Author’s response to reviews

Title: Design and evaluation of software for the objective and easy-to-read presentation of new drug properties to physicians

Authors:

Maia Iordatii (miordatii@yahoo.com)
Alain Venot (alain.venot@univ-paris13.fr)
Catherine Duclos (catherine.duclos@avc.aphp.fr)

Version: 6 Date: 16 December 2014

Author’s response to reviews: see over
We thank reviewers for their sound criticisms, questions and suggestions.

Reviewer's report

Title: Design and evaluation of software for the objective and easy-to-read presentation of new drug properties to physicians

Version: 5 Date: 16 November 2014

Reviewer: Birgit Eiermann

Reviewer's report:

1. Major Compulsory Revisions
   The method part is still a mixture of describing what you did, but also a discussion of why you chose certain steps and methods. This belongs into the discussion part or into introduction. The method should purely describe what you did, not why you did something. Example: Page 7: The amount of information a user can examine and process at a given moment is strongly limited by cognitive and perceptual abilities [14]. The physician therefore requires an overall idea of the new drug, from an overview of its main properties. Page 8: It has been shown [17] that standardized and consistent interfaces are required for users to be able to master their use without special training. Page 8: because it has been shown that users prefer graphical interfaces, which facilitate learning to a greater extent than purely textual interfaces [18].

   Our response: We have followed the reviewer's suggestion and have moved all aspects not directly relating to the method to the discussion section.

2. Minor Essential Revision
   Page 2: SUS - explain abbreviation first time you use it.

   Our response: The acronym SUS, which stands for System Usability Scale, is now explained in the abstract.

3. Minor Essential Revision
   Page 3 provide a comparison of the properties of the new pharmaceutical product with those of existing drugs for the same indication, in terms of efficacy, safety and ease of use. - add “if available” after “existing drugs” – if no comparable drug or only placebo exists you do not provide data; as I understood, that is often the case (you said so on page 10)

   Our response: This is now made clear in the abstract.

Our response: We have modified the text appropriately in the abstract and background sections.

5. Minor Essential Revision Page 4: However, this would require them to read the evaluation report…. Add that there are even other sources available “…. Or retrieve the information from other trusted sources……..” – there are drug committees or specialist groups, decision support systems…..

Our response: When a new drug appears on the market, the only sources of information available are the SPCs, evaluation reports and scientific papers arising from the clinical trials.
We have now added scientific papers as additional resources.

6. Minor Essential Revision
Page 4: This decision support system alerts the user to potential drug interactions and contraindications. It is a four-step system, with the last step providing access to the most detailed information about the drug. It was developed to decrease significantly the time required for doctors to obtain documentation about drugs. – there are many decision support systems which help physicians to retrieve knowledge about a certain drug in a condensed form and thereby saving time; - please add that there are other systems available; what is unique with your system is that you compare to existing drug alternatives for the same indication.

Our response: The existing decision systems mostly process safety information, to generate alerts relating to contraindications or drug-drug interactions. They do not provide comparative information about drug efficacy and safety. This is now stated in the text.

7. Minor Essential Revision
Page 4: to facilitate appraisal of the potential value….. I would say it is the “evaluation” which is facilitated.

Our response: The sentence has been modified as appropriate.

8. Minor Essential Revision In the Method part: still a mixture of ”past and present tense”; page 12 We use specific font colors…… The "serious drug-drug interactions" (SDDI) are presented

Our response: The text has been modified to homogenize the tenses, but the present tense is appropriate to describe what a computer program does and has therefore been retained, where appropriate, whereas the past tense is used to report what was done or found.

9. Minor Essential Revision Page 30: remove Figure 2: it doesn’t add any more value; you have already Figure 3 and can describe in the legend what you see.

Our response: Figure 2 is the only figure showing the highly synthetic level and we would therefore prefer to retain it in the text.
10. Minor Essential Revision the efficacy of the new drug and its comparator, the table includes the values of endpoints measured in clinical trials and the probability value p. please describe what you do when the endpoints vary!

Our response: The endpoints in a given trial are identical for the two drugs compared. This information was already provided in the discussion section, but has now been moved to the “Impact of the new drug in terms of efficacy” section of the Results.

11. Minor Essential Revision Page 20: Our objective was to provide physicians (mostly GPs) with a tool enabling them to decide rapidly whether a new drug is of potential interest for use in their practices. You should discuss, why you did not evaluate the tool within the GP group only if the focus group is GPs;

Our response: We wanted to have diverse opinions on the different elements and the classification of items, and it was, therefore, interesting to obtain the opinions of professionals with different skills. We have added more detail on this point to the Discussion section. We now plan to carry out an evaluation with GPs only, to compare the times required by GPs to find the correct answers to questions about a new drug from full-text information and with the software.

additionally you should discuss, that a major task will be to implement the IT tool. It is shown, that many CDSS are not used appropriately or not used at all and alerts and warnings are ignored. When should your tool be used by the physicians? Is it when he/she prescribes the first time a new drug for a patient – one should investigate the future usage of the tool. Please add that in your future investigation plans.

