PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Implementation of an evidence-based model of care for low back pain in emergency departments: Protocol for the Sydney Health Partners Emergency Department (SHaPED) trial
AUTHORS	Machado, Gustavo; Richards, Bethan; Needs, Chris; Buchbinder, Rachelle; Harris, Ian; Howard, Kirsten; McCaffery, Kirsten; Billot, Laurent; Edwards, James; Rogan, Eileen; Facer, Rochelle; Lord Cowell, David; Maher, Chris

VERSION 1 – REVIEW

REVIEWER	Shefton J Parker RMIT University
REVIEW RETURNED	30-Aug-2017

GENERAL COMMENTS	The study is an important one as it aims to improve 'best care' for patients based on current best practice provided by regional treatment guidelines. It is difficult to determine precisely what the objective is for the study, as it states the primary objective of the new care model is to investigate if it 'improves care'. This is a vague objective. It is unclear what this is based on; patient satisfaction with care?, reduced pain at discharge,? decreased time to discharge? Improves care depends on how you define it. Does improved care refer to more efficient care delivery in the eyes of the medical service provided ie lower costs, or in the eyes of the consumer is improved care better pain management and satisfaction with care provided? I would suggest the primary objective should provide a little more content about what 'improved care' means for hospital staff, governance and most importantly consumers (see comments below). From table 2 the 'intervention' period is quite short compared to the retrospective control period. Considering the significant work that has gone into the implementation strategy there could be considerable bias/impact on the results. How can the researchers ensure the implementation plan is not having the impact instead of the new model? I can imagine a strong education plan along with training and providing the ACI details to patients may have a significant influence on the outcomes of the trial. Particularly with a maximum time for intervention of 3 months prior to data analysis. With the short time frame it may be that the model is implemented consistently during this time whereas the previous model may not have had that level of education and training provided. Perhaps evaluating 12 months after implementation would be more reflective of the long term benefits of the new model?

	Can you please confirm dates in the study of when year 1 data collection commences and will end and when year 2 implementation will begin and intervention commence? There would likely need to be a gap between ending data collection with Year 1 data and beginning the intervention phase where data will not be collected. What time frame will this be? Other: Abstract – SNOMED provide full name not just acronym Strengths and limitations – states study will reduce 'unnecessary' treatments do you mean ineffective? Why would treatment be 'unnecessary'? - No patient-outcome measures is a significant gap in this research study how can you evaluate 'improved care' without evaluating what impacts the model has on patient-outcomes? This is the information of most important to consumers. If patient outcomes are not being measures how can you truly evaluate if care has improved? It appears this study is more about providing more efficient and cost effective care this does not enhance 'care' in general and may actually cause worse 'care' if patient outcomes are not measured. Participants - Please list all the SNOMED codes that will be included. Implementation intervention – It states existing models of care at each ED will be mapped how will this be conducted? Further you state important features of existing models will be incorporated with new ACI model. This effectively will create a hybrid model at each site, with potentially no sites implementing the same end model. How will this impact your results and the effectiveness of the ACI model overall? How might this impact your statistical analyses if there is model variation between hospital sites? Sample size – You calculate sample size based on a study on imaging referrals this is your primary outcome so shouldn't this also be placed as your primary objective? "to evaluate if the ACI model reduces the number of imaging referrals" Outcome measures – Back Beliefs questionnaire and questions. I could not find this amongst your secondary outcome measures, or in the statistical analyses or sample size calculation. Does this only target clinicians? How many clinicians (ED doctors, nurses, physios?) will answer these questions, at what time points and how was the sample size calculated and what is the outcome you are measuring for using these? It is noted there are no outcome measures investigating pain, quality of life or satisfaction. These are significant omissions. I find it difficult to understand how you can assess 'improved care' without these measures. Please discuss. Data collection methods – You state research staff will be blinded to intervention allocation when accessing and extracting hospital data. How will this be done? Statistical methods – why not provide a detailed statistical analyses plan now? It seems like all sites are getting the intervention so why do you need blinding and what is it trying to achieve? You say you will do statistical plan so prior to unblinding who will be blind at this point and what data will they be blind too? Economic evaluation –You state a sensitivity analysis will be conducted based on key paramaters. What are these? You should where possible provide all planned analyses up front (ie based on outliers, SNOMED classification, correlations, baseline imbalance?). Will these analyses also be determined prior to unblinding? Process evaluation – Clinician participant's reviews: What data will

	be collected? Ie focus groups using qualitative data themes? Quantitative survey? What samples sixe? Again no statistical information about how this data will be analysed. Ethics and dissemination – you state ".. specifically decreasing the rates of imaging referrals, opioid prescription and hospital admission." This sounds like your objective for assessing what 'improved care' means. This is what you should have as your objective from the abstract and background through to your primary and secondary outcomes. Overall summary: There are some weaknesses in the design or at least lack of detail/information provided to determine if they area weaknesses or just omitted from the protocol manuscript. These should be addressed by the authors. Whilst I support the implementation of clinical guidelines to standardise care for patients and ensure best practice, the guidelines are inconsistent with the most recent recommendations. There is great difference between most recent US recommendations and the ACI's. In particular ACi guidelines advise analgesic use and avoidance of passive therapy. This is a deficiency of the ACI model itself I assume as it partly based its finding on out-dated US guidelines: Chou R, Qaseem A, Snow V et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med 2007; 147(7): 478-91. There has been a significant shift in recommendations since these US guidelines were published and I would refer the researchers to the latest US guidelines: Qaseem A, Wilt TJ, McLean RM, Forciea MA, for the Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. 2017;166:514–530. doi: 10.7326/M16-2367 There are potential risks to patients if out-dated guidelines are implemented. Particularly, if local ED models have adopted international recommendations in their local models and then they are replaced by the ACI. I draw your attention to difference in recommendation in the use of analgesics and other more passive non-pharmacological therapies such as mindfulness, acupuncture and low-level laser therapy. I feel you should have a limitations section in the manuscript which discusses why patient outcome data is not being collected and what the impacts of this are. Whilst the premise to this study is very good the design and justification requires more clarification. If the researchers can ensure international 'best practice' is being implemented and standardised that would be of a great benefit to staff and patients. I empathise with the researchers as this is not an easy task and one that is difficult to standardise across hospitals. This study has the potential to have great impact when implemented so it's design and premise must be carefully thought out. Please see PDF for other minor comments.

