Author’s response to reviews

Title: Inclusion of a care bundle for fever, hyperglycaemia, and swallow management in a National Audit for acute stroke: evidence of upscale and spread

Authors:

Tara Purvis (tara.purvis@monash.edu)

Sandy Middleton (sandy.middleton@acu.edu.au)

Louise Craig (lcraig@bond.edu.au)

Monique Kilkenny (monique.kilkenny@monash.edu)

Simeon Dale (simeon.dale@acu.edu.au)

Kelvin Hill (KHill@strokefoundation.org.au)

Catherine D’Este (catherine.deste@anu.edu.au)

Dominique Cadilhac (dominique.cadilhac@monash.edu)

Version: 1 Date: 24 Jul 2019

Author’s response to reviews:

Response to reviewers’ comments: “Care bundle for fever, hyperglycaemia, and swallow management for patients with acute stroke: evidence of upscale and spread”

Manuscript ID: IMPS-D-19-00024

We thank the reviewers for their careful consideration of this manuscript and the feedback they have provided. We have clarified each of the points raised or provided additional information about the study. These changes have strengthened our manuscript. A point-by-point response is provided below.
Reviewer 1

This manuscript would benefit from further critical discussion about the systematic implementation of the care bundle into the national clinical audit programme. Currently the authors conclude that there was no systematic roll-out of the care bundle. However, it appears that the care bundle, and specific patient outcomes related to the care bundle, were included in the national stroke audit programme since 2013, following publication of the main trial. It is likely that this "active" national scale-up strategy, implemented through an established clinical audit programme, is a key driver to the study findings. More consideration around definitions of active and passive roll-out are needed in this study.

Thank you for this suggestion. We have altered the abstract, background and discussion to consider and explain this process in more detail, with further reference to the literature. These changes are outlined in more detail in the points below.

Title: Could better reflect the study

The title has been changed to “Inclusion of a care bundle for fever, hyperglycaemia, and swallow management in a National Audit for acute stroke: evidence of upscale and spread” to more closely reflect the study.

Abstract

Please consider using the term "retrospective" in the methods section.

We have added this to the methods section of the abstract (page 3) “Cross-sectional, observational study using self-reported organizational survey and retrospective clinical audit data…….”

Conclusion: Please remove the first sentence as this sentence does not relate specifically study findings. Please remove the term "despite no national systematic roll-out" (the inclusion of the care bundle measures in the national audit is an example of a systematic national roll-out and the active implementation of evidence into practice)

The first sentence “Very few evidence-based nursing interventions exist for stroke.” has been removed from the conclusion and added to paragraph 2, of the background (page 5).

The conclusion of the abstract now reads:
Use of the FeSS Protocols within Australia increased from 2013 to 2017 with inclusion of these care processes in the National Audit. Greater uptake in hospitals previously involved in QASC/QASCIP was evident. Our implementation methods may be useful for other national initiatives for improving evidence-based practice.”

Introduction

Reducing the description of the QASC and QASCIP into one paragraph would allow for the inclusion of more studies using similar designs to be presented in the introduction.

Thank you for this suggestion. We have condensed the second paragraph in the background (page 5), and it now reads:

“Very few evidence-based nursing interventions exist for stroke. The Quality in Acute Stroke Care (QASC) Trial was a complex healthcare intervention, involving multi-disciplinary supported nurse-initiated protocols for monitoring and managing of fever, hyperglycaemia (high sugar) and swallow dysfunction (FeSS Protocols) in the first three days post-stroke. This cluster randomised controlled trial was undertaken in 19 stroke units in New South Wales (NSW), Australia throughout 2005-2010 [8]. The intervention consisted of barrier identification, multidisciplinary teamwork, educational outreach, local adaption, use of site champions, and reminders [8]. An improvement in the quality of care provided [9], a 16% reduction in death and disability 90 days following stroke [8], and potential long term survival benefits were shown [10]. Following on, the FeSS Protocols were systematically introduced with training and the other strategies, into all 36 stroke services (31 with a stroke unit) within one Australian state, NSW. The Quality in Acute Stroke Care Implementation Project (QASCIP) was conducted during 2013-2014, to evaluate the implementation strategies used in the original trial to promote ‘scale up and spread’ of this proven intervention. Improvements in adherence to the three FeSS Protocols were found, demonstrating the successful state-wide scale-up of this complex, quality-improvement intervention [6].”

