

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Is establishing a specialist back pain assessment and management service in primary care a safe and effective model? Twelve month results from the Back pain Assessment Clinic (BAC) prospective cohort pilot study
AUTHORS	Moi, John H.Y.; Phan, Uyen; de Gruchy, Adam; Liew, Danny; Yuen, Tanya; Cunningham, John; Wicks, Ian

VERSION 1 – REVIEW

REVIEWER	Arnela Suman Radboud University Medical Center, Nijmegen, The Netherlands
REVIEW RETURNED	23-Nov-2017

GENERAL COMMENTS	<p>My first concern is that the paper is very specified to the Australian context. There is little background information on how the care pathways in Australia are designed and therefore what the new methodology adds. Also, there is close to no discussion of international literature and it is therefore unclear how the entire system and this study are related to other systems, how it is to be placed in other contexts, what the generalizability of the results is, etc. This concern regards the Introduction as well as the Discussion. I would suggest the authors make a thorough comparison with international evidence and literature. Regarding the Introduction specifically, it would be good if the authors could provide quantification of background they address. What exactly is the demand of LBP on primary care and hospital services?</p> <p>Another concern is that the Abstract mentions patients with neck pain and back pain, but the entire paper does not provide any background on or discussion about neck pain, nor does it describe methodology or results regarding patients with neck pain. The authors will need to address neck pain in addition to back pain in every part of the paper.</p> <p>Another major concern is the fact that objectives or aims of the study are not clearly described, neither are the outcomes of interest. The methodology section needs to be expanded with this information. Regarding the data that are addressed in the methodology and results sections, it is unclear which data are collected through which methods. Also, did patients provide informed consent to use their data? Which patients were followed during this study - only the patients that were referred to the 12-week rehabilitation program, or also patients that were referred to specialist care? Was there a follow-up at all? (It seems as if there were only baseline measurements).</p> <p>The list of exclusion criteria includes several criteria that seem to be</p>
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	<p>contradicting the results as described in the paper, for example "referral from another consultant surgeon or physician to neurosurgery or chronic pain services". The results of the paper however also mention patients that have already been referred to surgery entering the BAC program. Please clarify this, and also clarify other criteria:</p> <ul style="list-style-type: none"> - "Worsening upper or lower motor neuron deficits" - How did you measure worsening? - "High likelihood of need for surgical intervention" - How is this an exclusion criterion, if it is one of the goals of the BAC program to evaluate which patients need this intervention and which patients can do with rehabilitation? - "Presence of comorbid condition that also requires surgical assessment and management" - What kind of conditions? I don't see how for example unguis incarnatus that does need surgical management could be a contraindication, while bypass surgery could be. Where do you draw the line, and why? - "Patient or GP preference for patients to be assessed by a surgeon" - This needs to be discussed further. Why is this a contraindication? To what extent should these preferences play a leading role in the decision to provide guideline adherent referral behaviour? Should we refer patients for surgery if there are no red flags because of individual preferences, while taking into calculation the costs and harms for this referral? <p>Furthermore, the list of exclusion criteria is very long, which raises the question if the BAC program is feasible for use in practice?</p> <p>Another major concern is the absence of any description of the methods for collection and analysis of the qualitative data. If authors want to use qualitative data they need to describe the processes in detail! Thorough description of quantitative data analysis is also lacking. What kind of analyses were performed? In the current form of the paper, the study is absolutely not replicable.</p> <p>Table 2 is unclear. What does "seen" and "not seen" mean? Furthermore, this table shows that in all three groups, almost half or over half of the patients were already on a waiting list. This raises the question what the added value of BAC is. However, this is not discussed as a limitation or concern in the discussion paragraph.</p> <p>The calculation of economic data is incorrect and based on many assumptions made by the authors. They draw hard conclusions based on the inappropriate calculations and this is not acceptable. This is one of my mayor concerns in general: the authors draw hard conclusions that are not supported by the methodology of the study nor by the data presented, and the limitations of the study are not discussed properly.</p> <p>Bearing these concerns in mind, my advice is that this paper needs major revisions before it is suitable to be considered for publication. I will be happy to review this paper again once revised.</p>
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REVIEWER	Carmen Dirksen Maastricht University Medical Center, The Netherlands
REVIEW RETURNED	13-Dec-2017