REVIEWER	Luca Miceli University of Udine, Italy
REVIEW RETURNED	16-Sep-2017

GENERAL COMMENTS	Good and interesting paper

REVIEWER	Tara Potier Brunel University United Kingdom
REVIEW RETURNED	22-Sep-2017

GENERAL COMMENTS	A well consider study overall. However, please consider the below points: • In places the authors need to justify their statements, e.g. page 4, line 45 'where care is no more effective than what could be provided in primary care'. • The title states acute LBP is being looked at but the text states patients will also be included in the trial if they have an acute flare of a chronic condition. • Have the authors considered how transient a lot of Emergency Department staff are? How do they plan to capture them in the study? • More detail is needed in places, e.g. what are the online support tools that will be used and how will they be used? Page 8, line 3. • It is important to standardise the material, as much as possible, being used across the 4 different sites (page 8, line 13). It is obviously necessary to work with individual site clinicians but how can differences be minimised. • A clearer justification is needed for the use of the Back Beliefs Questionnaire and 'questions' which are being used to examine clinicians' beliefs and facilitators (page 8, line 48). Are these the best tools to do this? How much information will they give you to be able to answer one of the secondary outcomes stated looking at beliefs and facilitators? This is an integral part of the study and one which should be examined further.

REVIEWER	Pierre Borczuk Massachusetts General Hospital Boston, MA USA
REVIEW RETURNED	26-Sep-2017

GENERAL COMMENTS	SHaPED Trial Comments Summary: The hypothesis is improvement of care delivery in patients with low back pain and appears to be aimed at clinicians. Primary outcomes is whether there is improvement of care after implementation of ACI guidelines as manifested by imaging rates, medication use and inpatient admissions. Secondary outcomes of cost effectiveness and implementation barriers are mentioned. A base line period will be established, and a stepped wedge cluster randomized trial will be performed at 4 centers over 4weeks followed by 3 month follow up period. 1. Definitions of acute and chronic back pain are clear at < or > 3 months. Things are less clear to me regarding acute on chronic. The patient with pain for 4 months and now is same pain worse . Acute or chronic? The patient with low back pain 4 months resolved for 1 month and now same pain is back strong as ever (acute or

	chronic). 2. The pathway in table 1 is for acute And acute on chronic? 3. Are there any patients with pain < 3 months that will be excluded up front, or will all patients be followed? Some patient presentations are not really in the spirit of the study, ie the IV drug use patient with fever 102 and back pain, or the patient with cancer who has back pain and myelopathy. I can see how they will key ACI Principle 2,8. However these patients are not true population of interest. It should also be clear that the population being studies is not traumatic back pain. With that said, what is meant by trauma? Situation where someone fell 2 months ago and persistent lower back pain. Shoveling snow 1 month ago and since then back pain? 4. When you figured out sample size, the assumption one makes is these are non-traumatic patients without red flag signs and symptoms? if not is this a really small group that won't make your population different from an average ED. If all patients with back pain are included in the sample size calculation (acute and chronic) then as you know, the study will need to be a bit longer in duration. 5. This question is out of my ignorance of the medical system in AUS. How will you know, whether a patient has gone to your ED, becomes unhappy for whatever reason and then shops another ED (s) until they get imaged/admitted/invasive therapy. I bring this up as clearly modus operandi in some patients in the ED. 6. My feeling regarding the issue of increased imaging, inappropriate use of medications, is not due to caregiver ignorance. The clinicians are responding to patient demands that something should be done and figured out. "What if its not arthritis or a disk problem?" "I have already tried acetaminophen, NSAIDS and physical therapy for the past 2 months and nothing is working." I have low back pain for 6 weeks radiating to my right leg and my primary care doctor sent me to the ED for an MRI scan". I am somewhat extrapolating from my experience in the US where the concept of things take time and you make have to live with some amount of pain, from a process we have not yet investigated with imaging becomes a "hard pill" to swallow. Some clinician eventually gives in. Is the AUS population different? 7. While I understand that this study evaluates ACI model as well as some hard endpoints (imaging, med prescriptions and admissions, it does bother me somewhat that the patient is not included in any of these outcomes. Is the important outcome of low back pain management just the identification of lesions that cause devastating functional outcomes if missed? Is the main outcome in low back pain figuring out how to get patients educated regarding expectations? Or is the outcome a return to a level of pre-low back pain functional life patterns.

VERSION 1 – AUTHOR RESPONSE

We have revised the manuscript accordingly and present a point-by-point response to the comments in the attached response letter. Two copies of the manuscript have been submitted: one clean copy and one copy with marked changes highlighted in light grey.

Please consider the revised manuscript. We look forward to hearing from you in due course.

Sincerely,

Dr Gustavo Machado

On behalf of the authors

Editorial Requirements:
1. Please expand all abbreviations in the title.

Response: The abbreviation has been expanded (page 1, lines 2-3):
"Implementation of an evidence-based model of care for low back pain in emergency departments: Protocol for the Sydney Health Partners Emergency Department (SHaPED) trial"

2. Please complete and include a SPIRIT check-list, ensuring that all points are included and state the page numbers where each item can be found: the check-list can be downloaded from here: https://protect-au.mimecast.com/s/0RmgBrsZN7ldIZ?domain=spirit-statement.org

Response: The SPIRIT check-list has been completed and a reference has been included in the methods section of the revised manuscript (page 6, lines 143-144):
"The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines were followed in this report of the protocol.19"

Reviewer(s)' Comments to Author:

REVIEWER: 1
Reviewer Name: Shefton J Parker
Institution and Country: RMIT University
Please state any competing interests: None declared

The study is an important one as it aims to improve 'best care' for patients based on current best practice provided by regional treatment guidelines.
1. It is difficult to determine precisely what the objective is for the study, as it states the primary objective of the new care model is to investigate if it 'improves care'. This is a vague objective. It is unclear what this is based on; patient satisfaction with care? reduced pain at discharge? Decreased time to discharge? Improves care depends on how you define it. Does improved care refer to more efficient care delivery in the eyes of the medical service provided, i.e. lower costs, or in the eyes of the consumer is improved care better pain management and satisfaction with care provided?