The introduction section would benefit from more comparison with literature specific to the implementation of care bundles e.g. COPD, ITU, catheter-acquired infections, central line-associated bloodstream infections, delerium, dementia etc. Particularly those care bundles that have had successful implementation through inclusion in national audit programmes.

Additional paragraphs related to the inclusion of the bundled processes in the national audit, and comparison to the wider literature have been included in the background (paragraph 2, page 6):

“With the positive outcomes, individual indicators reflecting the bundled care processes in the FeSS Protocols were included in the voluntary, biennial, National Stroke Audit programme
(Australia) in 2013. This allowed the individual care processes, not already part of the audit (e.g. fever and glycaemia processes) to be monitored, nationally. No further national, systematic effort was made to implement the specific QASC intervention. However, uptake of the FeSS Protocols may have been indirectly supported via this audit and feedback process, which was not part of the original QASC/QASCIP intervention. Moreover, the data from the National Audit were not specifically bundled as ‘FESS processes’ in reports back to hospitals, which included a summary of some of these indicators.”

Paragraph 3, page 6:

“Implementation of care bundles, which comprise of a small number of evidence-based interventions, that when implemented together, improve patient outcomes [11], have been used to improve care in a variety of health related areas including chronic obstructive pulmonary disease, ventilator associated pneumonia [12], catheter related blood stream infections [13], and delirium [14]. Inclusion of these bundles in national audits [15] and registries [16, 17] have been used to effect.”

Please specify the dates of the QASCIP study, versus the inclusion of the FeSS Protocols in the national audit

The dates of the QASCIP study (2013-2014) are mentioned in paragraph 1, page 6. However, to aid clarity, an additional sentence has been included in the background (paragraph 2, page 6) to outline when the processes reflecting the FeSS Protocols were included in the audit: “With the positive outcomes, individual indicators reflecting the bundled care processes in the FeSS Protocols were included in the voluntary, biennial, National Stroke Audit programme (Australia) in 2013…..”

Methods

Data collection (Additional File 1- Table 1 would be better placed within the main article. This comparison of indicators included in the trials and the national audit is highly relevant to the study methods and could be combined with the current Table 1 to indicate the composite outcome measure e.g. through a table footnote).

Thank you for this suggestion. Data from Additional File 1 and the previous Table 1 have been combined and included in the main manuscript as new Table 1, which is now titled “Comparison of processes collected in QASC, QASCIP, and National Audits, with outline of FeSS processes included for analyses.”
Please discuss the rationale for only selecting the audit period post-publication of the QASC in this study. Improvements may have occurred prior and during QASC. This important contextual information needs to be included in the background to this study. If no relevant measures related to the care bundle were included in the national audit data-set before 2013, then this should be clearly stated.

Comparisons to periods prior to QASC was not possible as all the FeSS variables were not available in the National Audit until 2013, after the QASC Trial was completed in 2011. To improve the clarification around the time periods related to inclusion of the FeSS processes in the National Audit, the following sentences have been modified and added in the background (paragraph 2, page 6):

“With the positive outcomes, individual indicators reflecting the bundled care processes in the FeSS Protocols were included in the voluntary, biennial, National Stroke Audit programme (Australia) in 2013….” as outlined above.

And methods sections:

“For example, data included in the 2013 audit, reflected patient admissions from 2012.” (paragraph 3, page 7).

“Other than processes relating to swallow function (prior to oral intake), no other indicators related to the FeSS processes were included in the National Audit prior to 2013.” (paragraph 2, page 8).

A comment related to not having baseline data related to the FeSS process prior to 2013 has also been included in the discussion:

“Inclusion of FeSS processes prior to 2013 was limited to swallow related indicators that were not directly comparable to the processes included in the FeSS Protocols. Therefore, no national baseline measure was available to determine potential secular trends in changes in adherences to these processes.” (paragraph 3, page 19).

Further justification of using the composite measure versus individual component measures is needed. Why was this approach preferred?
The intervention tested in the original QASC trial related to a bundled composite outcome of processes of care. Therefore, to remain consistent with the existing evidence, a composite measure was also used as the primary outcome for this study. We do acknowledge in the discussion that there are differences in this composite measure, as data for all the original FeSS monitoring processes were not collected in the audit. To outline the reasoning behind using the composite measure as the primary outcome further, we have added the following to the statistical analysis section of the methods (paragraph 3, page 8):

“As with the original QASC trial, the process of care outcome was a derived composite measure, which reflected compliance to all fever, hyperglycaemia and swallow processes.”