GENERAL COMMENTS	In this paper the authors present results of a pilot study evaluating a novel clinic, the Back pain Assessment Clinic (BAC). I have some comments to improve the structure and content of the paper.
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	<p>A thorough description of some of the outcomes is missing, especially regarding the operationalisation of the VIRIAF dimensions (both for the quantitative and qualitative part). For example, regarding 'access to care' (page 10) patients only seem to value travelling; was this the only item questioned for within this dimension? The authors could add a table explicating which outcomes/concepts were measured, how they were measured and at what moment in time? The paper also lacks a description of how the qualitative research was performed, e.g. which topics were questioned for the different subgroups (patients, GPs etc.), who performed the interviews, whether they were recorded and how results were analysed. This makes it impossible to judge whether all outcomes/results are presented in the paper.</p> <p>Following triage, patients were either referred for BAC (73.7%) or for outpatient specialist clinic (26.3%). However, the results of the latter group are not presented in this paper. As the new BAC strategy (compared to the traditional referral strategy) starts from triage, for a complete picture the pilot should also have included the group of patients that was immediately referred to an outpatient specialist clinic. This also applies for the clinician cost of staffing BAC (Table 4); a complete analysis of staffing costs related to BAC should have included costs of triage added with the weighted average costs for the remaining 26% of patients. The authors should adapt this or at least mention this as a limitation.</p> <p>In my opinion, the cost comparison regarding MRA ordering (page 11) should be removed from the results section. The comparison is based on an assumed 89.8% MRI utilisation rate in outpatient neurosurgery clinics in a 2008 paper (reference 14). I don't consider this a valid comparison; furthermore it is not a result of this pilot study. The conclusion regarding BAC being a cost-saving strategy can therefore not be drawn from this research and should also be removed from the discussion section (page 12 middle) ; this also applies to the title, abstract and the study strengths. At best, the authors could speculate about potential MRI cost savings in the discussion section.</p> <p>The authors should add as a limitation that the pilot lacks a (historical) comparator group. In the absence of a valid comparator group, we cannot make hard judgements about whether results of BAC are satisfactory . I suspect they are, but it is not demonstrated in this study.</p> <p>The pilot study ended in June 2015 which is 2 ½ years ago. The authors mention that the BAC model warrants further validation, preferably in a RCT, and that evaluation is ongoing to determine the cost-effectiveness, longer term and broader societal impact (page 13). Can the authors be a bit more explicit about this ongoing research?</p> <p>Some parts of the discussion seem to present results which are not presented in the results section?</p>
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REVIEWER	Peter Smith University of Southampton UK
REVIEW RETURNED	06-Feb-2018

GENERAL COMMENTS	The statistical analysis of this observational study of a pilot of the
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	<p>BAC, presented in this paper, is appropriate. Also, the limitations of the study are clearly articulated.</p> <p>Given the relatively small numbers in some of the groups, it is good to see that confidence intervals are presented and no significance tests are performed. Consequentially, there is no need for a statement regarding significance in the Statistical Methods section.</p> <p>Also, I recommend that the words 'significant' or 'significantly' are not used in the Efficiency and Sustainability, and Discussion sections. I think 'substantial' would be a better word. Finally, the categories of the variable 'Catchment' need clearer definitions: there seems to be a footnote missing from Table 1.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1 Comments:

1. ***My first concern is that the paper is very specified to the Australian context. There is little background information on how the care pathways in Australia are designed and therefore what the new methodology adds. Also, there is close to no discussion of international literature and it is therefore unclear how the entire system and this study are related to other systems, how it is to be placed in other contexts, what the generalizability of the results is, etc. This concern regards the Introduction as well as the Discussion. I would suggest the authors make a thorough comparison with international evidence and literature. Regarding the Introduction specifically, it would be good if the authors could provide quantification of background they address. What exactly is the demand of LBP on primary care and hospital services?***

The introductory paragraph and discussion have been revised to incorporate data from international literature, beginning with the 2015 Global Burden of Diseases Study that highlighted both LBP and neck pain as the leading musculoskeletal causes of disability worldwide. The increasing healthcare burden of LBP, in particular, on primary and tertiary (hospital) healthcare resources is illustrated using Australian, U.K. and U.S. data which show that it is the most common musculoskeletal complaint for which patients seek care in general practice and hospital emergency departments. Moreover, it is associated with more frequent attendance to healthcare providers (e.g. ≥ 10 visits/annum in U.S. adults), hospitalisation and growth in the number of inpatient procedures performed to treat LBP [lines 92-102, 336-350].

