Author's response to reviews

Title: Improving the implementation of perioperative safety guidelines using a multifaceted intervention approach: protocol of the IMPROVE study, a stepped wedge cluster randomized trial

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Editors, Implementation Science

18 November 2014

Cover letter

Concerning Article submission

Dear professor Sales and professor Wensing,

Please find enclosed our manuscript entitled: ‘Improving the implementation of perioperative safety guidelines using a multifaceted intervention approach: protocol of the IMPROVE study, a stepped wedge cluster randomized trial’ for your consideration for publication as a study protocol in Implementation Science.

We report on a study protocol of a stepped wedge cluster randomized trial design to measure the effect of a strategy to implement perioperative safety guidelines. Implementation of these guidelines is expected to reduce adverse patient outcomes. In addition, several studies showed that using stop moments and the timely administration of antibiotic prophylaxis improve perioperative outcome.

The perioperative setting is an unexplored area with respect to implementation issues. Our study will provide a better understanding of guideline implementation within the perioperative care process. With this study we hope to show that a tailored multifaceted implementation strategy will be as successful in the perioperative setting as in other settings. This is important for the further implementation of the perioperative guidelines in all Dutch hospitals. Knowledge on the effects of our multifaceted approach to implement the perioperative safety guidelines can be used to improve perioperative patient safety.

The major strength of this study is the randomized comparison made possible by the multicenter stepped wedge cluster randomized trial design. Another strength of our study is that we use a multifaceted approach covering 6 interventions; education, audit and feedback, organizational interventions, team directed interventions, reminders as well as patient-mediated interventions, of which most have been shown to be effective in other studies. To tailor the implementation activities, we developed a questionnaire to identify barriers for effective guideline adherence experienced by perioperative key professionals, based on (a) a theoretical framework for classifying barriers and facilitators, (b) an instrument for measuring determinants of innovations and (c) 19 semi-structured interviews with perioperative key professionals.

The study protocol is approved by the Ethical Committee of the Radboudumc (registration number: 2011/318). The study conforms to Dutch law and privacy regulations and was judged not to involve human-subject research. The study is furthermore funded by ZonMw (project number: 71103008). Relevant documentation on received ethics approval and funding are uploaded as attachments to this cover letter.

Our paper has not been published or reviewed elsewhere, nor is it currently under consideration by another journal. At the time of submission, no data cleaning or analysis has begun. Furthermore, the manuscript has no copyright constraints.
The manuscript has been seen and approved by all authors. No conflict of interest is reported. An authors contribution to the manuscript is provided below.

We look forward to your kind consideration of the manuscript.

Yours sincerely,
on behalf of all the authors,

Yvette E.J.J.M. Emond, MSc
Hub C. Wollersheim, MD, PhD

<table>
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<tr>
<th>Authors contribution to the manuscript:</th>
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</thead>
<tbody>
<tr>
<td>Yvette Emond       Wrote the article.</td>
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<tr>
<td>Hiske Calsbeek    Contributed substantially to the conception and design of the study, and participated in drafting and critically revising the article.</td>
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<tr>
<td>Steven Teerenstra  Contributed substantially to the conception and design of the study, and critically revised the article.</td>
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<td>Gerrit Bloo        Critically revised the article.</td>
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<td>Johan Damen        Contributed substantially to the conception and design of the study, and critically revised the article.</td>
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<td>Hub Wollersheim    Contributed substantially to the conception and design of the study, and participated in drafting and critically revising the article.</td>
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All authors approve this final version to be published and agree to be accountable for all aspects of the work, thereby ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.