Author's response to reviews

Title: Did a quality improvement collaborative make stroke care better? A cluster randomised trial

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Author's response to reviews: see over
RE: 1655092472108010 - Did a quality improvement collaborative make stroke care better?
A cluster randomised trial

Dear Editor

Thank you for the review of our manuscript. Please find attached a revised manuscript with track changes which address the points made by the reviewers. We have at the same time submitted a revised version of our manuscript 3467929041080088, which reports a qualitative study of the quality improvement collaborative that we evaluate in this paper. The two manuscripts are submitted as a pair and cross reference each other. In the event that one is accepted and not the other, we will need to amend accordingly.

We hope our manuscript is now satisfactory but will be pleased to make any further revisions you may require.

Kind regards

Mary Dixon-Woods

**Comment 1.** I have concerns about measurement error in that the collaborative collected data before and after for controls and before for interventions but hospitals collected their own data in the after period of the intervention group. Surely findings are due to differences in who took the measurements? If you can't explain why this is not a problem then you need to be much more circumspect in the conclusions you draw in the abstract and main paper.

**Response 1:** We agree that the potential for bias due to variation in data reporting exists, and we have added a sentence in the limitations section in the discussion to acknowledge this. Within improvement approaches, data is often collected prospectively by improvement teams. This data is used to inform front line teams as to whether their work is resulting in the improvements they are aiming for. Within this study, for pragmatic reasons, we used a blended approach to data collection. Here we used the data collected prospectively by improvement teams, and where that was not readily available, supported data collection from the central project team. In the control group, the data was collected retrospectively, and again where data was not forthcoming, the central project office provided support. We had concerns about data completeness and validity, and the potential for bias. Consequently, we conducted a number of data validity exercises. We can include this as a table in the appendix, or provide this to reviewers for their assessment if required. In summary, of 22 records subject to extraction by two separate data reviewers, agreement for the bundle elements was:

**Bundle 1:**
Brain Scan within 24hrs of Hospital Admission (95%)
Aspirin in 24hrs of hospital Admission (91%)
Swallowing Screening Recorded in 24hrs of Hospital Admission (77%)
Weighed during Hospital Admission (91%)
Rehabilitation (77%)

Bundle 2:
Ward of 50 Percent + Of Stay (86%)
Physiotherapist Assessment in 72hrs of Hospital Admission (82%)
Occupational Therapist Assessment in 4 days of Hospital Admission (100%)
Mood Assessed during Hospital Admission (91%)
Rehabilitation Goals set during Hospital Admission agreed by MDT (86%)

Comment 2. You need to attend to the CONSORT statement. You have not actually included some of the information required by CONSORT e.g. p8 How did random allocation take place? Can you return to CONSORT and check that you have reported exactly what is required.

Response 2: We have reviewed the CONSORT statement again, and have amended the section on randomization (Page 8) to provide a clearer description of the process.

Comment 3. It is unclear whether the primary outcome measured was based on National Audit data or the 20 patients per month. It is not clear that 20 patients per month were measured in both arms of the trial. Much more clarity is needed on how measurements were taken.

Response 3: The primary outcome measure was based on 20 patients per month, not the national audit data. We have clarified this on page 9 of the manuscript. In addition, we can provide a table as an appendix showing the data collected per month from each site if required.

Minor essential:

Comment 1. This intervention is evaluated by the intervention lead and some attention needs to be given to this in the discussion regarding potentially having a strong desire for a positive outcome.

Response 1: The data collection and analysis were carried out independently of the intervention lead. MP (intervention lead) interacted with the intervention teams and used their local data to identify opportunities for improvement, in all cases this came from local intelligence from clinical teams, for example from local data bases, ward white boards (visual management systems) or tests of change, not the study data. There was no interaction between MP and the controls until month 11 of the study when she was
involved in recruitment for Phase II of the study which is beyond the scope of this paper. The data analysis on the study data was carried out by GJP from a collaborating site in the USA (as per study protocol) who was not involved in delivery of the intervention. This can be added to the limitations of the study of required but the authors do not see this as a critical issue for this study.

