Author’s response to reviews

Title: Vital sign monitoring with continuous pulse oximetry and wireless clinical notification after surgery (the VIGILANCE pilot study) - a randomized controlled pilot trial

Authors:

James Paul (paulj@mcmaster.ca)
Matthew Chong (matthew.a.chong@gmail.com)
Norman Buckley (buckeyn@mcmaster.ca)
Prathiba Harsha (harshap@mcmaster.ca)
Harsha Shanthanna (shanthh@mcmaster.ca)
Antonella Tidy (tonitidy@mcmaster.ca)
Diane Buckley (dianamariabuckley49@gmail.com)
Anne Clarke (annepaulclarke@gmail.com)
Christopher Young (christopher.young@albertahealthservices.ca)
Timothy Wong (timmywong@gmail.com)
Thuvaraha Vanniyasingam (tvanniya@stjosham.on.ca)
Lehana Thabane (thabanel@mcmaster.ca)

Version: 1 Date: 07 Dec 2018

Author’s response to reviews:

Associate editor

1. Pg 4, Line 16 – need to add “and” before “2) system alarm types and detail”
   a. "and" was added

2. Pg 7, Line 18 – need to add “to” before “investigate the implementation”
   a. "to" was added
3. Please include randomised pilot trial in the title. The current title ("Vital sign monitoring with continuous pulse oximetry and wireless clinical notification after surgery (the VIGILANCE pilot study) – a randomized controlled pilot trial") already includes these words.

4. Abstract: Please include detail on trial design (parallel?), how participants were allocated, any blinding, number randomised to each group, and any adverse events. These details were added to the abstract, as suggested.

5. Study design- please state. Parallel? Allocation ratio? Type of randomisation – simple, stratified, blocked? Who enrolled participants and assigned them to the interventions (I think it’s the nurses from the text but could be more explicit). These details were added to the Study Design section of the Methods.

6. Pg 8 line 17 – what about blinding of the statistician?
   a. The statistician was not blinded.

7. Pg 8 line 20 – OR abbreviation not previously defined.
   a. We have fully defined this abbreviation.

8. Outcomes – please explain here how you measured whether patients accepted and tolerated the monitoring system.
   a. We took a pragmatic approach regarding the patients' ability to accept the monitoring system (e.g. able to complete the full course of monitoring for the study without asking to be withdrawn) and we have added our criteria as suggested.

9. Pg 10 line 7 – the criteria for success of feasibility appear to be missing?
   a. Good point. The criteria for success is now explicitly stated on page 10, line 9. The criterion for success was set at 14 patients per week.

10. Sample size – can you give any further rationale for your convenience sample size of 250?
    a. A rationale is given for the sample size on page 10, line 3.
11. Other information: Please state where the pilot trial protocol can be accessed, if available.

a. The URL for the record was added under the 'Availability of data and materials' section.

Reviewer 1

1. The authors stated that the study was registered on ClinicalTrials.gov retrospectively. Is there a reason or rationale for why this wasn't done prospectively? Providing more information regarding whether any deviations from protocol in study conduct or omission of certain outcomes in the reporting would help strengthen this point.

a. We had intended to register the trial prospectively, but unfortunately and truthfully the registration was not submitted due to a clerical error.

2. It appears that the power calculation for the subsequent RCT is based on the event rate reported in the literature. Since the event rate in the present pilot trial was lower than that reported in the literature (possibly due to healthier patients in the study wards), is there reason to suspect that this issue will persist in the RCT? How do the characteristics of the eligible patients admitted to the ICU post-operatively differ from those randomized into the study (if this information is available)?

a. We thank the reviewer for the discussion around the event rates. We were reluctant to alter the power calculation for the full RCT given the small sample size of this pilot trial. However, as the reviewer correctly points out, it is certainly possible that this may be the true event rate in our population -- in which case the full RCT would end up being underpowered. Regarding the second point, the characteristics of the patients admitted to ICU were not extracted as part of this study, but certainly the reviewer raises an interesting clinical question.

Reviewer 2

1. Abstract: The following line "The analysis of the outcomes was based on descriptive statistics with estimates reported using point (95% confidence intervals)" in the method section does not make sense.

a. We apologize for the typographical error in this sentence. We have replaced the 'with' with an 'and' to make the sentence make more sense: "The analysis of the outcomes was based on descriptive statistics and estimates reported using point (95% confidence intervals)."
- Page 10: Criteria for success for feasibility: this heading seems odd as it does not match with other section headings or sub-headings. I think it's better to discuss the criteria under this section.

The criterion for success in terms of recruitment rate and patient acceptance of treatment is now stated under the outcomes section, page 9, line 20.

- No follow-up period was mentioned in the method section.

Added the sentence "Patients were followed until discharge." to clarify the follow-up period.

- Handling of missing data was not discussed.

The handling of missing data is now discussed on page 11, line 9.

- Title of table 2 is odd. It needs a better title.

The title was changed to "Baseline demographics" to be more concise.

- Table 2 needs to present in table format with columns border. Also it needs to add mean(sd) or n(%) beside variables. The variables were labelled as showing the mean (SD) or n (%) and the column borders were added back to Table 2.

- This is a study on individuals. However, the average patient recruitment per week was reported in fraction 13.6 patients/week [95%CI:12-16.2]. Number of patients cannot be fraction, which needs to be addressed.

We have rounded these values to whole numbers as suggested by the reviewer.

- It needs to use ':' after 95% CI in the results section.

We added ':' after 95% CI (e.g. 95% CI:) as suggested.