Author’s response to reviews

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

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Author’s response to reviews: see over
Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. Robyn Clay-Williams, Jeanette Hounsgaard and Erik Hollnagel

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<th>Editor's Comments</th>
<th>Authors' Response</th>
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<td>Both reviewers raise serious issues about the organization and clarity of this manuscript, and need to be addressed with a substantial revision that clarifies, as Dr. Iwashyna suggests, the intent of this manuscript. In addition to addressing these issues, please ensure that the final manuscript stays below our 5500 word limit; you may use additional files to include material that does not fit within the word count limits. Dr. Costa's comment that you should separate the Results and Discussion section is correct; we will not review the revised manuscript unless this is done.</td>
<td>Thank you for consideration of our manuscript and provision of valuable advice, which we have used to revise and strengthen our submission. The purpose of our paper is that suggested by Reviewer 2, point 1, i.e. as an introduction to FRAM analysis and an argument for its potential usefulness. We have modified our text to satisfy that aim, by (a) discussing FRAM as a method of resolving differences between WAI/WAD, (b) providing additional detail on how FRAM works, and (c) providing our case studies as illustrations/examples. We have also separated the Results and Discussion sections.</td>
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<td>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</td>
<td>We would like to thank reviewer 1 for support of the intent of our manuscript, and excellent advice, which we have used to improve our paper. We have revised our submission as follows:</td>
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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.

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<th>1. The section on FRAM has been expanded, to provide more detail on how this method might be used to improve guideline implementation and uptake. In particular, we have included more detail on how FRAM was used in the case studies.</th>
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| 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. |
| 2. Clinicians, including doctors and nurses who were involved in the guideline implementation on the two ICU wards, participated in FRAM for both cases. Participation was under the guidance of the researchers (RCW for the Australian case, and JH for the Danish case). We have included additional information in the manuscript on clinician participation in the process.  
   The clinicians involved in the process did not find it burdensome. Even though the process occurred over a few weeks, clinician involvement was only a couple of hours total. We have included additional information in the manuscript on clinicians’ perceptions of the process.  
   Information has been included on which functions were added/deleted following discussions with clinicians. |
### 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.

We have added comments in the limitations to address the situation where the guideline (or part of the guideline) is not negotiable, and must be implemented as written. It is not intended, however, that the intent of a guideline be subsumed so that clinicians can work how they wish. Although the FRAM helps to resolve anomalies between WAD and WAI, that does not mean that elements of WAD are not changed through involvement with the process. The advantage is that problems can be ironed out prior to implementation, making it more likely that introduction of the new procedures will be successful.

### 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.

We have included additional detail on the steps used to develop and modify the FRAM.
### Minor Essential Revisions

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.

The discussion of what a clinical guideline is has been moved to the Background section, towards the start of the paper, and the Background has been partially re-written.

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

A paragraph has been added to address study limitations.

### Discretionary Revisions

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

The results and discussion has been divided into two separate sections.

### Reviewer 2 Comments

This is a potentially very interesting article. The Work-As-Imagined (WAI) vs Work-As-Done (WAD) distinction is potentially of great value in thinking about implementation and guidelines; it resonated with me immediately, but is not an application that had occurred to me before. The whole manuscript is really quite well written. Unfortunately, the present manuscript is stuck betwixt and between 3 incompatible aspirations: -1- an introduction to FRAM analysis and argument for its potential usefulness -2- an application of FRAM analysis to 2 specific problems to an audience not familiar with it -3- a technical report of 2 FRAM analyses

We would like to thank reviewer 2 for also supporting our manuscript, and for the suggestions for improvement. The aim of our paper is -1- to introduce FRAM analysis and argue for its potential usefulness, therefore we have revised our submission as follows:
I confess I was not familiar with FRAM analysis prior to reading this report. But I suspect the authors’ think more potential Implementation Science readers are not, either — why else would one include such basic introductory domains as Figure 1 and the 2nd two paragraphs under “FRAM” heading?

My recommendations depend on which of the 3 manuscripts the authors really want to write.

If it is -1-, then please:
- discuss the relationship between FRAM as an approach to distinguishing WAI vs WAD in relation to other approaches. Drawing the distinction between WAI and WAD has, of course, been one of the core ways ethnographers, particularly those of a certain anti-establishment bent, have defined themselves for decade. How does FRAM build upon yet break from that tradition?
- take us much more slowly through FRAM network construction. What do TCORPI mean at the vertices of each hexagon? How does one decide which steps are primitive enough to warrant their own hexagon? How is the network lay out down such that these things are somehow readily interpretable, rather than simply being a hairball?

If -2-, then please:
- a condensed version of -1- is clearly needed
- a methods section is needed that is actually a description of the reproducible methods used to generate the results. Presumably this involves a discussion of the field work and how WAD is actually ascertained. How is variation across providers

This is our aim.
We agree that there are other ways to distinguish between WAI and WAD, but few are solution-focused. Unlike ethnography, which seeks to understand/explain how social systems function, FRAM has a more practical aim of not only identifying, but also resolving anomalies in order to solve a specific problem. Ethnography may provide a potential source of data for the FRAM, however, observational data are usually supplemented with interviews/focus groups (and quantitative process data, where available/relevant). In our two cases, the primary data came from the written guidelines themselves. As suggested, we have expanded the introductory section on FRAM, to provide more detail on how a FRAM might be constructed, and how it might then be used to facilitate discussion with clinicians to revise and improve a guideline. We have also provided additional detail along these lines in our case presentations.

Not our aim.
or sites in WAD measured and incorporated? The current methods section is really just a description of two case sites, not a description of how the analysis was actually done.

| If -3-, then, please consider, with editorial guidance, whether Implementation Science is the right journal of your — you may want to presume a degree of familiarity with FRAM that is greater than Implementation Science’s readers have to offer. | Not our aim. |