Response: The primary objective of the study has been modified to (page 5, lines 126-128):
"The primary objective of this study is to evaluate if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive imaging in the emergency department."

2. I would suggest the primary objective should provide a little more content about what 'improved care' means for hospital staff, governance and most importantly consumers (see comments below).

Response: We have modified our primary objective to reflect our primary outcome measure, as suggested by Reviewer 1 on question #6 (page 5, lines 126-128):
"The primary objective of this study is to evaluate if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive imaging in the emergency department."

3. From table 2 the 'intervention' period is quite short compared to the retrospective control period. Considering the significant work that has gone into the implementation strategy there could be

considerable bias/impact on the results. How can the researchers ensure the implementation plan is not having the impact instead of the new model? I can imagine a strong education plan along with training and providing the ACI details to patients may have a significant influence on the outcomes of the trial. Particularly with a maximum time for intervention of 3 months prior to data analysis. With the short time frame it may be that the model is implemented consistently during this time whereas the previous model may not have had that level of education and training provided. Perhaps evaluating 12 months after implementation would be more reflective of the long-term benefits of the new model?

Response: We are testing the effectiveness of the implementation of the new model. The model was released in November 2016 and any influence would be the same for each emergency department. What we control in the study is the sequential roll-out of the implementation of the new model to the four emergency departments. We agree that evaluating 12 months after implementation would be more reflective of long-term benefits and we are planning ongoing evaluations to measure if changes are sustained. This will be done separately to the main trial.

4. Can you please confirm dates in the study of when year 1 data collection commences and will end and when year 2 implementation will begin and intervention commence? There would likely need to be a gap between ending data collection with Year 1 data and beginning the intervention phase where data will not be collected. What time frame will this be?

Response: To clarify, the first paragraph of "Data collection methods" has been modified as (pages 10-11, lines 295-306):
"In the week prior to the implementation intervention, the 12-month retrospective baseline health service delivery data will be extracted directly from participating hospitals' electronic record systems. The Sydney Local Health District (SLHD) Targeted Activity and Reporting System (STARS) will be used to access and extract data from SLHD emergency departments. STARS is data analytics program which monitors clinician performance and service utilisation. At Dubbo Base Hospital, health service delivery data will be extracted from its electronic record system. During the implementation intervention, health service delivery measures will be extracted from all participating emergency departments every week until the end of the 3-month follow-up period. Data extraction will be conducted remotely for all participating emergency departments by research staff blinded to intervention allocation. Data collection through hospitals' electronic systems will also avoid additional workloads within the emergency departments."
Other:
1. Abstract – SNOMED provide full name not just acronym

Response: The full name has been provided in the abstract (page 2, lines 41-43):
"Low back pain presentations will be identified using Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS]) codes"

2. Strengths and limitations – states study will reduce 'unnecessary' treatments do you mean ineffective? Why would treatment be 'unnecessary'?

Response: We have replaced the term 'unnecessary' to 'inappropriate overuse' to better reflect the aim of the study (page 3, lines 61-62):
"This is a novel implementation trial looking at reducing inappropriate overuse of tests and treatments for low back pain in emergency departments."

3. No patient-outcome measures is a significant gap in this research study how can you evaluate 'improved care' without evaluating what impacts the model has on patient-outcomes? This is the information of most important to consumers. If patient outcomes are not being measures how can

you truly evaluate if care has improved? It appears this study is more about providing more efficient and cost-effective care this does not enhance 'care' in general and may actually cause worse 'care' if patient outcomes are not measured.

Response: We agree with Reviewer 1 and after discussions with the SHaPED trial Investigators we plan to collect patient-reported outcome measures. We believe that this will strengthen the study by providing evidence that if using the ACI model of care reduces imaging, it does not lead to worse patient outcomes. For feasibility reasons, we plan to collect patient-reported outcomes from a random sub-sample from each trial period.
The following information has been added to the revised manuscript under the "Patient participant" section (page 7, lines 183-192):
"We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])21 to identify low back pain presentations (Supplementary Appendix 2) to the emergency departments. Presentations with codes related to low back pain with non-specific cause or those associated with neurological signs and symptoms (such as sciatica and lumbar spinal stenosis) will be included. Re-presentations to the emergency department, or low back pain presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina syndrome) will be excluded. A random sub-sample of 200 patient participants from each trial period will be referred to a brief self-reported online questionnaire to evaluate the effectiveness of the implementation of the ACI model of care on patient-reported outcomes."

We have chosen to measure pain intensity, physical function and quality of life as they were the three core outcome domains for clinical trials in non-specific low back pain identified in a recent international Delphi consensus study (Eur Spine J 2015;24:1127-42). To measure each domain, we have chosen brief outcome measures advocated by the National Institutes of Health (NIH) as outlined below (page 10, 283-292):
"Patient-reported outcomes will be collected using a brief online questionnaire that will measure pain intensity (Numeric Rating Scale, range 0–10). We will also use the Patient-Reported Outcomes Measurement Information System (PROMIS) to measure physical function (PROMIS Short Form – Physical Function 4a) and quality of life (PROMIS Scale – Global Health item 1) as advocated by the National Institutes of Health. We have chosen these outcomes as they are considered the three core outcome domains for clinical trials in low back pain identified in a recent Delphi study,23 and by the International Consortium for Health Outcomes Measurement (ICHOM).24 Patient experience with emergency service will be assessed using item 31 of the Emergency Department Patient Experience of Care (EDPEC) survey advocated by the American College of Emergency Medicine.25"

And the data collection method (page 11, 308-313):
"Patient-reported outcome measures will be collected using automated text messaging at one week (primary time point) and again at two and four weeks after index emergency department presentation. A random sub-sample of patient participants will be referred to a brief self-reported online questionnaire containing the Patient Information Statement. Completion of the online questionnaire indicates patient consent to participate in the study. Reminder messages will be used to ensure a high response rate."