Table 3. Please replace drug name with generic name

Paracetamol and Insulin have been used in Table 3, both of which are generic names for the drug. ‘Panadol’ has been changed to ‘Paracetamol’ in the footnote of this table.

Statistics analysis

More clarity related to the statistical methods are needed, particularly around techniques investigated repeated measures to look for differences between groups of patients. Was ANOVA used?

The outcome data collected in the audits relating to adherence to processes were categorical, including yes, no or not documented/unknown responses. As outlined in the methods, the ‘not documented/responses’ were assumed to be negative and included in the denominator, meaning the adherence variables were all binary. Therefore, logistic regression was used. To be clearer, the first paragraph in the statistical analysis section of the methods on page 8 has been altered:

“Not documented and unknown responses to the categorical questions related to adherence were assumed to be negative and included in the denominator”

It appears that most of the gains in the audit data occur in the period between 2013 to 2015 and not 2015 to 2017? How were differences in these time points analysed, particularly for adherence over time to protocols?

Year of audit was included in the mixed effects logistic regression models, which allowed comparisons between the audits. National changes in adherence between 2013 and 2015 and 2013 and 2017 were presented in Table 3. However, an additional column presenting comparisons from 2015 to 2017 has been included in this Table to outline more clearly over
which periods the changes occurred (nationally). As shown from these additional results, at a national level, greater improvement in adherence to the composite outcome (and many of the individual processes) was seen between 2015-2017 compared to 2013-2015. Paragraph 2, page 9 (statistical analysis section), has been altered to:

“To assess whether adherence to the FeSS processes changed over time, and if so, between which years, separate logistic regression models, which included the year of the audit, were generated for the composite outcome and each individual process.”

An additional line in the results has also been included in paragraph 2, page 11:

“Adherence to individual fever and hyperglycaemia processes, and most individual swallow components (except for swallow treatment) improved from 2013 to 2017, with greater improvements evident between 2015 and 2017, compared to 2013 to 2015 (Table 3).”

There are few non-stroke units in this study. How are the analyses comparing SU’s and non-SU’s valid given the small sample of non-SU’s? How confident are you these are true findings?

You are correct that the majority of hospitals that participate in the national audit in all years have a stroke unit. However, there were still 1,930 (16%) patients included in the audit that were not treated in a hospital with a stroke unit, providing a reasonable sample for comparison. This information has been included in the first paragraph of the results on page 10: “The majority of participating hospitals in the clinical audits had an SU (2013: 87; 2015: 88; 2017: 94). However, a total of 1,930 patients were still treated in a hospital without an SU in the audits (2013: 673; 2015: 664; 2017: 593).”

Additional information related to this is also provided in a response to a comment in the discussion section below.

Comments around comparing the study findings to the QASC and QASCIP results should not be included in the statistical methods section.

Comparing the recent audit results to prior QASC/QASCIP findings remains an aim of the study as outlined in paragraph 2, page 7. However, the sentence referring to this comparison has been removed from the statistical methods section.
The final paragraph, particularly the final sentence in this section, needs further explanation and referencing to support this statistical approach.


“Post hoc power calculations provided evidence that the study had at least 80% power to detect absolute differences in adherence to the composite outcome between audit years of 4.5%-6.5%, with a 5% significance level. This calculation assumed an average of 30-36 audits per hospital, intraclass correlation coefficients of 0.02 to 0.1, consistent with previous work [8, 23], resulting in design effects of 2-4 due to correlation of outcomes within hospitals [24].”

Results

Please consider including Figure 1 in the Methods section, not the results. Please include previous stroke audit dates on this timeline and put all QASC studies on the bottom row of the timeline.

Thank you for this suggestion. Figure 1 is now referenced in the data collection section of the methods (paragraph 2, page 8). Changes to this Figure have been made, with National Audits included above the timeline, with reference to related FeSS processes included in national guidelines. All information related to QASC/QASCIP now sits below the timeline.

Pg.10 line 10-17. Please describe the "reduction in the severity of stroke over time" rather than "variation"
As suggested we have altered this sentence to now read (paragraph 1, page 11): “There was a reduction in the severity of stroke across the audits, as indicated by differences in the proportion with arm weakness, and an inability to walk on admission, and incontinence within 72 hours reported from the 2013 to 2017 audits (please see Additional File 1).”

Discussion

The discussion needs to relate more to the findings of this specific study, rather than repeating findings from the original QASC studies. (e.g. as described on page 15 line 1-17). More critical discussion around the use of national clinical audit programmes to drive national scale-up and spread of evidence-based practice is needed (as introduced in the 3rd paragraph of the discussion). Greater comparisons with the literature around care bundle implementation is needed.

