PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	The Macquarie Surgical Innovation Identification Tool (MSIIT): a study protocol for a usability and pilot test
AUTHORS	Blakely, Brette; Selwood, Amanda; Rogers, Wendy; Clay-Williams, Robyn

VERSION 1 - REVIEW

REVIEWER	Ara Darzi Institute of Global Health Innovation Imperial College London London UK
REVIEW RETURNED	18-Aug-2016

GENERAL COMMENTS	BMJ Open Manuscript Review The Macquarie Surgical Innovation Identification Tool (MSIIT): a study protocol for a usability and pilot test - bmjopen-2016-013704 This paper was well written and presents an interesting concept of measuring innovative activity. Thoughts and suggestions are intended to help develop the research study Introduction Review “Identification of surgical innovation is essential to ensuring patient safety” “Reliably flagging innovation prospectively means an untested procedure can be managed” Is the purpose of this study to identify surgeons who are performing procedures that fall outside standard practice, and if so is this then the definition of innovation in surgery? If identified by the tool what is the next step? Have the team considered the ethical issues? For example if a surgeon is performing a procedure not previously undertaken in the hospital before, or they have not previously performed such a technique, will this raise concerns with the hospital management? What if the patient hasn’t been consented for such a procedure? What if there is a complication? Is the hospital / surgeon liable if this procedure is identified as “innovative” and there is a complication What if the new technique is carried out but is not subject to formal ethical approval?

	"True innovation" – as mentioned by the team is perhaps more accurately described as invention. Methods Review Phase 1 & 2 Strength • Good idea to do focus groups with a wide range of people to establish usability. Suitable methodology for undertaking data collection from interviews / focus groups. Weakness • The survey questionnaires (1 & 2) are not presented so unable to evaluate the question relevance • The researchers do not present their interview protocol for performing the face-to-face and focus group interviews. Therefore, it is difficult to establish if the questions will help achieve the objectives. • The researchers make the assumption that their tool "MSIIT" will identify innovation. They need to consider how they will establish internal validity – i.e. That it is actually identifying examples of innovative practice • The researchers do not consider how reliable the use of the tool is. They might consider having 2 independent assessors use the tool to establish the inter-rater reliability. • In future work the researchers should consider how this tool will be used by assessors not familiar with the tool • The researchers do not identify any limitations to the study o Surgeons might be biased to state that they are innovative as an act of self promotion o Surgeons might be biased to state that they are familiar with the technique / device / instrument so as not to raise alarms that they are performing surgeries they are not capable of. • The researchers do not consider the ethical issue of what to do in the case that a surgeon is performing a new procedure with new instruments and there is a problem. Should the researchers report this to a risk management officer of the hospital? • How likely are the researchers to identify innovation from a sample of 100 operations? Surely surgeons are most likely to be performing standard procedures and as such 100 cases is likely to be too low. Have the team done a power study? Thoughts on MSIIT How will MSIIT work for surgical trainees? Many surgeons in training perform operations, and use instruments that they are unfamiliar with or have not performed previously. Question 1 could potentially identify training rather than innovation – hopefully the usability study in phase 1 will identify this. New instruments, techniques or devices? Very often surgeons perform a standard surgery with new instruments or devices, is this innovation? Possibly in the surgeons own practice, but this is not necessarily relevant to a system. For example, it is not an innovation by a builder to use a new brand of hammer.

	With respect to the patient (sex, age and comorbidities) these are not the most obvious variables for considering a new innovation? Is it an innovation if a surgeon operates on a middle-aged man patient with diabetes and cancer? I may have never done this specific operation on this type of patient before, but the anatomy is the same and therefore the sex/age/morbidities are of little relevance. Does this work meet the study objectives? Objectives 1) To determine the current rate of surgical innovation and existing means of identifying it. a. Phase 1 may help to identify the existing means of measuring surgical innovation, however, this would need to be reflected in the interview questions. b. It is unclear how the team intend to measure the current rate of surgical innovation 2) Whether MSIIT is appropriate for use in the surgical setting a. This study will help improve usability b. This study will help define when the tool should be used c. However, this study does not evaluate internal validity or reliability. That is to say is it really measuring surgical innovation 3) Whether it is easy and quick to complete or requires modification based on feedback a. The implied goal is that it will, however, the interview protocols and survey questionnaires need to be evaluated to see what questions the researchers actually intend to ask 4) When MSIIT should be completed and by whom a. The process mapping element will help to establish this 5) Where is best fits into established hospital processes a. Similar goal to objective number 4, however, this implies that the researchers will consider the tool fit at both the individual and organizational level. If so then the interview protocol needs to be considered to see if this fits. b. Furthermore, at the organizational level they should consider the fit with the operational management and risk management teams. 6) Capacity to identify surgical innovation compared to existing means within participating hospitals. a. It is unclear how this is different to objective number 1 Summary Identifying innovative practice in surgery is useful to help disseminate good ideas. However, this study has a number of weaknesses, which mean it is unlikely to achieve the objectives. First, it has not been established that MSIIT can identify surgical innovation and that it is a reliable tool. Second, the survey questionnaires and interview protocols have not been presented so it is unclear whether the questions will help the researchers satisfy the objectives Third, the sample size at phase 2 (100 surgeries) seems too low to prospectively identify innovative activity.