The traditional or existing system of managing referrals for hospital outpatient specialist review of LBP and neck pain is outlined in an additional figure (Figure 1, page 8 of the manuscript), and its recognised shortcomings that contribute to delays in care have been added to the second introductory paragraph. We agree with the reviewer's comments that by outlining the issues with the existing system, we can provide readers with greater insight into its problems, as it has been identified within the Australian context. This will help readers to recognise the similarities with their own healthcare setting and the opportunity for change. Together, this provides a foundation for understanding the potential generalisability of the BAC model to other settings.

2. ***Another concern is that the Abstract mentions patients with neck pain and back pain, but the entire paper does not provide any background on or discussion about neck pain, nor does it describe methodology or results regarding patients with neck pain. The authors will need to address neck pain in addition to back pain in every part of the paper.***

The BAC model was established for addressing both neck and LBP referrals for hospital specialist review. The data collection methods and outcome measures used to assess patients with neck pain are identical to those used for LBP, except that the Oswestry disability index (ODI) is substituted with the neck disability index (NDI) for assessing function. As patients with LBP (63%), rather than neck pain (24%), were the predominant referral type encountered during the BAC pilot, the study results and discussion were naturally weighted more to low back rather than neck pain. However the manuscript has been edited to ensure neck pain is also mentioned in all relevant sections.

- 3. Another major concern is the fact that objectives or aims of the study are not clearly described, neither are the outcomes of interest. The methodology section needs to be expanded with this information. Regarding the data that are addressed in the methodology and results sections, it is unclear which data are collected through which methods. Also, did patients provide informed consent to use their data?**

The study aims appear in the abstract and are stated in the last sentence of the third introductory paragraph (lines 120-123) – which are to report on the design, implementation and initial evaluation of the 'Back pain Assessment Clinic' (BAC) model, as an alternative pathway for delivering community-based, outpatient specialist review of neck and LBP.

The study outcomes were defined by the Victorian Innovation Reform Impact Assessment Framework (VIRIAF), which is a Victorian (state government) Department of Health and Human Services (DHHS) requirement for evaluating pilot projects that have been recipients of Victorian DHHS Workforce Innovation Grant Funding. The primary study outcomes were therefore to demonstrate improvements in the four domains of the VIRIAF: i) access to care; ii) appropriate and safe care; iii) workforce optimisation and integration; and iv) efficiency and sustainability. The methods section of the manuscript has been expanded in response to the reviewer's request. Furthermore, an additional table (Table 2, page 10 of the manuscript) has been included in the methods section that details the study outcomes, data sources and collection methods used for both quantitative and qualitative data.

A response to the query about patient consent to use of their data has been provided in question 4 of the editor's comments/questions (above).

- 4. Which patients were followed during this study - only the patients that were referred to the 12-week rehabilitation program, or also patients that were referred to specialist care? Was there a follow-up at all? (It seems as if there were only baseline measurements).**

Only patients who were seen in BAC and received referral to complete the 12-week community-based spinal rehabilitation program were followed up in this study. We have acknowledged this as a limitation of the study (lines 353-357).

- 5. The list of exclusion criteria includes several criteria that seem to be contradicting the results as described in the paper, for example "referral from another hospital surgeon or physician to neurosurgery or chronic pain services". The results of the paper however also mention patients that have already been referred to surgery entering the BAC program. Please clarify this, and also clarify other criteria:**

The BAC model was a collaborative initiative between tertiary specialist services that are most commonly called upon to assess and manage neck and LBP and was implemented in close partnership with community health services. During the central triage process that was instituted to support BAC's implementation, representatives from neurosurgery and orthopaedic spinal surgery expressed that it would be the appropriate *professional courtesy* for them to see all **new** referrals, received during the BAC pilot, that had been made by another hospital-based consultant surgeon, physician or pain specialist requesting a neurosurgical or orthopaedic spinal opinion, while all other potentially suitable new referrals could be triaged to BAC. Furthermore, all patient referrals that were already on the outpatient surgical waiting lists for an initial consultation (e.g. had already waited ≥6months) that met the BAC inclusion/exclusion criteria, were offered the opportunity to receive earlier care through re-direction into the BAC model.

