Author’s response to reviews

Title: Anesthesiology Control Tower: Feasibility Assessment to Support Translation (ACTFAST) - a feasibility study protocol

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Version: 1 Date: 15 Dec 2017

Author’s response to reviews:

Reviewer #1: Thank you for submitting this well-written study protocol. I only have a few minor suggestions for improvement.

1) It would be helpful to add two sections to the end of the "Background": firstly, relating to the study "Hypothesis" and secondly the "Aims and Objectives" of the study. There may be primary and secondary objectives, which would link to the primary and secondary outcomes of the study (see next point). The primary objectives of a pilot study should relate to the demonstration of feasibility/acceptability/deliverability/safety etc of the interventions/outcome assessments/recruitment etc or to provide reliable estimates for sample size calculation for a future definitive trial.

Response: Thank you for this suggestion to improve the background section. We have included these edits as suggested.
2) Please clarify the primary and secondary outcomes. The primary (secondary) outcomes should link directly to the primary (secondary) objectives.

Response: We have added explicit details regarding our primary and secondary outcomes.

3) Pilot studies should focus on confidence interval estimation; therefore, please add "(and 95% confidence intervals)" when you state that means will be reported in the two data analysis sections.

Response: Confidence intervals have been added to the relevant sections of the manuscript.

Reviewer #2: This is a well written and interesting manuscript. Please find my suggested revisions below which I hope will help improve this article:

Title: Please state that this is a 'feasibility study' in the title.

Response: The title has been edited as suggested.

Abstract: It would be good to mention the future definitive RCT. i.e. include a sentence in the abstract explaining that results will inform the revision of the prototype, which will then be evaluated in the form of a definitive RCT.

Response: This has been included in the end of the abstract as suggested.

Background: Improved structure for this would be to start the background section with a paragraph on how anesthesiology processes currently operate, followed by some explanation of
why this needs to be improved, followed by a more thorough description of the ACT and more thorough explanation of in what way you expect ACT to improve things. Then this can be followed with your uncertainties about the feasibility/usability of ACT and reasons for needing to conduct a feasibility study i.e. testing the usability and identifying problems prior to the main trial. Please then explicitly list your specific feasibility objectives.

Response: Thank you for this suggestion. We have restructured the background section as suggested.

pg 4 lines 76-78: It wasn't immediately obvious to me whether (2) here is the same as phase II described in the abstract with the in-situ usability analysis. Perhaps make this more explicit.

Response: The plan for this aim (2) regarding the assessment of barriers and facilitators through surveys with key stakeholders has been removed from our planned protocol. This plan was previously mentioned in the following areas: the end of the background section, Table 1, and the final sentence of the method section right before the discussion.

pg 5 lines 99 and 100: Approval for this protocol would be better placed at the end of the document e.g. near ethics approval.

Response: This has been moved to the ethics approval section as suggested.

pg 6: You describe how participants will be recruited via email, but more description and clarity is needed here on exactly how participants will be identified.

Response: This has been addressed by adding a new section to the methods section (third paragraph of methods section).

pg 6: Do you have eligibility criteria for participants in your feasibility study? Will you obtain written consent from participants for collection of data on them?
Response: Our eligibility criteria and process of obtaining consent is now included as suggested (third paragraph of the methods section).

Methods: This section should relate back to your specific feasibility objectives that you list in the background section, with explanation of how you will assess/measure each objective.

Response: We now include an expanded description of our objectives and our planned assessments.

pg 8 line 152: Would help to have some examples of the closed-ended questions. Do you have any study instruments with the questions you will be asking that you can include in the appendix?

Response: Most of our interview questions are actually open-ended and we removed the mistaken reference to closed-ended questions. The open-ended items are included in Appendix II.

pg 8 lines 154-155. What are the data management procedures? How will the data be stored?

Response: This has been addressed in the methods section of the manuscript.

pg 10 line 209: You mention measures of effectiveness. Do you mean potential effectiveness of the ACT? You should include a caveat about the small sample size.

Response: An expanded description regarding effectiveness as it specifically relates to usability analysis is now included in the Data Analysis subsection of the methods section for Phase II. We acknowledge the limits of the sample size in our analysis and we state this in the discussion.

Discussion pg 12 lines 244 and 252: delete 'the'; include 'on'
Response: This has been addressed.

pg 15 line 310: iPhone
Response: This has been addressed.

Funding: You say that this protocol has not received any specific grants from funding agencies, but will you be receiving funding for the actual feasibility study? If so please detail this.

Response: The feasibility study has received grant support which is now described in the funding section.

Reviewer #3: Thank you for the opportunity to review this manuscript. I have the following comments:

'Think-aloud' protocol analysis was used in the feasibility assessment which I think is one of the better methods. But I think the authors could clarify to the readers why this approach was chosen and whether there are perceived benefits to other approaches.

Response: We have included additional information related to the “think-aloud” approach both in the methods section and in the discussion section, and we also include acknowledgements of some of the limits of this testing, namely its interference with task completion and cognitive processes.

-It would also be beneficial to have either a focus group or semi-structured interviews/surveys with anesthesiologists post interaction with ACT, not just other stakeholders.

Response: We agree that this would be beneficial and we have now included an additional comment on this in the second to last paragraph of the discussion section.
-Recruitment of participants are through emails - could authors potentially select those who are more engaged with computer/IT technology - it is important to recruit participants that are representable of the general population of anesthesiologists.

Response: The primary method of communication within our department is via email and other electronic avenues, hence we are planning to use this for our recruitment. This is now explicitly stated in the manuscript.

-The questions from qualitative survey could be included as an appendix.

Response: The qualitative survey has been removed from the planned pilot study as noted above. We do now include the questions from the debriefing sessions are now included in a new Appendix II as suggested.

-I would suggest adding clinical trials reference of ACT in main body of text so that the reader can look this up without looking up the Appendix.

Response: We have included the clinical trials registration number for the randomized controlled trial in the abstract and the body of the report.

-The authors should also clarify that the users testing will be independent of or do not have any conflicts in testing a system that has been invented from the same institution.

Response: We appreciate this feedback and have provided additional information on the relationship between the research team physically involved with the testing and both the inventers and the research participants. In the first paragraph of the methods section, we note that the company responsible for inventing and refining the AlertWatch Tower Mode software has was not involved with the design of the current study nor will they be involved with data collection or analysis. Also, in order to minimize potential conflicts between the researchers and the participants, session moderators will only those members of the research team who do not
have any supervisory roles within the department, i.e. junior anesthesia residents (TM), medical students (FW), and research assistants (MB). This is noted under the procedure section for Phase Ia: “Think-aloud” with ACTors.