Author's response to reviews

Title: A pragmatic study exploring the prevention of delirium among hospitalized older hip fracture patients: applying evidence to routine clinical practice using clinical decision support.

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Author's response to reviews: see over
Dear Editors, 

Thank you for considering our manuscript for publication. We have reviewed the comments made by the reviewers and have attempted to edit the manuscript accordingly. Specifically we have addressed the concerns around reporting and the handling of the qualitative data. We have also included a figure with the order set. Outlined below are our responses to the specific comments made by the reviewers.

Reviewer 1:

1) Improved reporting could contribute to wider evidence base of such interventions. Two useful papers to improve reporting are the SQUIRE guidelines and Ramsay et al 2003 paper on ITS designs.

We have made changes throughout the manuscript in an effort to better meet the SQUIRE guidelines and the guidelines outlined by Ramsay et al.

2) The most interesting aspect is the section on the focus groups, is there enough information not reported here to be written up fully in another paper?

We agree with the reviewer that the information obtained from the focus groups is of particular interest. We have expanded the description of the focus groups within the methods and the discussion but feel there is not enough information to warrant a separate paper (last paragraph of the Methods section; first and second paragraph of the Discussion):

“At study completion, focus groups (one at each hospital) were conducted with the frontline orthopedic nursing staff in order to explore issues around the implementation of the pathway. Nurses were recruited through postings and using snowball sampling. Participation was considered to be implied consent. Focus group participants were asked about facilitators and barriers to using the pathway, ease of use and for specific feedback on its components. The focus groups were conducted, prior to analyzing the quantitative outcomes, by the principal investigator guided by a standardized list of questions. A research assistant took notes, which were later merged with data transcribed from audio recordings. The transcripts were coded by the investigator using a content analysis approach. Themes were identified and categorized. Only two focus groups were conducted due to limitations around the availability of frontline nurses to participate.”

“Although we made efforts to obtain in-put from all levels of the health care team during development, this project highlights the importance of continuing to engage frontline personnel because of issues like staff turnover and the development of unexpected barriers[26]. The focus groups highlighted the potential impact of organizational culture, personnel change and structure on the uptake of the delirium prevention strategies. Multiple factors can influence the uptake of evidence by different stakeholder groups with challenges operating at different levels within the system[26].

Effective knowledge translation includes adaptation of the intervention to address identified barriers[27]. Specifically, the order set was subsequently redesigned to address the concerns of the focus groups about the volume of information included. Although the content has not markedly changed, formatting changes have reduced the total number of orders. The modified intervention is informing a provincial hip fracture care pathway currently under development.”
3) Given the sample size, event rate and number of time points it would be difficult to fit an appropriate time series model. A graph of the primary outcome pre- and post-intervention would be useful to convey this to the readers.

We have inserted a graph of the primary outcome (Figure 2).

4) Given there are only 2 hospitals, a full blown cluster level ITS is not possible, but a dummy variable for hospital in the logistic regression would adjust for this.

This is in fact how the analysis was done and we have made this clearer within the Methods (paragraph 4 of the Methods).

“A Durbin Watson test was conducted to test for serial correlation between weekly delirium rates, and since no correlation was found Chi-Square and Wilcoxon tests were used to make univariable comparisons, while logistic regression analyses was used to compare the effect of phase on delirium rates, while adjusting for hospital.”

5) If it is felt that hospital is important perhaps break Table 1 down by hospital.

We have now modified Table 1 to include the results by hospital.

6) The statistical methods are not described in enough detail.

We have improved the description of the statistical methods (paragraph 4 of the Methods).

“A Durbin Watson test was conducted to test for serial correlation between weekly delirium rates, and since no correlation was found Chi-Square and Wilcoxon tests were used to make univariable comparisons, while logistic regression analyses was used to compare the effect of phase on delirium rates, while adjusting for hospital.”

7) There is no evidence of a planned sample size or indication of what an appropriate effect size would be.

Based on estimated delirium rates of 25-65% and annual local hip fracture admission rates of approximately 400 patients, five months post-intervention surveillance (40 data points overall) was felt to be sufficient to detect uptake of the intervention into practice. Sample size calculations for ITS are challenging, but our review of the literature suggested the 40 data points would be sufficient (reference 25). What we underestimated was the number of patients that we would not be able to enrol given issues around capacity. Alberta does not allow substitute decision makers to give consent for research study participation unless the incapable subject has a personal directive indicating this can be done.

We have now clarified this issue in the manuscript. (paragraph 4 in the Methods; Limitation section)

“Based on annual local hip fracture admission rates of approximately 400 across the 2 hospitals, five months post-intervention surveillance (40 data points overall) was felt to be a sufficient to detect uptake into practice [25].”
“We estimated that 40 data points would be sufficient to detect a change to practice[25]. However, we underestimated enrolment issues. Specifically, 138 patients were not enrolled due to issues around obtaining consent from patients. Extending the recruitment period was not feasible given funding limitations.”