	Fourth, the researchers do not appropriately consider the limitations of the study. Fifth, the team doesn't consider the ethical issue of identifying a surgeon performing a procedure that is outside of his/her standard practice, which has a complication. Finally, the team doesn't fully disclose the consent form so it is difficult to know what the participants are agreeing to be involved in. In summary, I believe this study needs revision to better establish the validity of the tool, and appropriateness of the research protocols.

REVIEWER	Peter Angelos, MD, PhD, FACS Linda Kohler Anderson Professor of Surgery and Surgical Ethics Chief, Endocrine Surgery Associate Director, MacLean Center for Clinical Medical Ethics The University of Chicago
REVIEW RETURNED	28-Aug-2016

GENERAL COMMENTS	Blakely and colleagues have clearly described a two phase study protocol to examine the Macquarie Surgical Innovation Identification Tool (MSIIT). The justification for the study is stated and the methods used in the protocol are well-defined. The authors adequately state the value of performing this study and the potential benefits of completing the study. This protocol will be a valuable addition to the literature on surgical innovation.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Ara Darzi
Institution and Country: Institute of Global Health Innovation, Imperial College London, London, UK
Please state any competing interests: None declared

Reviewer's comment:
This paper was well written and presents an interesting concept of measuring innovative activity. Thoughts and suggestions are intended to help develop the research study

Authors' response:
We appreciate the reviewer's comments and thoughts and have used them as an opportunity to clarify and strengthen this study; we will also revisit the reviewer's suggestions moving forward should the MSIIT be considered usable and suitable for a second, larger international trial.

Reviewer's comment:
Is the purpose of this study to identify surgeons who are performing procedures that fall outside standard practice, and if so is this then the definition of innovation in surgery? If identified by the tool what is the next step?

Authors' response:
No, the purpose of the study is to test the tool's usability and effectiveness at identifying what might be considered surgical innovation. It is not aimed to target surgeons and names of staff completing the forms will not be recorded.

In all instances the tool will be tested within the normal functioning of hospital surgical safety and management processes. How participating hospitals address surgical innovation will vary, but all have their own processes that they may choose to apply in such instances. In phase one of the study, the completed forms will be used in an observational capacity and be collected by the researchers. They will not trigger any immediate changes to existing hospital protocol. In phase two, the completed forms will be anonymous and will not be linked to surgeons or patients.

We have endeavoured to clarify this pg 15. “The researchers are collecting de-identified data with the aim of analysing the tool, not the conduct of surgeons or other surgical staff. The data collected will not be used to audit surgeries and will not be matched to any measures of surgical outcome.”

Reviewer’s comment:
Have the team considered the ethical issues?
For example if a surgeon is performing a procedure not previously undertaken in the hospital before, or they have not previously performed such a technique, will this raise concerns with the hospital management?

Authors’ response:
As stated above, in all instances, the MSIIT is being tested within normal hospital processes, therefore if hospital management would normally concern themselves with a particular surgery, then they may do so as usual. If they would not, then the study does not necessitate action.

Given the anonymity of Phase 2, it will not be possible for hospital management to identify which surgeries by which surgeons are identified as innovative by the MSIIT. However, in feedback to the participating institutions, it is possible that there will be a discrepancy between the number of innovations identified by the MSIIT and the number identified by the hospital’s usual processes. Such a finding would be a matter for the individual hospitals to address.

We have endeavoured to clarify this. Please see response at number 1 and 11.

Reviewer’s comment:
What if the patient hasn’t been consented for such a procedure?
What if there is a complication? Is the hospital / surgeon liable if this procedure is identified as “innovative” and there is a complication
What if the new technique is carried out but is not subject to formal ethical approval?

