Author’s response to reviews

Title: Designing an automated clinical decision support system to match clinical practice guidelines for opioid therapy for chronic pain

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Author’s response to reviews: see over
We would like to sincerely thank the editors and Drs. Dobscha and Zacharoff for their extremely helpful reviews and suggestions regarding our manuscript. We have attempted to address their suggestions in the manuscript and describe our changes and responses below.

Response to Dr. Dobscha’s suggested revisions:

Suggestion 1: More could be done by the authors to define the model they use to develop the system. Did the investigators base their iterative process of designing, testing, and revising on any previous models or experience? It would be great to reference or show such a model. The model could be illustrated using a figure or flow chart, labeling the objectives of each step, who exactly participated in each step (which is not very clear especially when comes to how or how many primary care providers were involved).

Response 1: We based our guideline translation process on experience gained in development of ATHENA-Hypertension as well as general principles from medical informatics literature encouraging iterative design based on interim evaluation and testing (for example, the ADDIE (Analysis, Design, Development, Implementation and Evaluation) process (see Dick W, Carey L. The Systematic Design of Instruction 4th ed. New York: Harper Collins; 1996.) We now indicate this in the methods and explain which elements of the process were borrowed from previous development experience (e.g. the accuracy testing procedures) versus designed during development of ATHENA-OT.

We have added a figure to depict the process used to translate the clinical practice guideline into a computerized decision support system (see figure 1). The figure includes the goals, team members and products of each of the main the review processes used for guideline translation. This model is now described in the first paragraph of the methods section.

We note that only one primary care provider participated in the guideline translation process (indicated in the description of accuracy testing), but many were involved in the separate iterative usability testing procedures which are described in a second manuscript, under revision for Pain Medicine.

Suggestion 2: The Clinical Tools part of this paper seems like a bit of an add-on. I can understand the authors’ wanting to disseminate information about these potentially important tools, but the presentation doesn’t fit well with the main objective. I might suggest integrating the presentation of tool development into the rest of the model/paper. I think the tools themselves could be described and/or presented in an Appendix.

Response 2: We have removed the description of the final clinical tools and moved this to an appendix. Because portions of the CPG were more easily or appropriately translated into clinical tools rather than individualized patient recommendations, we believe it appropriate that we mention development of these tools as part of the CPG translation process. Thus, the text describing how portions of the CPG were turned into clinical tools has been retained in the main manuscript.

Suggestion 3. Consistent terminology and flow should be used throughout the manuscript. Ideally the subsection headings in the methods section should match the subsection headings in the Results section. What exactly constitutes an end-user?

Response 3: The methods and results sections have been reordered and renamed to be more consistent across the manuscript. New sections have been created to improve manuscript flow. Because the review and redesign process was iterative, we felt it was important to complete reporting on revision of
the rules document and Protégé/EON algorithm before jumping to reporting of the more independent process of clinical tool design. The methods section was ordered to facilitate comprehension of the new figure 1. While the headings in the methods and results are not identical, they are now aligned to facilitate flow across manuscript sections.

An end-user refers to the intended user of the computerized decision support system, in this case a clinician who manages patients on opioid medication. This is now indicated in parentheses in the first instance of use of the term “end-user”.

Suggestion 4: In the discussion, it would be very helpful to know what the developers might have done differently in terms of the process—what did they learn? How might the findings presented here influence development of similar sets of tools by other developers?

Response 4: We have now added a paragraph to the discussion outlining suggestions to improve the CPG translation process based on our experience. This paragraph reads as follows:

“Experience with this iterative process suggested several improvements that might have streamlined CPG translation into a CDSS. Specifically, we would now recommend:

1) Including an explicit focus on defining the boundaries or limits of the CDSS and how they would be handled at the start of the translation process. Outlining these in the Rules Document for review would help insure that they are considered and addressed thoroughly during initial CDSS design.

2) Collecting information from CPG authors regarding prioritization of CDSS recommendations during review of the Rules Document. Both CPG authors and end-users participating in usability testing (Trafton et al., under review) brought up issues regarding distinguishing recommendations based upon their clinical importance.

3) Presenting specific wording of CDSS recommendations as well as an indication of whether the wording was to be presented on the main screen or only after end-user interaction with the system (e.g. presented following a mouse click) to CPG authors to review as part of the Rules Document. Subtle wording changes in the CDSS recommendations could alter author consensus on recommendations.”

Suggestion 5: What does ATHENA stand for? What does EON stand for?

Response 5: ATHENA and EON are names of the software programs and do not stand for anything. ATHENA was named after the eponymous Greek goddess of wisdom, strategy, industry, justice and skill, as these were qualities we hoped that the computerized decision support systems would promote. The EON system was so named because an early component of the software was designed to enable use of time-dependent data, and an eon is a unit of time that is too long to measure. They are customarily capitalized to distinguish them as the software products as opposed to a goddess or time scale. This explanation was not added to the manuscript because we felt it was too tangential.

Suggestion 6: I would note earlier in the manuscript and more overtly that results for providers (on usability and utility) are to be published separately.

Response 6: A sentence explaining this has been added to the last paragraph of the background section.
Suggestion 7: I don’t think Figure 2b is very interesting or helpful. I would rather see some type of example of true decision support—this is just a summary of data that has been collected from the patient.

Response 7: The figures depicting the clinical tools have been moved to an appendix, as suggested and described in point 2.

Suggestion 8: I really like the use of examples throughout the text and in tables. I think it would be helpful if a sample of the rules document could be included as an Appendix.

Response 8: The rules document has been provided to be included as an appendix.

Suggestion 9: In the discussion at the bottom of page 18 it might be further emphasized that pain guidelines may be especially challenging to operationalize due to the heterogeneity of patients, limited evidence-base for many criteria, and controversies surrounding treatment. As such, another guideline, for example, for depression, might be simpler to operationalize and implement.

Response 9: We completely agree with the reviewer on this point and have added a sentence to the discussion to emphasize this idea.

Suggestion 10. I might change the Title of Table 1 to be “Examples of Boundaries of ATHENA-Opioid Therapy.”

Response 10: We agree with this suggestion and have made this change.

Response to Dr. Zacharoff’s suggested revisions:
Reviewer’s report

Suggestion 1: There are some typos throughout, for example on the final page with Figure 3. The date of pain onset says September, 3 1466. I would recheck the grammar in some instances as well.

Response 1: We have reread and carefully edited the grammar, text and figures for typos and errors.

Suggestion 2: I would consider including a statement or two about situations where clinicians either ignore or decide against recommended decisions.

Response 2: We added mention of this point in the results section on “Validation of the Draft Rules Document by Authors of the CPG”. The following sentence was added:

“These comments helped clarify situations where clinicians might appropriately either ignore or decide against guideline recommended actions based on information not in the EMR, allowing alteration of the DSS to encourage less rigid use of recommendations in these circumstances.”