Thank you for these comments. The discussion has been reworked, to include more critical comment around care bundle implementation and use of audits to drive spread of evidence. This includes (paragraph 2, page 13):

“Translating evidence from clinical trials into routine clinical practice is inherently difficult [26], which can detrimentally affect patient care and outcomes [27]. Often implementation activities are focused on short term actions and effects [28]. Limited research has evaluated sustainability and uptake of evidence into practice post-implementation initiatives [29, 30]. Within the literature, various methods have been used to encourage routine adoption of evidence-based care, particularly related to care bundles, in clinical practice. In the review by Borgert and colleagues [15] it was demonstrated that audit and feedback was one of the most frequently used strategies to implement care bundles. Mandatory reporting [31], removal of perverse incentive payments [32], and more specific quality improvement programs focused on combinations of building leadership, shared learning, mentoring and on-going measurement have also been used with effect [13, 33].

Paragraph 1, page 14:

Adherence to the bundled care processes after the initial focused implementation efforts are often not maintained, or improved as in our study. Helmick and colleagues did report a small increase in compliance in ventilator associated pneumonia and catheter related bloodstream infection bundles after initial focused efforts to implement these into routine care [34]. Alternatively, Ferrer et al, reported that adherence to a sepsis care bundle returned to baseline one year after a national education program was ceased [35]. This is also in line with a recent systematic review....”
Overall change in adherence to the composite outcome from 2013 to 2017 was greater in hospitals that had participated in the previous QASC/QASCIP interventions, where active dissemination of the FeSS processes occurred via workshops, protocols and use of local clinical champions. In addition to the ‘audit and feedback’ implementation strategy of inclusion of related processes in the National Audit, other factors may have influenced uptake further. These include publicity related to the original trial, conference presentations or publications of the QASC or QASCIP results…”

In Australia, recent estimates indicate that only 75% of services providing acute stroke care have an SU [1]. Therefore, it was of interest to examine the care provided in hospitals without an SU related to the FeSS processes. While the absolute difference in adherence to the composite outcome between SU and non-SU hospitals is clear (2017 SU: 43%; non-SU: 29%), there was no difference in improved adherence between 2017 and 2013.”
Pg. 15 line 32 sentence re: To our knowledge...Please consider other international literature more fully. An example of an international audit e.g. UK SSNAP data includes "Patients with acute stroke should have their swallowing screened, using a validated screening tool, by a trained healthcare professional within four hours of arrival at hospital and before being given any oral food, fluid or medication".

You raise a valid point about the intended meaning of this sentence. It needs to be clearer to the reader, that although some FeSS processes are collected (specifically related to swallow processes), we are unaware of any other international audit program or registry where all processes related to the FeSS Protocols are collected. This has now been re-written to include (paragraph 1, page 18):

“While adherence to some individual FeSS processes is measured in international audit programmes and registries [16, 17], to our knowledge, not all FeSS processes are captured in the same way as the original FeSS Protocols outline. Therefore, it is difficult to generalize results related to the composite outcome to other countries.”

Limitations

Further explanation of changing FeSS monitoring process in the national audit would be useful

Thank you for this suggestion. An additional line has been added to paragraph 2, page 18, “Changes primarily reflected efforts to reduce data burden for clinicians (please see Additional File 5)”, with more specific detail provided in Additional File 5.

Statistical limitations, particularly around the use of a composite measure, need to be considered

Limitations related to the use of a composite measure were added to the discussion (paragraph 2, page 18/19): “Limitations to the use of composite measures have been reported [47]. However, our methods to negate the influence of missing data with decision rules to ensure all patients were eligible to receive all processes in the measure, and in-built logic checks in the data tool could address some of these concerns.”

Conclusion

Needs to better reflect the study findings. Comparisons to other countries would be better placed in discussion, not conclusion
Comparisons to other countries have been removed from the conclusion. In an effort to ensure the conclusion better reflects the study findings, it now reads (page 20):

“Increased adherence to the FeSS processes has occurred in Australia from 2013 to 2017 since inclusion of these processes in the National Audit. Greater improvements were evident in hospitals where active exposure to the original intervention occurred. Further improvement in adherence to the FeSS processes is still required, but our implementation methods may be used in other translation initiatives, potentially beyond stoke care.”