- i. "Worsening upper or lower motor neuron deficits" - How did you measure worsening?**

The central triage process was unable to 'measure' this per se through triage of a paper referral. However, if referrers stated in the referral information that a patient was developing progressively worsening neurological deficits over time, they were deemed unsuitable for BAC and triaged as more appropriate for consultation with a spinal surgeon. For example, referrals for patients with LBP that had developed complications of worsening unilateral or bilateral lower limb weakness, gait unsteadiness, and/or disturbance of normal bowel or bladder sphincter function resulting in incontinence, over time, were excluded from enrolment in BAC.

- ii. ***"High likelihood of need for surgical intervention" - How is this an exclusion criterion, if it is one of the goals of the BAC program to evaluate which patients need this intervention and which patients can do with rehabilitation?***

The BAC model aligns with the principle of ensuring that patients see the *right person* for delivery of the *right treatment* at the *right time*, while precluding use of alternative inappropriate pathways/treatments. As the reviewer has correctly pointed out, BAC served as a 'gatekeeper' to identify appropriate candidates for conservative management and expedited access to community-based spinal rehabilitation, while also triaging suitable candidates for surgery to surgical consultation. During the BAC pilot, the BAC inclusion/exclusion criteria were refined as part of the central triage process. It was the opinion of some surgical colleagues, expressed during the central triage process, that certain patients should receive a surgical consultation although they were also potentially suitable for BAC, on the grounds of "high likelihood of needing surgical intervention". Examples included patients that had failed an initial (albeit incomplete) trial of non-operative management for a potentially surgically amenable condition (e.g. persistent sciatica of >12weeks duration, spondylolisthesis, moderate-to-severe central spinal canal or lateral recess/foraminal stenosis) and experienced persistent symptoms. On these grounds, some surgical collaborators requested that "high likelihood of needing surgical intervention" be kept as an exclusion for BAC.

- iii. ***"Presence of comorbid condition that also requires surgical assessment and management" - What kind of conditions? I don't see how for example unguis incarnatus that does need surgical management could be a contraindication, while bypass surgery could be. Where do you draw the line, and why?***

Patients who met this criteria were those that had comorbidities that warranted surgical assessment, management, or routine follow-up, that were in addition to their problem of neck and/or LBP. Examples include patients that had been referred with neck and/or LBP who also required either evaluation, management or routine follow-up of their neurofibromatosis, ventriculo-peritoneal (VP) shunts, previous CNS tumour excision surgery, juvenile scoliosis, or peripheral nerve entrapment syndromes e.g. carpal tunnel release surgery for median neuropathy or transposition surgery for ulnar neuropathy.

- iv. ***"Patient or GP preference for patients to be assessed by a surgeon" - This needs to be discussed further. Why is this a contraindication? To what extent should these preferences play a leading role in the decision to provide guideline adherent referral behaviour? Should we refer patients for surgery if there are no red flags because of individual preferences, while taking into calculation the costs and harms for this referral?***

A key challenge for the BAC model's implementation was to first and foremost demonstrate that it was a safe alternative to the existing 'standard of care' or 'gold standard' at the time, which was for all neck and LBP referrals to be assessed and managed in outpatient spinal surgery clinics. This burden of proof was fuelled by initial concerns held by surgical colleagues that alternative care models posed an unacceptable risk of missing important 'redflag' causes of neck and LBP. Hence, when we set out to institute the collaborative BAC model, consensus inclusion and exclusion criteria for BAC were established by stakeholders, medical supervision of the model was embedded through inclusion of a rheumatologist, and the advanced practice physiotherapists underwent a credentialing process to demonstrate competency to work in BAC. It was not until the results from the 12-month BAC pilot had been collected and analysed, that data could be presented which supported our hypothesis that BAC was a potentially safe (alternative) model of care for patients with neck and LBP referred for outpatient specialist review. Hence, during the BAC pilot, in the absence of sufficient evidence to demonstrate that BAC was 'non-inferior' to the existing standard of care (i.e. outpatient spinal surgery clinics), GP and/or patient preference to be assessed by a surgeon was deemed to be an acceptable exclusion criteria from BAC, by the central triaging team, even though the referral was in all other aspects appropriate for BAC. It is noteworthy that during the BAC pilot, only 3 patients (0.6%) declined a BAC appointment because of their preference to be assessed by a surgeon. Similarly, only two GP respondents (7%) during the BAC pilot, indicated a preference for their patients to be seen by a surgeon rather than in BAC.

