Author's response to reviews

Title: Computational Challenges and Human Factors Influencing the Design and Use of Clinical Research Participant Eligibility Pre-Screening Tools

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RE: “Computational Challenges and Human Factors Influencing the Design and Use of Clinical Research Participant Eligibility Pre-Screening Tools” (Resubmission of Manuscript Number 1917401804664102)

Dear Sir or Madam:

Please find attached to this cover letter the resubmission of our manuscript entitled “Computational Challenges and Human Factors Influencing the Design and Use of Clinical Research Participant Eligibility Pre-Screening Tools”. On the behalf of my co-authors, I am very pleased to submit to you this revised article for your consideration and potential publication in BMC Medical Informatics and Decision Making.

Our submission presents the design and results of a multi-modal evaluation of a tool that was developed to aid in the pre-screening of patients for recruitment in clinical trials. This report leverages data from several perspectives, including usability testing with potential end-users, expert heuristic analysis, and a quantitative evaluation. We believe that this report addresses the significant challenges associated with cohort identification in clinical trials and presents a tool that may provide practical use to address this need.

We have made revisions to this manuscript per the suggestions of the reviewers. I will address the reviewer critiques individually:

Editorial Comment 1: The only minor comment that should be easily addressed by the authors is that there should be some direct discussion about how tools like i2b2 or TRIAD underpin tools like ASAP for cohort identification.

- **Response 1:** We have edited the discussion to include how tools such as caGRID, TRIAD, and i2b2 may be used for better cohort identification.

Editorial Comment 2: Positive predictive value reported in study is 0.007% in table and abstract. Is it error? Positive predictive value is the proportion of patients with positive test results who are
correctly diagnosed. This number means that only 1 patient out of 700000 diagnosed correctly

- **Response 2:** We have corrected this error and we would like to thank the reviewer for making us aware. The manuscript has been revised to show a positive predictive value of 0.7%.

**Editorial Comment 3:** Aim of the study is not spelled out clearly in abstract and main text

- **Response 3:** We have revised the abstract and the background section in order to make it clear to the reader that we are presenting the evaluation of the ASAP tool and assess its ability to address the needs related to cohort identification in clinical trial recruitment.

**Editorial Comment 4:** The manuscript is focusing on the evaluation of design issues, however major part of background section describes problems with clinical trials enrolment and dealing with datamarts. Manuscript is lacking details about similar studies that was done on the heuristic evaluation of screening tools.

- **Response 4:** We do concur with the reviewer that the manuscript contains less information about other studies which use heuristic evaluation and more information about the general issues associated with clinical trial recruitment. We feel that the background information regarding the importance of clinical trial recruitment is more important to a potential reader, as it demonstrates the motivation for this study. We do acknowledge other studies in the discussion section as we report on the results of the various components of our study in context.

**Editorial Comment 5:** Method section is essential part of the manuscript placed at the end of draft. It is confused order. Better to have traditional order

- **Response 5:** We have followed the BMC outline for the order of the sections in this manuscript.

**Editorial Comment 6:** Diagnostic performance of 4 trials combined to 2 resulted number sets (table 1). Please explain.

- **Response 6:** We have revised the section to describe that the trials we combined into two categories based upon the similarity of the inclusion criteria.

**Editorial Comment 7:** “The results of validation study...” Statement overestimated ability of tool to rule in and rule out eligible patients given moderate sensitivity and specificity. Better to avoid.

- **Response 7:** We believe that our results indicate that the ASAP does demonstrate an ability to create a pre-screened list of patients, which can then be further screened by the study.
coordinator for additional criteria. We have indicated that the ability to “rule out” patients, based on the sensitivity scores, is low but less important since this tool is intended to only pre-screen based patients for potential eligibility. The specificity scores are relatively high, especially for the Family Medicine trials, and we use this results as evidence that the tool does have sufficient ability to “rule in” patients for potential eligibility. We also provide suggestions for how these scores can be improved and link them to other studies.

**Editorial Comment 8:** Small sample size is not addressed in limitation part of the manuscript

- **Response 8:** We have included our sample size in the usability test and the heuristic evaluation as a limitation to this study.

**Editorial Comment 9:** Nielsen’s heuristic principles – citation missed

- **Response 9:** We have corrected this error and added the appropriate citation.

**Editorial Comment 10:** Figures 5 and 6 can combined focused on particular parts.

- **Response 10:** Both Figures 5 and 6 are screen shots of the ASAP tool. We believe that the figures should not be combined, as they highlight different areas for end-user mistakes, as evidenced in the usability testing.

Please do not hesitate to contact me if you require any further information as you evaluate this re-submission. On behalf of my co-authors, we look forward to your comments and feedback on our manuscript.

Respectfully,

Taylor R. Pressler