4. Participants - Please list all the SNOMED codes that will be included.

Response: The SNOMED CT-AU (EDRS) codes relevant to low back pain presentations have been included in Supplementary Appendix 2 and more information was added to the revised manuscript (page 7, lines 183-190):
"We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])21 to identify low back

pain presentations (Supplementary Appendix 2) to the emergency departments. Presentations with codes related to low back pain with non-specific cause or those associated with neurological signs and symptoms (such as sciatica and lumbar spinal stenosis) will be included. Re-presentations to the emergency department, or low back pain presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina syndrome) will be excluded."

5. Implementation intervention – It states existing models of care at each ED will be mapped how will this be conducted? Further you state important features of existing models will be incorporated with new ACI model. This effectively will create a hybrid model at each site, with potentially no sites implementing the same end model. How will this impact your results and the effectiveness of the ACI model overall? How might this impact your statistical analyses if there is model variation between hospital sites?

Response: To clarify, we are mapping existing models of treatment at each site so that we can make clear to staff which of their existing practices will remain unchanged and which need to change to conform with the new model. Our aim is not to create hybrid models at each site, but to identify current practices that align or disagree with the ACI model of care we will implement. In addition, the stepped-wedge approach allows each site to act as their own control, therefore this should allow us to control for potential differences in the background of care. The paragraph has been modified in the revised manuscript (page 8, lines 213-216):
"We will identify existing models of care that are used to guide management of patients presenting with low back pain at each emergency department. Then, we will work with local clinical staff to ensure that each site practices according to the full ACI model of care."

6. Sample size – You calculate sample size based on a study on imaging referrals this is your primary outcome so shouldn't this also be placed as your primary objective? "to evaluate if the ACI model reduces the number of imaging referrals"

Response: We agree with reviewer 1. We have updated the primary objective of the study in the revised version of the manuscript (page 5, lines 126-128):
"The primary objective of this study is to evaluate if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive imaging in the emergency department."

7. Outcome measures – Back Beliefs questionnaire and questions. I could not find this amongst your secondary outcome measures, or in the statistical analyses or sample size calculation. Does this only target clinicians? How many clinicians (ED doctors, nurses, physios?) will answer these questions, at what time points and how was the sample size calculated and what is the outcome you are measuring for using these?

Response: The Back Beliefs Questionnaire (BBQ) and other questions will be used for the process evaluation within the trial, a secondary outcome of the study. Only the primary outcome of the study (proportion of patients receiving imaging) was used to calculate the required sample size. The BBQ and questions will only be applied to clinician participants for process measures, therefore, we have moved this information to the "Process Evaluation" section of the revised manuscript. We have also added more information on what time points they will be collected (page 12, lines 356-368):
"A process evaluation will be conducted to provide an indication of which elements of the implementation intervention are effective and worthwhile. In the week before the implementation period and in the week after it, clinician participants will be asked to answer a questionnaire containing the Back Beliefs Questionnaire.26 The Back Beliefs Questionnaire is a widely validated questionnaire27 designed to measure beliefs about low back pain and will be used in our trial to assess whether the use of the ACI model of care improves beliefs about low back pain among

emergency clinicians. This instrument was found to be reliable and responsive to change in a wide range of contexts, including in Australia.28 We will also use a set of questions aimed at eliciting knowledge about the management of low back pain and attitudes of emergency clinicians toward these patients.29 At the end of the implementation period, clinician participants will also be asked to review the content of educational materials. Potential barriers and facilitators will be investigated using qualitative interviews with clinician participants."

8. It is noted there are no outcome measures investigating pain, quality of life or satisfaction. These are significant omissions. I find it difficult to understand how you can assess 'improved care' without these measures. Please discuss.

Response: We now plan to collect patient-relevant outcome measures (pain, physical function, quality of life, experience with emergency service) from a sub-sample of patients with low back pain presenting to participating emergency departments. This point has been discussed into more detail in reviewer 1 question #3.

9. Data collection methods – You state research staff will be blinded to intervention allocation when accessing and extracting hospital data. How will this be done?

Response: Detailed information about blinding of data extraction has been added to the revised manuscript (page 10, lines 303-304):
"Data extraction will be conducted remotely for all participating emergency departments by research staff blinded to intervention allocation."

10. Statistical methods – why not provide a detailed statistical analysis plan now? It seems like all sites are getting the intervention so why do you need blinding and what is it trying to achieve? You say you will do statistical plan so prior to unblinding who will be blind at this point and what data will they be blind too?

Response: A more detailed paper will explain the statistical plan of this trial. All sites are receiving the intervention, but they do not commence at the same time. Blinding research staff who will extract data from emergency departments (outcome assessor) is particularly important since it is almost impossible to blind clinician participants or those delivering the intervention, as both will be aware of the 'step' from control to intervention status. This is likely to reduce potential risk of bias and manipulation of data in our trial. The sentence about "unblinding" has been deleted to avoid confusion.

11. Economic evaluation –You state a sensitivity analysis will be conducted based on key paramaters. What are these? You should where possible provide all planned analyses up front (ie based on outliers, SNOMED classification, correlations, baseline imbalance?). Will these analyses also be determined prior to unblinding?

Response: More information has been added about sensitivity analysis (page 12, lines 345-353):
"Univariate sensitivity analyses will be conducted around key parameters likely to influence cost-effectiveness, including cost and efficacy estimates. For example, effectiveness parameters used in the economic evaluation will be varied over the 95% confidence intervals to assess impact on the ICER. Intervention costs, including training costs, staff time and resource costs will be collected from individual emergency departments and similarly analysis will examine the effect on the ICER of varying these values over the range reported by participating sites. Bootstrapping will be used to estimate a distribution around costs and health outcomes, and to estimate the confidence intervals around the ICER. Results will be plotted on the cost-effectiveness plane."

12. Process evaluation – Clinician participant's reviews: What data will be collected? i.e. focus groups using qualitative data themes? Quantitative survey? What samples sixe? Again, no statistical information about how this data will be analysed.