- v. ***Furthermore, the list of exclusion criteria is very long, which raises the question if the BAC program is feasible for use in practice?***

Although the BAC exclusion criteria appears long, when the central triage team applied these criteria during the BAC pilot to new outpatient referrals received for neck and LBP, the vast majority (**73.7%**) were deemed appropriate for BAC. Diverting such a large volume of referrals away from overstretched outpatient surgical clinics into BAC, carries the potential of improving patient access to timely specialist care as well as improving deployment of surgeons' time and skill to seeing more appropriate candidates for surgery, especially those with time critical conditions. Furthermore, since the BAC pilot's completion and the safety of the BAC model has been demonstrated, surgical stakeholder units have agreed to relax some of the exclusion criteria used during the pilot, which is further evidence of the confidence that surgical units have come to place on the 'safety' of the BAC model for assessing and managing patients with neck and LBP. For example, since the completion of the pilot, BAC now also sees patients referred with "radiological evidence of moderate-to-severe central canal stenosis, lateral recess or foraminal stenosis, or a large disc protrusion accompanied by signs and symptoms of radiculopathy or neurogenic claudication. MRI scans are therefore routinely performed on **all** new patients seen in neurosurgery clinic, even in those that have been referred for localised neck or LBP that have no referred upper or lower limb symptoms respectively. For this reason, the authors used the data from the 2008 Huang et al. paper as it was deemed to be an accurate and conservative estimate of the number of MRI scans ordered in traditional spinal surgery clinics, such as neurosurgery, in comparison to BAC.

Reviewer 2 Comments:

1. ***A thorough description of some of the outcomes is missing, especially regarding the operationalisation of the VIRIAF dimensions (both for the quantitative and qualitative part). For example, regarding 'access to care' (page 10) patients only seem to value travelling; was this the only item questioned for within this dimension? The authors could add a table explicating which outcomes/concepts were measured, how they were measured and at what moment in time? The paper also lacks a description of how the qualitative research was performed, e.g. which topics were questioned for the different subgroups (patients, GPs etc.), who performed the interviews, whether they were recorded and how results were analysed. This makes it impossible to judge whether all outcomes/results are presented in the paper.***

We have added in table 2 (page 10 of the manuscript) as suggested by the reviewer's comments. Please see our response to reviewer 1 question 6, for a detailed outline of how the qualitative research was performed. The patient surveys were conducted by a person who was independent of the BAC project that had experience in evaluating pilot projects for the Victorian Department of Health and Human Services (DHHS) and conducting qualitative research. All patient, clinician, stakeholder, and GP interviews were conducted by this person, were recorded and the results presented mostly as direct quotes that were grouped according to similarities in the responses. The authors summarised the general messages conveyed in these quotes, rather than incorporating verbatim quotes from interviews in the manuscript results.

2. ***Following triage, patients were either referred for BAC (73.7%) or for outpatient specialist clinic (26.3%). However, the results of the latter group are not presented in this paper. As the new BAC strategy (compared to the traditional referral strategy) starts from triage, for a complete picture the pilot should also have included the group of patients that was immediately referred to an outpatient specialist clinic.***

We have amended the manuscript to acknowledge this as a study limitation (lines 354-357). This was primarily not performed due to limitations in human resources to follow-up the latter group, which was beyond the scope of the study investigators.

