Reviewer’s report

Title: A clinical decision support tool to screen health records for contraindications to stroke thrombolysis-a pilot study

Version: 4 Date: 13 October 2015

Reviewer: Farrant Sakaguchi

Reviewer’s report:

I like the paper. I believe it is improved. However, I still feel like further refinement is necessary.

Major Compulsory Revisions:
1) I have no single major compulsory revision. I have enough discretionary revisions that I hope that many will be addressed prior to publication.

Minor Essential Revisions
2) I would recommend against the abbreviation on page 4 lines 3-5. The abbreviation for the US Health Information Technology for Economic and Clinical Health Act is "HITECH." If the abbreviation for Information Technology (IT) or Health Information Technology (HIT) is used, it should not break up the name of a specific name or piece of legislation.

3) Please review the difference between EFFICACY and EFFECTIVENESS trials. http://www.ncbi.nlm.nih.gov/books/NBK44024/ Rather than a trial of the CDS "efficiency" I would consider this an "efficacy" trial. I assume that "efficiency" refers to the speed of the task completion, but I still believe the research methodology should use more established design criteria unless a more compelling argument is made.

4) Abstract: Materials and Methods, Page 2, lines 11-19. Please rewrite, following the reporting guidelines from either CONSORT or STROBE. http://www.equator-network.org/reporting-guidelines/consort/ or http://www.equator-network.org/reporting-guidelines/strobe/ The study design is significantly more clear in the full Methods section, but this deserves better organization. I would recommend identifying A) the study design (e.g. pre-post design vs cross-over design), B) the mock patient case development, C) the study cohort, and D) the task for the study participants.

Discretionary Revisions
I apologize for not identifying these more explicitly before. I like your paper overall, but feel the writing should be significantly strengthened. The grammar is fine, but the flow would benefit from significant refinement. While not all of my recommendations needs to be followed, if I were to have my name on this paper, I would consider the following changes.
5) Abstract: Background, Page 2, line 4. Recommended changes in CAPS. Start the sentence “THE USE OF intravenous thrombolysis…”


7) Abstract: Conclusions, Page 3, line 13. If you have the space, I would recommend something about the mechanism by which the CDS works. For example, “By extracting or identifying relevant contraindications, the CDS tool may reduce the time needed…”

8) Background, Page 4. Starting with the HITECH act does not seem to fit in with the rest of the paper. I would recommend starting with your second paragraph, (page 4, line 11).

9) Background, Page 4. I still do not understand the relevance of the HITECH act with regards to your intervention. Your tool would not be relevant to Meaningful Use, even if it were available in the US. Meaningful Use has not yet shown any improvements in the delivery of care to date. Thus, I would remove the first sentence (page 4, line 3-5). I would move the last sentence in the paragraph (Strong evidence supports…) to be the first, and I would change the next sentence to : A systematic review of the literature shows that most studies report that health IT interventions…

10) Background. I do not have specific recommendations for the order, but feel that much of the literature sited in the Discussion would work better in the Background and would create a more compelling argument for the need for your CDS tool.

11) Methods: Page 6, line 13-16. The following sentence should be used as a closing sentence in the background or else as the first sentence in this paragraph. Suggested minor changes in CAPS. (The CCHS iStroke was developed to allow for rapid screening of THE relevant medical history for stroke thrombolysis among all ELECTRONIC CCHS hospital RECORDS to support clinical decision making.)

12) Methods, CCHS iStroke: Page 6. There should be 1 sentence indicating the total number of contraindications for tPA according to the guidelines, and the number or percentage or significance of those contraindications identified by iStroke.

13) Methods, CCHS iStroke: Page 7, lines 5-7. I would recommend moving the sentence “The treating physician…” down to line 13, just before the last sentence. This way, the flow is more logical, describing the application and database, then how it is used.

14) Methods, Test use of the CCHS iStroke: Page 7, line 17. I would recommend changing the subsection heading to “EVALUATION of the CCHS iStroke.”
15) Methods, Page 8, line 1-3. I would recommend changing the sentence to something like the following (recommended changes in CAPS). “To limit the situational variables and increase the significance, four mock patient records WERE GENERATED. THESE RECORDS WERE DERIVED from the stroke registry that contained records from two or more CCHS hospitals.”

16) Methods, Page 8, line 3-4. I would recommend moving this sentence “Table 1 shows…” down to line 11 before the sentence “The four cases…”

17) Methods, Page 8, line 11. I would recommend a sentence something like, “Of the 13 total contraindications for tPA, iStroke helps to identify 10 that can be extracted from the EHR…”

18) Methods, Page 8, lines 11-12. I would recommend rewriting something like, “The four cases had A TOTAL OF NINE CONTRAINDICATIONS, SIX OF WHICH WERE UNIQUE.”

