knowledge throughout this section. For
example, the authors refer to the term “drug banks” but do not define this. More vaguely still, the authors use terms like “basic axes of drug impact” and “characteristics of each element” without clearly stating what the axes or elements are, or using parallel construction throughout the manuscript to consistently refer to these using the same term(s).

5. Overall, there was limited correspondence and precision between the words used in the concept maps and those in the text, which made the manuscript much more confusing than it otherwise needed to be. For example, the authors refer to “different types of treatment” in the text, yet “types of effects” in the concept map.

6. Although the concept map design is indeed helpful, I wonder whether it may also be helpful for readers for the authors to report the entirety of their model in a table (e.g., list each variable as well as the total number of levels or forms that that variable can take)

Smaller specific comments
7. Although focused on providing a much more narrow amount of information to consumers, there is a literature on the development of a “drug facts box” that the authors may find of interest. For example, see: Ann Intern Med. 2009;150:516-527.
8. The fact that monographs are written by industry and therefore inherently biased seems like an elephant in the room.
9. Introduction. The section beginning with the system of Caprino and Russo was a bit confusing and seemed almost tangential, given that this is focused only on innovation, whereas the authors are attempting to do something much more comprehensive.
10. Methods. The introduction of the term “stratification methods” was quite opaque. Rather than referring to this vaguely, perhaps the authors could simply state that they selected drugs stratified by three (or however many) characteristics, and then report these. Space permitting, perhaps they could include a table on on-line only appendix that captures this information.
11. Methods. The term “drug banks” may not be familiar to some readers.
12. Methods. It may be helpful to state that there was a 1:1 correspondence between drugs and concept maps, or indeed to clarify what this relationship was.
13. Results, characteristics of drugs used to define the model. The first section of the Results might be better presented either in the Methods or as an Appendix.
14. Results. It wasn’t clear what was meant by “the ‘new data’ concerns new clinical studies…”. What aspect of the prior paragraph is this referring to?
15. Discussion. It may be helpful to state what the “systematic medical-literature surveillance services” do as well as what the analyses of them show, rather than
simply stating what they do NOT do.

16. It seems a bit naïve to think that this model would be useful to industry, given that industry generally stands to lose, rather than gain, by greater comparative effectiveness and safety analyses.

17. I do not believe Figure 4 was mentioned in the text.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

i do not have any competing interests to declare