Authors’ response:
As above, the tool should not influence what types of surgeries are being carried out, and the risks to patients therefore should be unchanged by the use of the tool. If the surgeons or hospital are concerned about a particular surgery, then existing mechanisms for ethical approval, oversight, reporting, extra support etc typically performed by the hospital should still apply. As part of the early phase one focus groups and interviews, we will be asking about existing hospital protocols for innovative surgery and asking the individual hospitals at what point they would like the tools completed.

We will not be collecting data on individual patient consent nor linking our data to subsequent surgical outcomes. However, these are important issues that we may wish to include in a second trial should the MSIIT prove successful at identifying innovation.

We have endeavoured to clarify this. Please see response at number 11.

Reviewer's comment:
"True innovation" – as mentioned by the team is perhaps more accurately described as invention.

Authors' response:
We agree that there are many ways to define innovation. In this case, we are using the definition of innovation surgery developed during the preceding Australian Research Council (ARC) linkage grant project. The results of that study have been published previously:
Hutchison K, Rogers W, Eyers A, Lotz M. Getting Clearer About Surgical Innovation: A New Definition and a New Tool to Support Responsible Practice. Annals of Surgery 2015;262(6):949–54 doi: 10.1097/sla.0000000000001174

Reviewer's comment:
The survey questionnaires (1 & 2) are not presented so unable to evaluate the question relevance
The researchers do not present their interview protocol for performing the face-to-face and focus group interviews. Therefore, it is difficult to establish if the questions will help achieve the objectives.

Authors' response:
Thank you for this advice. We have added the surveys and interview/focus group open questions as an appendix to the protocol (see Appendix A).

Reviewer's comment:
The researchers make the assumption that their tool "MSIIT" will identify innovation. They need to consider how they will establish internal validity – i.e. That it is actually identifying examples of innovative practice

Authors' response:
We appreciate that the tool is completely untested at this point and therefore have tried to include mechanisms to establish its potential to accurately identify innovations. As stated pg 12 and 14 we will be collecting comparative data from existing mechanisms in the hospitals aimed to identify surgical innovation. We will also be asking for approximations from staff on the amount of innovation occurring in normal surgery in the hospitals. The surveys request participants to rate the tool's accuracy. As there is no existing gold standard for comparison, we will need to make novel evaluation of the tool through comparative and expert opinion methods. We have now clarified this as a limitation pg 3

In this research, however, we do not assume that all cases identified as innovative by the MSIIT are innovations. We have added clarification for this point pg5. "The purpose of the MSIIT is not to determine definitively whether or not a particular procedure is innovative, but rather it is to flag procedures that may require extra support to manage innovation."

Reviewer's comment:
The researchers do not consider how reliable the use of the tool is. They might consider having 2 independent assessors use the tool to establish the inter-rater reliability.

Authors' response:
Multiple personnel will be completing the MSIIT for each surgery, in order to investigate inter-rater reliability. We realise this may be limited, as the staff will have different roles, which might influence

their perspective on innovation.

Edited for clarity pg 11:
“At least two surgical team members will be asked to individually complete the MSIIT for each surgery. This will provide data on the inter-rater inter-rater reliability of the tool, with the understanding that having different staff roles will also influence perspectives on innovation.”
We also note that the tool may be revised following this pilot study, therefore our investigation of inter-rater reliability will be qualitative rather than quantitative.

Reviewer’s comment:
In future work the researchers should consider how this tool will be used by assessors not familiar with the tool

Authors’ response:
We agree that this is important for future work, however we will also obtain some information on this aspect in the initial trial. Part of the usability testing is aimed at determining if the tool is easily completed without explanation and how it might be integrated into hospital processes without recommendation by researchers.

Reviewer’s comment:
The researchers do not identify any limitations to the study

Authors' response:
Limitations to the study are identified in the summary on pg 3, taking account of the reviewer’s suggestion:
“• Depending on the timing of MSIIT completion, it may not identify unplanned innovations or those arising during surgery.
• This is a usability study and is not designed to determine possible effects of the MSIIT on surgical outcomes.
• As there is no gold standard measure of surgical innovation available, the reliability of the MSIIT to identity surgical innovation will rely on comparison to existing hospital processes and user ratings.”

A formal limitations section has been added on pg 16.

Reviewer’s comment:
Surgeons might be biased to state that they are innovative as an act of self promotion

Authors’ response:
We recognise this potential but as the completed forms will not be linked to particular surgeons we hope to decrease the likelihood of this.

Reviewer’s comment:
Surgeons might be biased to state that they are familiar with the technique / device / instrument so as not to raise alarms that they are performing surgeries they are not capable of.