Reviewer 2

Methods

1. Audit and feedback can be an effective tool for improving health care processes, as the authors discuss. However, it can also lead to bias in the measures when the abstraction/measurement is self-reported by each hospital. The authors should describe to what degree the medical record abstractors were blinded to the study’s hypotheses, and include this as a possible limitation in the Discussion section.

You raise an important point about biases associated with self-report and retrospective auditing of medical records. The National Audit Program is conducted biennially by the Stroke Foundation, primarily as a quality improvement initiative to monitor and improve stroke care, both nationally, but also at local levels. The staff who abstract data have been trained, and have access to a data dictionary to assist with reliability of abstraction (paragraph 2, page 18). Further information related to reliability checks is outlined in the next response.

In addition, clinical data were collected retrospectively. Therefore, 2013 data was reflective of admissions in 2012. This, along with the fact that the processes related to the FeSS Protocols were included in the audit as single variables, rather than as a complete care bundle or FeSS tool, meant none of the staff at the hospitals were aware of the study hypothesis.

Overall, this study provides an example of secondary use of data, therefore results would not be affected by any hypotheses related to this study. Limitations around the use of audit data are outlined in paragraph 3, page 19, however an additional sentence to reflect your point has also been included:

“This study provides an example of the benefits of secondary use of data. As such, biases in retrospective data abstraction and results were not affected by prior knowledge of the study’s hypotheses.”
2. Inter-rater reliability sample size. 5 cases were re-audited for interrater reliability testing. I did not see any results from this testing, and am not sure that 5 cases is sufficient for adequately assessing inter-rater reliability/kappa statistics.

Results of the reliability testing were not reported in this study. An internal reliability report for the Stroke Foundation is generated each audit cycle reporting kappa statistics for the majority of processes of care collected in the total audit. Between a third to half of all hospitals participate in the reliability testing in each cycle, contributing from 180-230 records in total.

In the QASCIP publication, Middleton and colleagues (Middleton et al, From QASC to QASCIP: successful Australian translational scale-up and spread of a proven intervention in acute stroke using a prospective pre-test/post-test study design, BMJ Open, 2016, 6:e011568) did publish results of the inter-rater reliability testing of processes and methods aligned with those used in the current study. Their results showed substantial inter-rater reliability for almost all processes. Reference to this has been made in the discussion (paragraph 2, page 19)

“Reliability checks involving repeated audits were performed to address this. Previous inter-reliability reports of indicators relating to the FeSS processes provided evidence of substantial agreement [6].”

Results/Discussion

3. While these data show improvements in FeSS process measures and although QASC and QASCIP showed impacts of processes improvements on death or dependency, this manuscript does not attempt to link these improvements and dissemination of process measures to patient outcomes. If possible, it would be very interesting to include some analysis of any relationships between these improvements in FeSS process metrics with changes in outcomes, and if such changes in outcomes are modified by previous QASC/QASCIP participation for instance. This is particularly relevant since definitive links have been difficult to make in certain instances (e.g. unclear effect of dysphagia screening protocols on reducing the rates of pneumonia, death, or dependency after stroke. Stroke. 2018;49:e123-e128; https://doi.org/10.1161/STR.0000000000000159)

As you mentioned, the original QASC trial provided robust evidence of improved patient outcomes when adherence to the care bundle was achieved. The focus of this current study was around evidence translation, and the influence of a National Audit programme to encourage wider spread of evidence into practice. As a consequence, looking at patient outcomes (for which no 90 day outcomes are collected in the National Audit) was beyond the scope of this current study, but is a potential area of interest for future work in considering broader implications on public health. A sentence reflecting this has been included in the discussion (paragraph 1, page 19):
“Investigating any association with changes in patient outcomes and improvements in FeSS processes was beyond the scope of this study, but an area of interest for future work.”

4. Including any information on timing of any changes to associated guidelines related to FeSS processes on the timeline might be helpful

Thank you for this suggestion. Inclusion of evidence related to the fever and hyperglycaemia FeSS Protocols were not included in National guidelines until 2017. Recommendations related to the swallow processes were included in preceding guidelines in 2007 and 2010. This information has been added to Figure 1 as suggested, with a sentence also included in the discussion (paragraph 1, page 20):

“While information related to swallow processes have been included in national guidelines since 2007 [48], recommendations related to the fever and hyperglycaemia FeSS Protocols have now been included in the recently released 2017 national guidelines [3]. Therefore, the next audit will also provide stronger indirect evidence as to the impact of these new guideline recommendations around the FeSS processes.”