Our response: This tool was not designed to guide prescription decisions during consultations with patients. Other tools have already been developed for this purpose. Instead, this tool was designed to be consulted periodically by physicians seeking information about new pharmaceutical products.

12. Discretionary Revisions
Your questionnaire evaluation just left the option to answer with a yes/no alternative; you should offer more choices of answering – Likert Scales with an option of 3 to 5 choices are an better option.

Our response: In fact, for the semi-quantitative evaluation, the SUS questionnaire offers five-response options. Furthermore, when completing the questionnaire, the physicians were asked to provide Comments and Suggestions, particularly as concerned any missing information.

Level of interest: 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.
Reviewer's report

Title: Design and evaluation of software for the objective and easy-to-read presentation of new drug properties to physicians

Version: 5 Date: 13 November 2014
Reviewer: Harry Hochheiser

Reviewer's report:
This paper is improved, providing significantly more detail and clarity. I believe that the question is somewhat well-defined, the data and the approach are reasonably sound, and there are no fundamental difficulties. I still have several concerns, many of which might be addressed through appropriate edits and additional detail.

Major Compulsory Revisions
1. This work is built on the largely un-discussed premise that somehow distinct information systems are needed for new drugs. Although the need for education regarding new medications is indisputable, the workflow here seems somewhat troublesome. Specifically, I can imagine situations where users might use this tool to investigate a new drug, and then subsequently reject that option in favor of an older drug. They would then be forced to use a different resource to get detailed information about the older drug. Wouldn't users be better off with a tool that described all drugs? Why is this approach superior?

Our response: It would be impossible to design a tool capable of comparing the impact of all the drugs that could be prescribed for the same indication. For each drug, different comparators and endpoints would be used. Information processing would thus be highly complex in any system aiming to compare all the possible drugs for the same indication. This tool was not designed for use during consultations with patients. Other tools providing guidance for prescription purposes already exist. Instead, this tools is designed to be consulted periodically, by physicians seeking information about new pharmaceutical products. Typically, physicians might wish to use this software to identify the drugs most recently released onto the market for a given indication, and to determine whether these drugs are potentially interesting for use in their practices.

2. The details of the previous model that informs this work are not available. The authors should provide a description of the main points of this model. Doing so would help the paper illustrate the guiding points behind the design.

Our response: Additional details have been added to the “Overall approach” part of the Methods and an open-access link to our previous study has been added to the References.

3. The design of the system seems potentially inefficient. Why couldn't the highlighted information be shown on the screen all at once, perhaps with controls for drilling down into separate areas? As is, requiring the user to press individual buttons for display of what is new, what other options are available, etc. seems cumbersome and slow. Please justify the design.
Our response: The first screen allows physicians to determine directly whether the new drug is of potential interest to them. On this first screen, the square next to the buttons corresponding to the impact of the drug displays the synthetic result of the comparison in terms of efficacy, safety and ease of use.

4. The evaluation is a bit puzzling. The claim is made that users estimated the time required to form an opinion about the potential of a new drug as being between two and 10 minutes. This seems comparable to the time required to read the two-page US labels described in the introduction. Is the proposed information tool superior to those labels in some demonstrable way?

Our response: The US labels do not provide comparative information.

Minor Essential Revisions
1. The acronym "SPC" is introduced in the abstract without any definition.

Our response: This acronym is now defined in the abstract.

2. The description of related work seems to criticize drug fact boxes for being concise and brief. Why is that a problem? This seems puzzling, as I might imagine that those boxes could be a good comparison point for the proposed tool.

Our response: We have removed the term “highly synthetic”. The principal disadvantage of drug fact boxes is actually their format (on paper, rather than computerized).

3. I found the design section hard to read. A table listing the design decisions made and the goals behind them might facilitate interpretation.

Our response: We have modified and simplified the text. We have moved aspects not relating to the method used to the discussion.

4. I counted at least three places where color-coding was discussed. The diffusion of the discussion of this topic confused me.

Our response: We have removed the description of color-coding from the “Choice of the type of graphical representation of information” section of the “Methods”.

5. The "Claude Bernard database" is introduced without reference or description. More details are needed.

Our response: We have added a reference for the Claude Bernard database.

6. There is a grammatically incorrect sentence on page 10: "The comparator was that used in the clinical trial and described in the evaluation report of the French National Authority for Health (HAS)."
Our response: We selected the comparator from the clinical trials described in the evaluation report of the French National Authority for Health (HAS). The sentence has been modified accordingly.

7. I'm not sure what this sentence means: "We obtained the conclusions of the experts from the 12 evaluation reports."

Our response: There is no “12” in our version of the paper. The experts wrote evaluation reports and their conclusions were extracted from these documents. We have modified this sentence in the “Methods used for system implementation” section.

8. The calculation of the SUS score is not discussed. I assume the standard algorithm was used, but this is not stated directly.

Our response: We used the standard algorithm and this is now specified at the end of the “Methods” section.

Discretionary Revisions

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

**Quality of written English:** Needs some language corrections before being published

A professional scientific editor and translator has checked the English of this new version.

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

**Declaration of competing interests:**

I declare that I have no competing interests