Authors’ response:
We agree that this is a possibility. To guard against this to the extent achievable, each surgery will be rated by at least two healthcare professionals, thus we may identify cases where there is a

discrepancy, and if this occurs, it will inform future deployment of the MSIIT (e.g it may be the case that the MSIIT must always be completed by two healthcare professionals). In addition, all data collected will be treated confidentially and there is no scope for the researchers to inform hospital management about any specific surgeries.

Reviewer's comment:
The researchers do not consider the ethical issue of what to do in the case that a surgeon is performing a new procedure with new instruments and there is a problem. Should the researchers report this to a risk management officer of the hospital?

Authors' response:
The researchers will be collecting completed, coded MSIIT but will not be linking these to surgical outcomes. Hospitals will receive aggregate data on innovations only. It will be up to the hospitals to compare aggregate data with those collected by their current processes for identifying innovation and follow up on discrepancies if they so choose. This has been clarified as follows on pg 16:

"The aim of this study is to test the MSIIT and does not extend to influencing existing hospital processes around surgical innovation. The amount of surgical innovation in the participating hospitals and its current level of oversight should remain unchanged during the course of this project. Should hospitals, after the completion of the project, find that the MSIIT identified more surgeries than their existing mechanisms during the course of the trial, they may independently wish to review hospital processes, however the collected MSIIT will be coded and individual staff data not supplied. Furthermore, it will be stressed that without further research, a larger trial of the MSIIT, such interpretations may be premature."

Reviewer's comment:
How likely are the researchers to identify innovation from a sample of 100 operations? Surely surgeons are most likely to be performing standard procedures and as such 100 cases is likely to be too low. Have the team done a power study?

Authors' response:
We conducted a number of stakeholder meetings in preparation for the study, and the consensus was that 100 surgeries would be adequate for our purposes. We have added clarification of this selection pg 11.
"Discussions with hospital based colleagues have suggested that 100 surgeries per hospital will be adequate to capture a representative sample. During this time researchers expect to have sufficient data for both usability and piloting purposes, sufficient to confidently design a large scale, international study with a greater variety of surgical settings." A power analysis will be performed as part of the large scale study.

Reviewer's comment:
How will MSIIT work for surgical trainees? Many surgeons in training perform operations, and use instruments that they are unfamiliar with or have not performed previously. Question 1 could potentially identify training rather than innovation – hopefully the usability study in phase 1 will identify this.

Authors' response:
In order to avoid this problem, the MSIIT was designed to be completed only by fully qualified specialist surgeons. We will explicitly exclude surgical trainees in the recruitment phase.

Reviewer's comment:
New instruments, techniques or devices? Very often surgeons perform a standard surgery with new instruments or devices, is this innovation? Possibly in the surgeons own practice, but this is not necessarily relevant to a system. For example, it is not an innovation by a builder to use a new brand of hammer.

Authors' response:
This idea was explored in the ARC linkage grant and related publications. New devices may vary in their novelty and impact on surgical practice and systems. We agree with the reviewer that many new devices won't necessitate any action concerning innovation, but likewise, some new devices will. How the tool is used in such instances will be of great interest to the researchers and we are certainly open to the possibility of the MSIIT failing usability testing or needing revision to narrow the scope of procedures that it flags.

Reviewer's comment:
With respect to the patient (sex, age and comorbidities) these are not the most obvious variables for considering a new innovation? Is it an innovation if a surgeon operates on a middle-aged man patient with diabetes and cancer? I may have never done this specific operation on this type of patient before, but the anatomy is the same and therefore the sex/age/morbidities are of little relevance.

Authors' response:
These parameters were developed through the initial research, drawing on cases where surgical innovations had catastrophic effects when, for example, a tool previously used only in adults was used in a child (see Hutchison et al 2015). The variables may not be relevant for all cases, which is why questions 2b and c include caveats ("where sex differences relevant", "c.f. pediatric and elderly patients"). If they prove not to be of practical value that will be an interesting outcome and discussion point for the different finding between the previous study's results and the testing of the MSIIT.

Reviewer's comment:
Does this work meet the study objectives?