Response: More information has been added to the process evaluation (page 12, lines 356-368):
"A process evaluation will be conducted to provide an indication of which elements of the implementation intervention are effective and worthwhile. In the week before the implementation period and in the week after it, clinician participants will be asked to answer a questionnaire containing the Back Beliefs Questionnaire.26 The Back Beliefs Questionnaire is a widely validated questionnaire27 designed to measure beliefs about low back pain and will be used in our trial to assess whether the use of the ACI model of care improves beliefs about low back pain among emergency clinicians. This instrument was found to be reliable and responsive to change in a wide range of contexts, including in Australia.28 We will also use a set of questions aimed at eliciting knowledge about the management of low back pain and attitudes of emergency clinicians toward these patients.29 At the end of the implementation period, clinician participants will also be asked to review the content of educational materials. Potential barriers and facilitators will be investigated using qualitative interviews with clinician participants."

13. Ethics and dissemination – you state "...specifically decreasing the rates of imaging referrals, opioid prescription and hospital admission." This sounds like your objective for assessing what 'improved care' means. This is what you should have as your objective from the abstract and background through to your primary and secondary outcomes.

Response: The objectives of the study have been modified.
Abstract (page 2, lines 32-35):
"We hypothesised that the implementation of an evidence-based model of care will improve care by reducing inappropriate overuse of tests and treatments and improving outcomes for patients with low back pain presenting to emergency departments."

Background (pages 6-7, lines 126-141):
"Primary objective
The primary objective of this study is to evaluate if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive imaging in the emergency department.

Secondary objectives
The secondary aims of the study are:
- To determine if implementation of the ACI model of care significantly reduces the proportion of patients presenting with low back pain who receive opioids in the emergency department, and the proportion of patients subsequently admitted to hospital.
- To determine if implementation of the ACI model of care significantly improves patient-reported outcomes in people who present with low back pain in the emergency department.
- To determine the cost-effectiveness of the ACI model of care compared with current emergency department practice for people who present with low back pain.
- To determine the barriers and facilitators to the implementation intervention of the ACI model of care for people who present with low back pain in the emergency department."

14. Overall summary: There are some weaknesses in the design or at least lack of detail/information provided to determine if they are weaknesses or just omitted from the protocol manuscript. These should be addressed by the authors.

Response: We have added more details about the design of the trial in the revised version of the manuscript as requested by reviewer 1 in his previous questions.

15. Whilst I support the implementation of clinical guidelines to standardise care for patients and ensure best practice, the guidelines are inconsistent with the most recent recommendations. There is great difference between most recent US recommendations and the ACI's. In particular ACI guidelines advise analgesic use and avoidance of passive therapy. This is a deficiency of the ACI model itself I assume as it partly based its finding on out-dated US guidelines: Chou R, Qaseem A, Snow V et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med 2007; 147(7): 478-91.

Response: The launch of the ACI Model of Care for Acute Low Back Pain preceded the publication of the most current national guideline in the US (Qaseem A, 2017). However, most recommendations in the ACI model of care align with the current US guideline, such as provision of educational information, recommendation of non-pharmacological treatments, and if necessary start with simple analgesics (that is, avoid opioid use). Importantly these two guidelines provide similar recommendations with regard to our key outcomes, e.g. they both clearly advise against the use of imaging for patients with non-specific low back pain, and recommend judicious use of opioid analgesics.

16. There has been a significant shift in recommendations since these US guidelines were published and I would refer the researchers to the latest US guidelines: Qaseem A, Wilt TJ, McLean RM, Forciea MA, for the Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. 2017;166:514–530. doi: 10.7326/M16-2367.

Response: We are aware of the recent national US guideline, however, we think it is most appropriate to implement a model of care that reflects the Australian healthcare system and context and that was developed with input from local consumers, clinicians, health profession, funders and policy makers. Moreover, the majority of the key messages and recommendations in the ACI model of care and the latest US guideline are consistent, particularly the ones related to the outcomes of our study.

17. There are potential risks to patients if out-dated guidelines are implemented. Particularly, if local ED models have adopted international recommendations in their local models and then they are replaced by the ACI. I draw your attention to difference in recommendation in the use of analgesics and other more passive non-pharmacological therapies such as mindfulness, acupuncture and low-level laser therapy.

Response: The emergency departments where we will implement the ACI model of care have not adopted any international guideline for managing low back pain, rather they follow recommendations from the Emergency Care Institute NSW. As mentioned above, the ACI model of care and the current US guideline are in accordance in terms of the healthcare delivery outcomes we will measure: imaging, opioids, and inpatient admission.

18. I feel you should have a limitations section in the manuscript which discusses why patient outcome data is not being collected and what the impacts of this are.

Response: After discussions with the SHaPED Investigators we now plan to collect patient-reported outcome measures. More details have been explained in reviewer 1 question #1.

19. Whilst the premise to this study is very good the design and justification requires more clarification. If the researchers can ensure international 'best practice' is being implemented and standardised that would be of a great benefit to staff and patients. I empathise with the researchers as this is not an easy task and one that is difficult to standardise across hospitals. This study has the potential to have great impact when implemented so it's design and premise must be carefully thought out.

Response: We have added more details in terms of the study design as requested by reviewer 1 in his previous questions.

20. Please see PDF for other minor comments.

Response: The minor comments from the PDF file have been addressed in the revised version of the manuscript. Thank you.

REVIEWER: 2
Reviewer Name: Luca Miceli
Institution and Country: University of Udine, Italy
Please state any competing interests: None declared

1. Good and interesting paper.
Response: Thank you.

REVIEWER: 3
Reviewer Name: Tara Potier
Institution and Country: Brunel University, United Kingdom
Please state any competing interests: None declared

A well-considered study overall. However, please consider the below points:
1. In places the authors need to justify their statements, e.g. page 4, line 45 'where care is no more effective than what could be provided in primary care'.

Response: The sentence has been modified for clarification (page 4, lines 97-99):
"Another issue is the increasing rate of hospital admissions. More than one third of low back pain presentations to the emergency department lead to the patient being admitted to hospital,7 where care is likely to be similar to what could be provided in primary care."