19) Methods, Page 8, Lines 12-13. I would recommend moving the sentence “Case 3 had a record…” to line 16, after describing Case 2 and prior to discussing Case 4.

20) Methods, Page 8, line 18. I would recommend starting a new paragraph after “…a known history of diabetes and stroke.” I would begin it something like, “A pilot study using a pre-post (vs crossover) design was used to study the efficacy of the CDS tool.”

21) Methods, Page 8, line 19, I would recommend changing the sentence to something like, “…with the CDS tool SO THAT EACH MOCK PATIENT APPEARED SIX TIMES IN EACH GROUP.

22) Methods, Page 9, Line 1. I would recommend changing the sentence to something like, “…during off-duty hours WERE RECRUITED AND INFORMED CONSENT WAS OBTAINED.”

23) Methods, Page 9, line 3. If you identify that the number of participants was limited to 12, please explain the rationale – e.g. power calculation. If this was not predefined in the study protocol, then eliminate that sentence.

24) Methods, Page 9, Line 4. Recommend creating a new paragraph here and rewriting the sentence to something like, “EACH PARTICIPANT WAS PRESENTED WITH A SET OF STROKE TEST CASES. EACH CASE BEGAN WITH THE SCENARIO OF THE PATIENT ARRIVING AT CCH WITHIN 1 HOUR OF THE STROKE ONSET.”

26) Methods, Page 9, line 12. Be cautious of identifying control groups here… Due to your study design, there is not really a “control group” but rather a “Control Series” or “set of control cases.”

27) Methods: Analysis, Page 9. There really should be some power analysis – how many subjects or the magnitude of the difference that you are looking as you go into the study.

28) Results, Page 10. I recommend describing the cases/scenarios prior to describing the participant recruitment. This would follow your Methods section closer. As such, I would suggest starting the paragraph with line 10-11.

29) Results, Page 11, Lines 1-4. The description of the two physicians belongs with the results of the individual participants rather than collapsing the results into “with vs without CDS.” I would recommend moving the sentence “Notably, two physicians…” to Page 10, line 17.

30) Results, Page 11, lines 7-10. I would recommend the following changes, “The time WAS 14.6+-7.4 MINUTES IN THE CONTROL GROPU AND WAS ONLY 7.3+-5.2 MINUTES IN THE ISTROKE GROUP (P=0.010). THE TOTAL NUMBER OF MISSED CONTRAINICATIONS WAS 23 IN THE CONTROL GROUP AND WAS ONLY SEVEN IN THE ISTROKE GROUP…”

31) Discussion, Page 11, lines 17-19, Page 12, Lines 1-4. Please see how to use this more in the Background. In the discussion it would be nice to see more about how your CDS tool fits into the literature, not just describing the literature (which is more of a Background thing). Certainly referencing this literature briefly is useful in the discussion, but please spend more time discussing your results and less describing the literature.

32) Discussion, Page 12, Lines 7-19, Page 13, Lines 1-2. Please see how to use this more in the Background. In the discussion it would be nice to see more about how your CDS tool fits into the literature, not just describing the literature (which is more of a Background thing). Certainly referencing this literature briefly is useful in the discussion, but please spend more time discussing your results and less describing the literature.

33) Discussion, Page 13, Line 2 – if you do not move the Background material, then the paragraphs describing your study “In our study…” should be the beginning of a new paragraph.

34) Discusion, Page 13, Lines 9-13. Please see how to use this more in the Background. In the discussion it would be nice to see more about how your CDS tool fits into the literature, not just describing the literature (which is more of a Background thing). Certainly referencing this literature briefly is useful in the discussion, but please spend more time discussing your results and less describing the literature.

35) Discussion, Page 14, Line 2. “Efficiency.” As described above, I believe you
are referring to the real-world “effectiveness” instead of the pilot-testing “efficacy.”

36) Discussion, Page 14, Lines 7-12. These sentences would fit better in the Methods section describing the iStroke application.

37) It would be interesting in the discussion to mention the number of days saved or the financial benefit gained between the difference of 7.3 minutes saved in reviewing the chart. Also I am curious whether a chart review would still be required as some contraindications are not captured by your CDS tool.

38) Conclusion, Page 14, line 19. “Efficiency.” As described above, I believe you are referring to trial “efficacy.”

39) Conclusion, Page 15, line 3. “Efficiency.” As described above, I believe you are referring to real-world “effectiveness.”

Level of interest: An article whose findings are important to those with closely related research interests

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

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.