Objectives
1) To determine the current rate of surgical innovation and existing means of identifying it.
a. Phase 1 may help to identify the existing means of measuring surgical innovation, however, this would need to be reflected in the interview questions.
b. It is unclear how the team intend to measure the current rate of surgical innovation

2) Whether MSIIT is appropriate for use in the surgical setting
a. This study will help improve usability
b. This study will help define when the tool should be used
c. However, this study does not evaluate internal validity or reliability. That is to say is it really measuring surgical innovation

3) Whether it is easy and quick to complete or requires modification based on feedback
a. The implied goal is that it will, however, the interview protocols and survey questionnaires need to be evaluated to see what questions the researchers actually intend to ask

4) When MSIIT should be completed and by whom

a. The process mapping element will help to establish this

5) Where is best fits into established hospital processes
a. Similar goal to objective number 4, however, this implies that the researchers will consider the tool fit at both the individual and organizational level. If so then the interview protocol needs to be considered to see if this fits.
b. Furthermore, at the organizational level they should consider the fit with the operational management and risk management teams.

6) Capacity to identify surgical innovation compared to existing means within participating hospitals.
a. It is unclear how this is different to objective number 1

Authors' response:
1) We thank the reviewer for pointing this out. The current rate of surgical innovation will be measured in phase one surveys and interviews, which are now included as an Appendix A.

2) As stated above, as there is no gold standard for identifying surgical innovation, we will evaluate the tool's validity using expert opinion and comparative data and we will evaluate reliability by comparing forms completed by at least two surgical staff for the same surgery.

3) Surveys and interview questions are now included in Appendix A.

4) Yes, that is correct.

5) We will consider tool fit at both the individual and organisational levels through interviews with both surgical staff and hospital management, including those involved in operational management and risk management.

6) Objective number 1 relates primarily to phase one, and is to determine the current rates of surgical innovation. Objective number 6 relates to phase two, and is to determine how well the MSIIT can identify surgical innovation and how that rates of innovation identified by the MSIIT compare to rates identified by current hospital processes (comparative data).

Reviewer's comment:
Summary
Identifying innovative practice in surgery is useful to help disseminate good ideas. However, this study has a number of weaknesses, which mean it is unlikely to achieve the objectives.
First, it has not been established that MSIIT can identify surgical innovation and that it is a reliable tool.
Second, the survey questionnaires and interview protocols have not been presented so it is unclear whether the questions will help the researchers satisfy the objectives
Third, the sample size at phase 2 (100 surgeries) seems too low to prospectively identify innovative activity.
Fourth, the researchers do not appropriately consider the limitations of the study.
Fifth, the team doesn't consider the ethical issue of identifying a surgeon performing a procedure that is outside of his/her standard practice, which has a complication.
Finally, the team doesn't fully disclose the consent form so it is difficult to know what the participants are agreeing to be involved in.
In summary, I believe this study needs revision to better establish the validity of the tool, and appropriateness of the research protocols.

Authors' response:
We thank the reviewer for their comments and have attempted to address them all. In summary:
1. We aim to determine the usability and reliability of the MSIIT through phase one and phase two. We are very aware that the MSIIT may fail to identify meaningful surgical innovation. As there is no gold standard for comparison, we will rely on comparison with existing hospital measures and the rating of users to ascertain the validity and reliability of the MSIIT. We have now listed this limitation clearly in the manuscript: "As there is no gold standard for measuring surgical innovation, the validity and reliability of the MSIIT will be established using multiple participant completion for individual surgeries and user rating of accuracy. The researchers recognise that these will be influenced by roles, individual experience and perceptions."
2. We have included the surveys and interview/focus group questions in the appendix.
3. We have selected this number by recommendation of the participating hospitals. Should it be too low to record instances of innovation, that will be valuable data. The inter-rater, usability and other data should still be valuable over this number.
4. We have added a second section to increase our recognition of study limitations and considerations.
5. We have clarified that we will not be matching MSIIT completion data with surgical outcomes or individual surgeons.
6. We have added the consent forms to the appendices.

Reviewer: 2
Reviewer Name: Peter Angelos, MD, PhD, FACS
Institution and Country: Linda Kohler Anderson Professor of Surgery and Surgical Ethics Chief, Endocrine Surgery
Associate Director, MacLean Center for Clinical Medical Ethics, The University of Chicago
Please state any competing interests: None declared

Reviewer's comment:
Blakely and colleagues have clearly described a two phase study protocol to examine the Macquarie Surgical Innovation Identification Tool (MSIIT). The justification for the study is stated and the methods used in the protocol are well-defined. The authors adequately state the value of performing this study and the potential benefits of completing the study. This protocol will be a valuable addition to the literature on surgical innovation.

Authors' response:
We would like to thank the reviewer for their positive feedback.

VERSION 2 – REVIEW

REVIEWER	Ara Darzi Institute of Global Health Innovation Imperial College London London UK
REVIEW RETURNED	17-Oct-2016

GENERAL COMMENTS	The authors have clarified several points and made amendments where necessary