2. The title states acute LBP is being looked at but the text states patients will also be included in the trial if they have an acute flare of a chronic condition.

Response: We have removed 'acute' from the title and text of the revised manuscript as we are studying people who present with low back pain as their main complaint (irrespective of previous history or duration of the episode). There is a large proportion of patients who present to the Australian emergency departments because of an exacerbation of a pre-existing low back pain condition. These presentations will also be included in the analysis, however, re-presentations to participating emergency department for the same problem as well those related to serious spinal pathologies will be excluded. In Supplementary Appendix 2 of the revised manuscript we list all SNOMED codes that will be used to select our patient population. To clarify, a 'Patient participants" section has been added (page 7, lines 183-190):
"We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])21 to identify low back pain presentations (Supplementary Appendix 2) to the emergency departments. Presentations with

codes related to low back pain with non-specific cause or those associated with neurological signs and symptoms (such as sciatica and lumbar spinal stenosis) will be included. Re-presentations to the emergency department, or low back pain presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina syndrome) will be excluded."

3. Have the authors considered how transient a lot of Emergency Department staff are? How do they plan to capture them in the study?

Response: Yes, we are aware that rotating clinical staff in the emergency department could be a challenge to our implementation strategy. To capture all emergency clinicians during the implementation period, we plan to run multiple educational sessions and individual meetings at each emergency department.

4. More detail is needed in places, e.g. what are the online support tools that will be used and how will they be used? Page 8, line 3.

Response: The online support tools we will use are educational websites and videos as described in the ACI model of care. They will be used by emergency clinicians to educate their patients presenting with low back pain to the emergency department. More information has been added to the revised version of the manuscript (page 8, lines 221-224):
"Clinician participants will receive a copy of the model and other printed materials, including the ACI consumer information booklet, as well as access to additional online support tools outlined in the ACI model of care, such as webpages and videos, to help them educate their patients."

5. It is important to standardise the material, as much as possible, being used across the 4 different sites (page 8, line 13). It is obviously necessary to work with individual site clinicians but how can differences be minimised.

Response: The same educational materials will be used across all sites. However, adaptation of materials may be necessary in cases such as need for translation to other languages to accommodate the diversity of the local population.

6. A clearer justification is needed for the use of the Back Beliefs Questionnaire and 'questions' which are being used to examine clinicians' beliefs and facilitators (page 8, line 48). Are these the best tools to do this? How much information will they give you to be able to answer one of the secondary outcomes stated looking at beliefs and facilitators? This is an integral part of the study and one which should be examined further.

Response: A justification for the use of these instruments has been added to the revised manuscript (page 12, lines 356-368):
"A process evaluation will be conducted to provide an indication of which elements of the implementation intervention are effective and worthwhile. In the week before the implementation period and in the week after it, clinician participants will be asked to answer a questionnaire containing the Back Beliefs Questionnaire.26 The Back Beliefs Questionnaire is a widely validated questionnaire27 designed to measure beliefs about low back pain and will be used in our trial to assess whether the use of the ACI model of care improves beliefs about low back pain among emergency clinicians. This instrument was found to be reliable and responsive to change in a wide range of contexts, including in Australia.28 We will also use a set of questions aimed at eliciting knowledge about the management of low back pain and attitudes of emergency clinicians toward these patients.29 At the end of the implementation period, clinician participants will also be asked to review the content of educational materials. Potential barriers and facilitators will be investigated using qualitative interviews with clinician participants."

REVIEWER: 4
Reviewer Name: Pierre Borczuk
Institution and Country: Massachusetts General Hospital, Boston, MA, USA
Please state any competing interests: none.

Summary: The hypothesis is improvement of care delivery in patients with low back pain and appears to be aimed at clinicians. Primary outcomes is whether there is improvement of care after implementation of ACI guidelines as manifested by imaging rates, medication use and inpatient admissions. Secondary outcomes of cost effectiveness and implementation barriers are mentioned. A base line period will be established, and a stepped wedge cluster randomized trial will be performed at 4 centers over 4weeks followed by 3 month follow up period.

1. Definitions of acute and chronic back pain are clear at < or > 3 months. Things are less clear to me regarding acute on chronic. The patient with pain for 4 months and now is same pain worse. Acute or chronic? The patient with low back pain 4 months resolved for 1 month and now same pain is back strong as ever (acute or chronic).

Response: We have removed 'acute' from the title and text of the revised manuscript as we are studying people who present with low back pain as their main complaint (irrespective of previous history or duration of the episode). There is a large proportion of patients who present to the Australian emergency departments because of an exacerbation of a pre-existing low back pain condition. In Appendix 2 of the revised manuscript we list all SNOMED codes that will be used to select our patient population. To clarify, we have created a 'Patient participants' section in the revised manuscript including the following information (page 7, lines 183-188):
"We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])21 to identify low back pain presentations (Supplementary Appendix 2) to the emergency departments. Presentations with codes related to low back pain with non-specific cause or those associated with neurological signs and symptoms (such as sciatica and lumbar spinal stenosis) will be included."

2. The pathway in table 1 is for acute 'AND' acute on chronic?

Response: Table 1 shows the management principles of the ACI model of care and will be used to guide management of low back pain at participating emergency departments irrespective of previous history or duration of symptoms.

3. Are there any patients with pain < 3 months that will be excluded up front, or will all patients be followed? Some patient presentations are not really in the spirit of the study, ie the IV drug use patient with fever 102 and back pain, or the patient with cancer who has back pain and myelopathy. I can see how they will key ACI Principle 2,8. However these patients are not true population of interest. It should also be clear that the population being studies is not traumatic back pain. With that said, what is meant by trauma? Situation where someone fell 2 months ago and persistent lower back pain. Shoveling snow 1 month ago and since then back pain?

Response: Patients with a SNOMED code reflecting a potential serious cause of the low back pain, such as fracture of the lumbar spine and cauda equina syndrome will be excluded. The following sentence has been added to the revised manuscript (page 7, lines 188-190):
"Re-presentations to the emergency department, or low back pain presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina syndrome) will be excluded."