8) **Even though a simple pre-post difference is used as an analysis strategy, an effect size and confidence intervals are required.**

These are now included in Table 1.

9) **It is correct that there is no evidence of effectiveness rather than evidence of ineffectiveness.**

We have clarified this in the manuscript. (Abstract; Conclusion)

“Translation of evidence-based multi-component delirium prevention strategies into everyday clinical care, using the electronic health record, was not shown to be effective at decreasing delirium rates among hospitalized hip fracture patients, although it was found to be clinically successful at one hospital.”

10) **Include the primary outcome in Table 1 and indicate what tests the p values are from. State n/N at all times and report percentages to the closest percent.**

We have made these changes to Table 1.

11) **Include start and end dates of the pre- and post- phase. Make a note of anything seasonal that might have happened (or not).**

We have now included these dates (paragraph 1 in the Methods).

“Patients were monitored on the orthopedic wards for five months prior to implementation (October 2008 – March 2009) of the care pathway and then for five months post-implementation (March 2009 – August 2009).”

There appeared to be no difference in the number of hip fracture admissions pre- and post- intervention (173 and 170) and we are unaware of any significant changes to practice during the study. (paragraph 1 in the results; paragraph 4 of the Methods)

“During the 40 week study period 343 patients were potentially eligible for enrolment (173 pre- and 170 post-intervention).”

“No other change to practice was known to have occurred during the study.”

**Reviewer 2:**
1) **The authors should present the results for both hospitals.**
This is now included in Table 1.

2) Was the study adequately powered and was the design robust enough to support the conclusion that the intervention was not effective.

We agree that all we were only able to determine was that we did not show the intervention to be effective. We have acknowledged the concerns around sample size. (Limitations; Conclusions)

“We estimated that 40 data points would be sufficient to detect a change to practice[25]. However, we underestimated enrolment issues. Specifically, 138 patients were not enrolled due to issues around obtaining consent from patients. Extending the recruitment period was not feasible given funding limitations.”

“Translation of evidence-based multi-component delirium prevention strategies into everyday clinical care, using the electronic health record, was not shown to be effective at decreasing delirium rates among hospitalized hip fracture patients, although it was found to be clinically successful at one hospital.”

3) In the background section, paragraph 4, the first sentence is unclear to me (“knowledge translation is the scientific study of the methods for closing the knowledge to practice gap”).

We have deleted this statement.

4) Why were fractures caused by MVAs excluded?

We excluded them because the mechanism of injury is different from a fracture resulting from a fall in an older patient with osteoporosis. We have clarified this in the manuscript. (paragraph 1 in the Methods)

“Exclusion criteria included an inability to speak English, fractures caused by a motor vehicle crashes (given the mechanism of injury),...”

5) A figure setting out the components of the order set would be very useful to understand the intervention.

We have now included a snap shot of the care pathway embedded into the order set. (Figure 1)

6) The authors should acknowledge the limitations of using a chart-based method for delirium detection.

We have commented on this within the Limitations section.

“Although we used a validated chart-abstraction instrument, determining delirium rates was dependant on relevant information being recorded within the medical chart.”

7) Did the 5 month post-implementation period start immediately after the order set. It is important to acknowledge the time it takes to introduce and embed complex interventions and when the intervention can be expected to influence outcomes.
The post-implementation phase started immediately after the order set change, which we have clarified in the manuscript. However, we do not think this is a significant issue given that observations were made for 5 months following implementation of the change (see Figure 2). The focus groups point more to an issue in organizational culture.

“Patients were monitored on the orthopedic wards for five months prior to implementation (October 2008 – March 2009) of the care pathway and then for five months post-implementation (March 2009 – August 2009).”

8) The authors report a significant interaction between study phase as well as hospital. However, no details are given about the impact of study phase.

To clarify, the interaction was between hospital and study phase.

9) The results and discussion section should be separated.

We have now separated the results from the discussion.

10) Comment on the limitations of power and using the chart-based method.

We have now commented on this within a Limitations section.

“Limitations: Although we used a validated chart-abstraction instrument, determining delirium rates was dependant on relevant information being recorded within the medical chart. Sample size calculations are challenging with interrupted time series studies[28]. We estimated that 40 data points would be sufficient to detect a change to practice[25]. However, we underestimated enrolment issues. Specifically, 138 patients were not enrolled due to issues around obtaining consent from patients. Extending the recruitment period was not feasible given funding limitations.”

11) The reference in the sentence for the “recent” systematic review indicates it is in fact 6 yrs old.

We have now deleted this from the manuscript (last paragraph of the Background).

12) The CAM is described as “very accurate”. However, the sensitivity and specificity have been shown to vary markedly by training of the assessor.

We have addressed this issue by including the results from a recent systematic review/meta-analysis of delirium screening tools (paragraph 3 in the Methods; reference 23).

“The care pathway also incorporates the Confusion Assessment Method (CAM)[21], which is a brief delirium diagnostic tool that is very accurate (sensitivity 86%, specificity 93%), with high interobserver reliability[23].”