Reviewer’s report

Title: A feasibility study of a randomised controlled trial to examine the impact of the ABCDE bundle on quality of life in ICU survivors

Version: 0 Date: 20 Jul 2017

Reviewer: Elizabeth Colantuoni

Reviewer’s report:

I applaud Sosnowski et al for an extremely well written manuscript describing the feasibility of a randomized controlled trial to examine the impact of the ABCDE bundle on quality of life in ICU survivors.

As my expertise in Biostatistics, I will leave the discussion on the merit of the ABCDE bundle to more relevant clinical reviewers.

I do have several questions/comments:

1) In the section "Intervention group", the authors describe the specific components of the ABCDE bundle and that education on the bundle commenced two months prior to study commencement. Given the this is a single site study and the clinicians/nurses were likely treating both intervention and control patients, were you able to compare receipt of the bundle elements in both the intervention and control groups? i.e. how much spill-over occurred into the control group due to the fact that the clinical team were using this care bundle on the intervention patients? It would be great to see these data reported.

2) Along the lines of comment 1), it would be great to see a discussion of whether the authors feel that the best design for a controlled trial of the ABCDE bundle is randomization of patients within units vs. the more traditional approach of a cluster randomized trial. Can the authors provide justification for why they decided to randomize within the single site and also, give a recommendation of how they would see a larger, sufficiently powered RCT implemented.

3) Although the authors are correct in not reporting results of statistical hypothesis tests within this feasibility study, it would be interesting for the authors to comment on the observed size of the mean outcomes across the intervention and control groups; i.e. are the means in the appropriate direction as you would expect given the goals of the bundle?

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