Reviewer’s report

Title: Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines

Version: 3
Date: 6 January 2015

Reviewer: Deena Costa

Reviewer’s report:

Thank you for the opportunity to review this interesting study about ICU guideline development. The study by Clay-Williams and colleagues is an innovative approach to understand how clinical guidelines represent (or deviate) from the clinical care provided in intensive care units. Using the Functional Resonance Analysis Method (FRAM), they identify functions that are currently being done that do not adhere to the guidelines or alternatively, functions that are present in the guidelines but not enacted in clinical practice. The advance here is using FRAM during guideline development to improve clinical care and practice and the manuscript explores a unique and important question. Nonetheless, the manuscript as-is, lacks specificity regarding how FRAM was used to examine and understand the two cases of ICU guidelines in Denmark and Australia and this unfortunately, limits the applicability of the FRAM approach to other guideline development.

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

1. I find the results in need of additional detail. FRAM seems complex but in my view, not enough time is spent fully exploring its complexity, which would increase its application and impact.

a. For example, the results section describes conclusions about each case and refers the readers to the Figures but taking the reader through how FRAM was employed in a more stepwise fashion would be very beneficial.

2. After reading the methods and results, I had lingering questions that I believe should be addressed:

a. Were clinicians involved in FRAM? If so, which clinicians, how were they identified and who were they? (i.e. clinical nurse specialists, bedside nurses, attendings?)

b. Did the clinicians view the amount of time spent on FRAM development (described as a few weeks) as burdensome?

c. For Case 2, the authors report that 22 functions were identified with the initial FRAM but then modified after discussions with clinicians to only 20 functions (some added, some deleted). I am quite curious to know what functions were added/deleted and how the group came to consensus on which to add/subtract. Describing this process would be beneficial to others attempting to use FRAM for
guideline development.

d. I like the idea that FRAM can be used to prevent workarounds at the beginning of guideline/protocol development by engaging staff and writing the protocol as ‘work is done’ not as imagined. But how practical or easy is it to use FRAM? Can clinicians do this without assistance from researchers? (This may be best addressed in the discussion section)

3. I have a broader conceptual question that the article does not currently address. The purpose of using FRAM (at least from my understanding after reading this manuscript) is to ensure that clinical guidelines match work as done not work as imagined. This assumes that work as done is the ‘appropriate’ way to reach the intended outcome/goal. It’s certainly plausible that ‘work as done’ may be more steps than necessary or may be incongruent with hospital or clinical policy. Thus, using FRAM in those instances would not be beneficial. How is this issue addressed? For example, using FRAM to examine clinical practice guidelines (recommended ventilator settings, titration of insulin or continuous sedation) would thus describe ‘work as currently done’ and not necessarily as how it should be done- which in those instances, the guidelines are recommended approaches to care. If FRAM should not be used for understanding clinical practice guidelines, this should be noted in a Limitations section.

4. The figures are helpful however; a more detailed explanation of Figure 2 & 3 is necessary. I am quite familiar with ICU guidelines and clinical practice however I am not well versed in FRAM and it is likely that many readers are not either. More detail about the steps that took place and how that is represented in the Figures would be helpful.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

5. I would recommend moving the discussion of what a clinical guideline is (first paragraph under the ‘Functional Resonance Analysis Method’) earlier in the manuscript – (I’d suggest moving it to the first or second paragraph of the introduction). Introducing the definition of a clinical guideline after much discussion of clinical guidelines reads disjointed.

6. I would add a paragraph about study limitations (2 ICUs, time intensive etc).

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

7. I would divide the results and discussion section into two separate sections.

**Level of interest:** An 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.

Declaration of competing interests:
I declare I have no competing interests.