5. I was surprised to read that adherence to the composite outcome in 2013 was the same for QASC and non-QASC hospitals. The authors should consider discussing reasons why there was not greater adherence following the original QASC trial (2005-2010), and why subsequent years did not show an improvement.

Within the QASC trial, half the hospitals were allocated to the intervention and the others to control. Information related to whether hospitals were randomised to the control or intervention arm of the QASC trial was not included in this analysis. Therefore, of the 17 hospitals involved in QASC that participated in the 2013 audit, it is conceivable that half would not have been directly exposed to the intervention prior. This would potentially have diluted the effect of ‘participation’ in the 2013 audit, and contributed to the similar adherence rates been groups in this audit. A sentence has been added to the discussion (paragraph 2, page 15):

“Adherence to the composite outcome in 2013 was similar in hospitals that participated in QASC and those that did not. Analyses were not conducted to examine differences by QASC group allocation to control or intervention, which could have diluted the effect of ‘participation’ in 2013.”
6. If possible, please clarify or confirm whether the National Audits included FeSS-related measures in the years prior to 2013 to give some sense of the potential previous and ongoing influences that could be impacting secular trends during the 2013 to 2017 period.

There were select questions relating to swallow function included in the earlier national audits. However, differences in wording and, therefore, meaning of these questions meant the data were not directly comparable. This makes it difficult to make accurate comparisons about secular trends. Nevertheless, as a proxy, data from the 2013 national report using the aforementioned indicators (that were not directly comparable), does indicate no improvement in 2013 compared to prior (Stroke Foundation. National Stroke Audit Acute Services. Clinical Audit Report 2013. Stroke Foundation. Melbourne).

To provide additional background related to the collection of any FeSS related measures prior to 2013, we have added the following sentence to the data collection section of the methods (paragraph 2, page 8):

“Other than processes relating to swallow function (prior to oral intake), no other indicators related to the FeSS processes were included in the National Audit prior to 2013.”

A sentence acknowledging potentially secular trends has been added to the discussion (paragraph 3, page 19):

“Inclusion of FeSS processes prior to 2013 was limited to swallow related indicators that were not directly comparable to the processes included in the FeSS Protocols. Therefore, no national baseline measure was available to determine potential secular trends in changes in adherences to these processes.”

7. While much of the manuscript is focused on ORs comparing 2013 to 2017 for instance, and although the absolute unadjusted adherence rates are included in Table 3, it might be helpful to highlight some sense of the absolute adherence rates in the abstract, and provide some rough comparisons about how theses rates compare to other settings, GWTG-Stroke for the US instance, or European stroke registries.

In addition to the ORs included in the abstract, actual proportions for adherence to the composite outcome in 2013 and 2017 have also been added: “An 80% increase in the odds of receiving the composite outcome in 2017 compared to 2013 was found (2013: 30%; 2017: 41%; OR 1.8; 95% CI 1.6, 2.0; p<0.001).”

“In addition, over a third of patients were still receiving oral medication/food/fluids prior to swallow screening, which is greater than that reported from recent data as part of the UK Sentinel Stroke National Audit Programme (26% did not get a swallow screen in 4 hours) [16].”

8. In the discussion, the authors discuss audit-feedback mechanism as one possible explanation for the rising adherence rates between 2013 and 2017. However, they also discuss "passive dissemination" as an underlying mechanism. It seems contradictory to posit both an active intervention (audit-feedback) along with passive dissemination in an observational study. It's possible that in the absence of audit-feedback that passive dissemination could have led to increases in adherence, but with an observational study design there is no way to know... Since one can't control or exclude audit-feedback as the primary driver of changes in adherence rates, it seems more appropriate to minimize the discussion of passive dissemination as an explanatory factor. In particular, it doesn't seem warranted to include this study as an example of "passive dissemination" in the Conclusion given the audit-feedback that occurred with all hospitals.

Thank you for this comment. All references to passive dissemination have been revised, with a focus now on scale up via inclusion and monitoring of relevant processes in the National Audit. The paragraph in the discussion reads (paragraph 2, page 15):

“Overall, change in adherence to the composite outcome from 2013 to 2017 was greater in hospitals that had participated in the previous QASC/QASCIP interventions, where active dissemination of the FeSS processes occurred via workshops, protocols and use of local clinical champions. In addition to the ‘audit and feedback’ implementation strategy of inclusion of related processes in the National Audit, other factors may have influenced uptake further. These include publicity related to the original trial, conference presentations or publications of the QASC or QASCIP results……”