**Comment 2.** *Was a process evaluation undertaken? If it exists then there should be some reference to it and its findings so readers can link these two parts of the same story.*

**Response 2.** A more detailed paper, describing the experience of the wider collaborative has been submitted to Implementation Science as a companion paper. We have added a sentence in the discussion that refers to this. The final reference will need to be added once it is available.

**Comment 3.** *An explanation for the large improvement in controls over time is given in the discussion. Does this temper the conclusion you can make? The context is a major national focus on stroke improvement so did your collaborative get its positive results because of the context? How would it have fared in a low priority for stroke environment?*

**Response 3.** The accompanying paper exploring the wider collaborative describes these important issues. The current paper is primarily quantitative in focus.

**Comment 4.** *There are lots of typos – it needs a good sub edit.*

**Response 4.** We have carried out a full review of the manuscript and amended accordingly.

**Comment 5.** *In the abstract - What is an ‘indicator of care’?*

**Response 5.** We have clarified this throughout the manuscript by changing “indicator of care” to “process of care”

**Comment 6.** *‘Bundle compliance’ is hard to understand as shorthand.*

**Response 6.** We have provided a clearer definition of “Bundle Compliance” under “Outcomes and Follow-up” on page 9.

**Comment 7.** *Revisit conclusions. I know you say the effectiveness is still ‘uncertain’ but its not clear why.*

**Response 7.** We have added a clarifying sentence on page 15, in the discussion. Our lack of certainty is due the socio-technical nature of this intervention, and the context within which it was set. That is, although there may be evidence that improvement occurred in this setting, the precise nature and mechanisms of change are not clear,
suggesting that we cannot be clear whether such an approach will ‘work’ in other settings.

Comment 8. p8 Sub heading ‘interventions’ but you talk about power calculation – this is confusing.

Response 8. We have amended the sub heading to read “Sample Size”.

Comment 9. p8 The power calculation is not specific enough. What about statistical power? Alpha? What about clinically significant change rather than what occurred in pilot?

Response 9. This section has been substantially amended to provide more specific information (see track changes).

Comment 10. p10 You must draw attention to differences in exclusion rates between groups.

Response 10. We have included this in limitations of this study in the discussion and in Data Collection and in Figure 2.

Comment 11. p11 I don’t understand what is written under the sub heading ‘primary measures’ – did controls improve in bundle 1? This is a key part of the paper and very difficult to understand.

Response 11. We agree that this paragraph is not clear, and have removed it. We believe the remaining sub-sections, now, more clearly describe that there was improvement in bundle 1 in the control group.

Comment 12. p14 What does ‘wicked’ mean?

Response 12. We have replaced ‘wicked’, with ‘socially complex’.

Comment 13. p14 I’d like a sub heading to draw attention to strengths and limitations for the reader. I would like attention paid to the variable drop out rates in arms and what direction bias might be operating in. You must point out and discuss the measurement error.

Response 13. We have added a sub heading to guide the reader to the limitations section in the discussion and directly addressed measurement error.

Comment 14. p15 The final sentence of the paper seems to pop out of nowhere and is not appropriate as an ending for this paper.

Response 14. We have deleted this sentence.
Comment 15. *Figure 2 shows why some hospitals dropped out or were not included but is there no intention to treat analysis because data on primary outcomes was missing (reason for exclusion?)* p 11 you say this was in the protocol but what is the justification for it?

Response 15. We were unable to undertake an intention to treat analysis because, when hospital dropped out, it did not submit data.

Comment 16. *Table 4 is unhelpful and is not your trial data. The only relevant info is 2008 compliance and this could be incorporated into your discussion.*

Response 16. We have removed this table and included the relevant information in the text as suggested.