4. When you figured out sample size, the assumption one makes is these are non-traumatic patients without red flag signs and symptoms? if not is this a really small group that won't make your

population different from an average ED. If all patients with back pain are included in the sample size calculation (acute and chronic) then as you know, the study will need to be a bit longer in duration.

Response: The Sydney Local Health District's emergency departments had over 2,650 presentations that fit our inclusion criteria in the last year, illustrating the feasibility of our study.

5. This question is out of my ignorance of the medical system in AUS. How will you know, whether a patient has gone to your ED, becomes unhappy for whatever reason and then shops another ED (s) until they get imaged/admitted/invasive therapy. I bring this up as clearly modus operandi in some patients in the ED.

Response: We wish to evaluate whether the emergency departments where the ACI model of care will be implemented reduce the proportion of patients who present with low back pain who receive imaging within the same department (i.e. during the initial presentation). We do not have details about where individual patients go after discharge from the participating emergency departments. However, we will measure re-presentation rates at participating emergency departments as one of our secondary outcomes.

6. My feeling regarding the issue of increased imaging, inappropriate use of medications, is not due to caregiver ignorance. The clinicians are responding to patient demands that something should be done and figured out. "What if its not arthritis or a disk problem?" "I have already tried acetaminophen, NSAIDS and physical therapy for the past 2 months and nothing is working." I have low back pain for 6 weeks radiating to my right leg and my primary care doctor sent me to the ED for an MRI scan". I am somewhat extrapolating from my experience in the US where the concept of things take time and you make have to live with some amount of pain, from a process we have not yet investigated with imaging becomes a "hard pill" to swallow. Some clinician eventually gives in. Is the AUS population different?

Response: We believe that is also the case in Australia. To address this issue our implementation strategy will provide emergency clinicians with the necessary tools and resources to educate their patients against the unnecessary use of imaging and opioids. We think that one of the reasons why clinicians eventually give in is because they often lack resources or knowledge to explain to the patient about potential harms and lack of benefits related to the use of imaging tests or opioids. Moreover, this study will occur in a public system setting, where patients are less able to demand imaging.

7. While I understand that this study evaluates ACI model as well as some hard endpoints (imaging, med prescriptions and admissions, it does bother me somewhat that the patient is not included in any of these outcomes. Is the important outcome of low back pain management just the identification of lesions that cause devastating functional outcomes if missed? Is the main outcome in low back pain figuring out how to get patients educated regarding expectations? Or is the outcome a return to a level of pre-low back pain functional life patterns.

Response: We agree with reviewer 4 and after discussions with the SHaPED trial Investigators we plan to collect patient outcome measures. We believe that this will strengthen the study by providing evidence that using the ACI model of care is resulting in same or better patient-relevant outcomes. We plan to collect patient-relevant outcomes from a random sub-sample from each trial period to ensure feasibility.

The following information has been added to the revised manuscript under the "Patient participant" section (page 7, lines 183-192):

"We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])21 to identify low back pain presentations (Supplementary Appendix 2) to the emergency departments. Presentations with codes related to low back pain with non-specific cause or those associated with neurological signs and symptoms (such as sciatica and lumbar spinal stenosis) will be included. Re-presentations to the emergency department, or low back pain presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina syndrome) will be excluded. A random sub-sample of 200 patient participants from each trial period will be referred to a brief self-reported online questionnaire to evaluate the effectiveness of the implementation of the ACI model of care on patient-reported outcomes."

We have also included information on which patient-relevant outcomes will be collected (page 10, 283-292):
"Patient-reported outcomes will be collected using a brief online questionnaire that will measure pain intensity (Numeric Rating Scale, range 0–10). We will also use the Patient-Reported Outcomes Measurement Information System (PROMIS) to measure physical function (PROMIS Short Form – Physical Function 4a) and quality of life (PROMIS Scale – Global Health item 1) as advocated by the National Institutes of Health. We have chosen these outcomes as they are considered the three core outcome domains for clinical trials in low back pain identified in a recent Delphi study,23 and by the International Consortium for Health Outcomes Measurement (ICHOM).24 Patient experience with emergency service will be assessed using item 31 of the Emergency Department Patient Experience of Care (EDPEC) survey advocated by the American College of Emergency Medicine.25"

And the data collection method (page 11, 308-313):
"Patient-reported outcome measures will be collected using automated text messaging at one week (primary time point) and again at two and four weeks after index emergency department presentation. A random sub-sample of patient participants will be referred to a brief self-reported online questionnaire containing the Patient Information Statement. Completion of the online questionnaire indicates patient consent to participate in the study. Reminder messages will be used to ensure a high response rate."

VERSION 2 – REVIEW

REVIEWER	Shefton J Parker RMIT University, Australia
REVIEW RETURNED	07-Dec-2017

GENERAL COMMENTS	The study design is a complex one, however authors have done their best to standardise their research methods across sites, in what is a very pragmatic ED environment. There will likely still be some variation in implementation based on each site's current model of care and will depend how well particular sites implement the experimental model of care. This variation though is largely unavoidable and although it could be interpreted as a weakness of the study, it is not significant enough to reduce the value of other data proposed to be collected. Please update your ANZCTR registration to reflect your latest changes to the design. My main concern is the current ACI model is arguably not best

	practice, as it was developed based on out-dated data. I am not sure use can be avoided though, unless a new model of care is developed encompassing the ACI and more recent published guidelines. Without this, results will be a reflection of the ACI model only and may not represent 'best care' available. This limits the extrapolation of results and the true effect of actual 'best care' may not be captured. The authors are aware of this limitation, but argue some advice is shared between ACI and newer guidelines and that such advice is in line with their key outcomes. This will be an important aspect to be discussed in their results when published. Particularly if some ED practices are in line with newer guidelines, (perhaps not an intended deliberate alignment) and not the ACI. This will be a later debate no doubt about what actual 'best care' looks like and will likely generate some interesting discussion. The greater value of the study may be in the design itself of developing a strategy for implementing a new care model across many hospital sites. Value of other measures, will be limited and specific to their selected model. The intensiveness of the education and implementation strategy will no doubt impact compliance of staff with the ACI model. It is though a variable which is difficult to standardise, and a confounder that would be even more difficult to allow for when conducting analyses of results. Qualitative data though may provide some valuable insights into improving ED education on 'best care'. It is encouraging to see evaluation will be extended to 12 months. This will better evaluate the sustainability of any improvements to care. Also reassuring to see PROMs have been included in the study. A full statistical analyses plan has not been included. If a plan is not published prior to the trial commencing this could be viewed as a potential bias. The additional detail on sensitivity analyses to be conducted though is wise and may reduce perceptions of bias later. The premise behind this study is very good. The changes that have been made significantly improve the study design and the quality of the paper. I wish the researchers good luck with the trial and look forward to reading their results when published.

