Author's response to reviews

Title: Do large-scale systems interventions improve patient outcomes? A systematic review

Authors:

Robyn Clay-Williams (r.clay-williams@unsw.edu.au)
Hadis Nosrati (hadisnosrati@icloud.com)
Frances Cunningham (frances.cunningham@menzies.edu.au)
Ken Hillman (k.hillman@unsw.edu.au)
Jeffrey Braithwaite (j.braithwaite@unsw.edu.au)

Version: 5  Date: 26 March 2014

Author's response to reviews: see over
Since the publication of To Err is Human the patient safety movement has spawned large numbers of interventions. This paper is important, in many ways, because of what it fails to show or hints at—-the very small number of rigorous wide‐scale studies, the disparity between the time it takes to have measurable effects and the time devoted to the study, the issue of whether safety culture and organizational factors lead improvement or result from it. One conclusion I find interesting, concurring with my own experience, is the effect of time on cultural change, taking more than two years.

Although we suspected as much, we were also disheartened to find so little research on this topic. Given the number of co‐morbidities suffered by the average hospital patient, and the typical patient journey that may traverse a number of hospital departments, we believe there is a need to take a more system‐wide approach to improving safety than is currently occurring. The effect of time on cultural change that you mention concurs with your own experience has also been found in other research—it is unfortunate that typical behavioural intervention research timelines are so short, as it is quite possible that a number of important effects of interventions have been missed.

The weakness of the paper as written, that it is a pile of facts culled from the studies under review, is inherent in the subject matter and the variability in the methods and results. I would appreciate an attempt at making the results section easier to read (Table 3 certainly helps here).

We have tried to make the results section easier to read by adding a paragraph at the start of the reporting section. This paragraph summarizes the factors that were extracted from the literature, directs the reader to the summary Table 3, and provides an outline of how the results are reported.

I would also appreciate more discussion of why the results, including some of the apparent contradictions, are as the studies found. While the authors were scrupulous in their selection of the studies for review, they could usefully use reference to the wider literature in their discussion.

The short term negative outcomes for culture and performance, as stated in the discussion, are not atypical of short term outcomes during organisational change (see Braithwaite J, Westbrook J, Iedema R: Restructuring as gratification. Journal of the Royal Society of Medicine 2005, 98:542-544) – we believe that the study authors simply did not wait long enough for change to take effect before gathering data. In general, we tried to avoid discussing individual study outcomes, as these can be found in the individual studies, but we have included aggregated...
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<th>Reviewer 2’s comments</th>
<th>Authors’ response</th>
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<td>Authors need to clarify the main question they are addressing - at the moment it is confused in terms of whether they are addressing WHETHER changes made within large-scale systems can improve patient safety and/or HOW these changes can be made i.e. organisational factors for successful implementation. If they are focusing on the 'how', they need to refer to the fairly extensive literature on eg the role of contextual factors in quality/safety improvement. see eg Kaplan et al Milbank Quarterly 2010.</td>
<td>Thank you for your review and insightful comments. In response, we have made changes that we believe have strengthened our paper. Details of our actions are as follows: The intent of the review was to focus on WHETHER changes made within large-scale systems can improve patient safety. We felt that this point could be clarified by amending the title of the article. Exploration of how those systems change would be an area for future examination.</td>
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<td>Once they are clearer about i), the authors need to justify why a traditional ‘Systematic Review’ is the best method for addressing these questions. If they are attempting to address the 'how' question, the narrow focus of this review means that they have excluded studies using qualitative methods which address these question and are important for understanding how to improve patient safety on a large scale. see eg Dixon-Woods, Milbank Quarterly. 2011.</td>
<td>We have added a sentence to the background to explain why we believe a systematic review on this topic would be justified. We agree with the reviewer that the narrow focus we have taken would be inappropriate to answer the ‘how’ question. Nevertheless, we argue that a review such as this – synthesising large-scale studies meeting our selection criteria – will prove to be a valuable contribution and resource.</td>
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| The discussion of organisational factors for successful implementation reads rather naively at present. E.g. to conclude that 'leadership' is an important factor is not very helpful as it does not distinguish in any way between different types of leadership which might be effective. Again, there is some evidence on this which the authors should refer to and the discussion also needs to take account of this literature already referred to above. | This is a good point and we have strengthened the relevant text in response. We were unable to determine which organisational factors were common between the studies at a deeper level than 'leadership and clinical champions', etc, due to insufficient information in the published material. With leadership, there appeared to be some commonality regarding executive/management endorsement, but the detail was lacking. We have added a paragraph on leadership in the discussion to
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<th>The narrow focus of their search means they have missed some important studies e.g. Pronovost et al (2006): <a href="http://www.nejm.org/doi/full/10.1056/NEJMoa061115a">http://www.nejm.org/doi/full/10.1056/NEJMoa061115a</a></th>
<th>Can the authors justify this exclusion?</th>
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<td>We are aware that we excluded the Pronovost Michigan study on central line infections (and a number of other important studies conducted within individual hospital departments, albeit in many hospitals, such as Hayne’s surgical safety checklist), and this resulted in some very active discussion within our review team when we were scoping the review about the question we were trying to answer. We believe that one of the difficulties in improving patient outcomes in hospitals is the interface between departments. Patient demographics are changing, with older patients with co-morbidities forming an increasingly large portion of the patient population. These patients often require cooperation between departments for successful outcomes, so we were trying to find the effects of safety interventions that crossed across individual departments, rather than those contained within the ICU, ED, surgery, etc. So our focus was on hospital- or systems-wide change. As you can see by our results, this is a gap that has not been addressed.</td>
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