3. ***As this also applies for the clinician cost of staffing BAC (Table 4); a complete analysis of staffing costs related to BAC should have included costs of triage added with the weighted average costs for the remaining 26% of patients. The authors should adapt this or at least mention this as a limitation.***

We agree that the costs of triaging referrals could have been included as part of the analysis of staffing costs. During the pilot, however, the four staff members representing neurosurgery, orthopaedics, rheumatology and physiotherapy that met at fortnightly intervals to conduct the central triage process, did so voluntarily (i.e. triaging referrals was performed in addition to their usual hospital duties), and clinicians were not remunerated for their time spent triaging referrals. Acknowledgement of this as a study limitation however, has been incorporated into the manuscript in line 352. It is also noteworthy that at the conclusion of the pilot, the central triage process was replaced by a single clinician (the rheumatologist that participated in and was calibrated through the central triage process) assuming responsibility for triaging all spinal referrals for neck and LBP to neurosurgery and orthopaedic spinal clinic. This role substitution further improves deployment of spinal surgeons' skills and time by reducing their non-clinical workload and time spent triaging referrals.

- 4. In my opinion, the cost comparison regarding MRA ordering (page 11) should be removed from the results section. The comparison is based on an assumed 89.8% MRI utilisation rate in outpatient neurosurgery clinics in a 2008 paper (reference 14). I don't consider this a valid comparison; furthermore it is not a result of this pilot study.**

See response above to Reviewer 1 Question 8.

- 5. The conclusion regarding BAC being a cost-saving strategy can therefore not be drawn from this research and should also be removed from the discussion section (page 12 middle); this also applies to the title, abstract and the study strengths. At best, the authors could speculate about potential MRI cost savings in the discussion section.**

We believe that the economic aspects of BAC are an important consideration for any health service. As discussed above, the assumptions we have made are simple, conservative and justified. However, if the Editorial Committee would prefer that this part be omitted, we are happy to comply.

- 6. The authors should add as a limitation that the pilot lacks a (historical) comparator group. In the absence of a valid comparator group, we cannot make hard judgements about whether results of BAC are satisfactory. I suspect they are, but it is not demonstrated in this study.**

We have added the reviewer's comment as a study limitation (lines 89 and 354).

- 7. The pilot study ended in June 2015 which is 2 ½ years ago. The authors mention that the BAC model warrants further validation, preferably in a RCT, and that evaluation is ongoing to determine the cost-effectiveness, longer term and broader societal impact (page 13). Can the authors be a bit more explicit about this ongoing research?**

Since the BAC pilot ended in the middle of the year in 2015, results from the BAC pilot led to it being continued and adopted as an established clinical service/pathway for managing patients referred for outpatient specialist review of neck and LBP in our institution. Data collection is ongoing and being expanded to include outcome measures beyond those specified in the VIRIAF, and also extended to patients seen in neurosurgery clinics. The study authors are also continuing work towards securing grant funding to conduct an RCT to perform a more comprehensive comparative effectiveness study of BAC compared to traditional spinal surgery clinics.

- 8. Some parts of the discussion seem to present results which are not presented in the results section?**

We were unable to identify any 'new results' being presented in the discussion of the manuscript that had not already been reported in the results.

Reviewer 3 Comments:

- 1. The statistical analysis of this observational study of a pilot of the BAC, presented in this paper, is appropriate. Also, the limitations of the study are clearly articulated.**

Given the relatively small numbers in some of the groups, it is good to see that confidence intervals are presented and no significance tests are performed. Consequentially, there is no need for a statement regarding significance in the Statistical Methods section. Also, I recommend that the words 'significant' or significantly' are not used in the Efficiency and Sustainability, and Discussion sections. I think 'substantial' would be a better word.

The words significant or significantly have been replaced in the manuscript with substantial as requested in the results section, under the subheading of Efficiency and Sustainability (line 290), and in the discussion (lines 325-327).

2. *Finally, the categories of the variable 'Catchment' need clearer definitions: there seems to be a footnote missing from Table 1.*

The authors have added to the inclusion criteria in Table 1 that patients need to reside within the primary catchment area of the hospital in order to attend BAC and an explanatory footnote has been included.

VERSION 2 – REVIEW

REVIEWER	Peter W F Smith University of Southampton, UK
REVIEW RETURNED	08-May-2018
GENERAL COMMENTS	In making the revisions in response to the reviewers' comments, you have improved the paper. However, you did not remove or provide a justification for not removing the statement regarding significance in the Statistical Methods section on line 206. I suggest it is removed before publication