REVIEWER	Pierre Borczuk Massachusetts General Hospital US
REVIEW RETURNED	31-Dec-2017

GENERAL COMMENTS	1. There will be a clinician education program, There will likely be instances where some clinicians will be seeing low back pain patients who have not received education. Will these patients be included? Will they be tracked in some way. 2. A patient centered outcome online form was added to the protocol. Will the consent process ensure that patients have smartphones what can receive these automated text messages and

	that patients have adequate access to do online form data entry? Does this method of patient involvement create certain biases (younger , more technical group). Is there a plan B considered that includes a telephone call system?

VERSION 2 – AUTHOR RESPONSE

Editorial Requirements:

1. Please include a model patient consent form, as per the requirements of the SPIRIT checklist.

Response: The Patient Consent Form has been submitted.

Reviewer(s)' Comments to Author:

REVIEWER: 1

Reviewer Name: Shefton J Parker

Institution and Country: RMIT University, Australia

Please state any competing interests: None declared

1. The study design is a complex one, however authors have done their best to standardise their research methods across sites, in what is a very pragmatic ED environment. There will likely still be some variation in implementation based on each site's current model of care and will depend how well particular sites implement the experimental model of care. This variation though is largely unavoidable and although it could be interpreted as a weakness of the study, it is not significant enough to reduce the value of other data proposed to be collected.

Response: Thank you for the comment. No action required.

2. Please update your ANZCTR registration to reflect your latest changes to the design.

Response: The ANZCTR registration has been updated.

3. My main concern is the current ACI model is arguably not best practice, as it was developed based on out-dated data. I am not sure use can be avoided though, unless a new model of care is developed encompassing the ACI and more recent published guidelines. Without this, results will be a reflection of the ACI model only and may not represent 'best care' available. This limits the

extrapolation of results and the true effect of actual 'best care' may not be captured. The authors are aware of this limitation, but argue some advice is shared between ACI and newer guidelines and that such advice is in line with their key outcomes. This will be an important aspect to be discussed in their results when published.

Response: We acknowledge that publication of the ACI model of care preceeded recently published guidelines, such as the one by American College of Physicians. However, the evidence informing both these documents is very similar. As a result, the key messages in the ACI model of care are aligned with recommendations in current guidelines and with our key trial outcomes. This aspect will be discussed in our results. No action required.

4. Particularly if some ED practices are in line with newer guidelines, (perhaps not an intended deliberate alignment) and not the ACI. This will be a later debate no doubt about what actual 'best care' looks like and will likely generate some interesting discussion. The greater value of the study may be in the design itself of developing a strategy for implementing a new care model across many hospital sites. Value of other measures, will be limited and specific to their selected model.

Response: As we noted above the key messages in the ACI model of care are aligned with recommendations in current guidelines and with our key trial outcomes so this hypothesised limitation does not exist.

5. The intensiveness of the education and implementation strategy will no doubt impact compliance of staff with the ACI model. It is though a variable which is difficult to standardise, and a confounder that would be even more difficult to allow for when conducting analyses of results. Qualitative data though may provide some valuable insights into improving ED education on 'best care'. It is encouraging to see evaluation will be extended to 12 months. This will better evaluate the sustainability of any improvements to care.

Response: Thank you for the comment. No action required.

6. Also reassuring to see PROMs have been included in the study.

Response: Thank you for the comment. No action required.

7. A full statistical analyses plan has not been included. If a plan is not published prior to the trial commencing this could be viewed as a potential bias. The additional detail on sensitivity analyses to be conducted though is wise and may reduce perceptions of bias later.

Response: Thank you for the comment. No action required.

8. The premise behind this study is very good. The changes that have been made significantly improve the study design and the quality of the paper. I wish the researchers good luck with the trial and look forward to reading their results when published.

Response: Thank you for the comment. No action required.

REVIEWER: 4

Reviewer Name: Pierre Borczuk

Institution and Country: Massachusetts General Hospital, Boston, MA, USA

Please state any competing interests: none.

1. There will be a clinician education program, There will likely be instances where some clinicians will be seeing low back pain patients who have not received education. Will these patients be included? Will they be tracked in some way.

Response: We will attempt to capture all emergency clinicians by providing multiple educational sessions and educational outreach during the 4-week intervention period. Although some clinicians might miss these sessions, they will still be exposed to other educational strategies, such as posters outlining key messages of the ACI model of care, our audit and feedback approach that will be sent via email to each emergency clinician. We will not exclude patiens who have been seen by clinicians whom might have missed an educational session. Our trial reflects the real world and this scenario is likely to happen in clinical practice.

2. A patient centered outcome online form was added to the protocol. Will the consent process ensure that patients have smartphones what can receive these automated text messages and that patients have adequate access to do online form data entry? Does this method of patient involvement create certain biases (younger , more technical group). Is there a plan B considered that includes a telephone call system?

Response: Australia is one of the leading global adopters of the smartphone, with 88% of the population owning one (Deloitte Mobile Consumer Survey 2017). Therefore, it is unlikely that there will be selection bias. We have planned an automated text messaging system which the patient will receive multiple reminders about the survey and we will not use a telephone call system, as we currently do not have sufficient resources to set up one.

VERSION 3 – REVIEW

REVIEWER	Shefton J Parker RMIT University, Australia
REVIEW RETURNED	05-Feb-2018

GENERAL COMMENTS	No further comments