PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Mapping Structure, Process and Outcomes in the Removal of Low-Value Care Practices in Canadian Intensive Care Units: Protocol for a Mixed-Methods Exploratory Study
AUTHORS	Parsons Leigh, Jeanna; Petersen, Jennie; de Grood, Chloe; Whalen-Browne, Liam; Niven, Daniel; Stelfox, Henry

VERSION 1 - REVIEW

REVIEWER	Matthew Anstey University of Western Australia, Australia Prior chair of Choosing Wisely Australia advisory group.
REVIEW RETURNED	24-Aug-2019

GENERAL COMMENTS	Thanks for preparing this proposed study plan. The idea is worthwhile. My main comment relates to identification of either ineffective or harmful ICU therapies in action. PPIs might be a good example - recent evidence (NEJM RCT) suggests reduction in bleeding but increase in infectious complications. You could potentially interpret the practice result of this in two ways. You point to use of albumin in resuscitation - which might not be beneficial, but is not harmful except in head injury (although in some jurisdictions it may be more expensive than crystalloid). So I think an explicit framework for how things are deemed inappropriate would be good - ie cost-effectiveness, clinical effectiveness, etc. and determining these from the outset (based on current evidence and perhaps a Canadian Delphi process would be important. It would be important to also understand the prevalence of outdated therapies - ie tight glycaemic control is unlikely to be widespread in practice anymore. The problem with just surveying people, is you don't actually know what is happening - ie director might say - yes we have improved our ventilation strategies and only ventilate with low tidal volume, but unless they have measured their practice, you don't know how successful or not they are. Will you only be using Choosing Wisely items or do you have other methods of identifying the "de-adoption" items? Secondarily, do you think your sampling will truly tell you what is happening in Canadian ICUs? 2 ICUs from all available in each province, especially between teaching, metro, rural etc, may actually lead to reflection of scattered variation in practice. Would it be possible to increase the sampling, perhaps in your province?

	Finally, I have read the paper several times, and still struggle to define the outcome variables you will be reporting on. I think it would be worthwhile really trying to write out what your primary and secondary outcomes will look like:For example: ie we will report the items that - are most agreed on that are possible to de-adopt, that would provide the most patient benefit to de-adopt (risk), that would provide the most cost-benefit to de-adopt (ie not beneficial but costly), that have already been de-adopted. Secondary outcomes will be the composition of the teams and resources (education, decision support etc) required to achieve this. Minor edits: Intro: "This is particularly. problematic in Intensive Care Units (ICUs)" - what evidence do you have for this statement? ICUs are probably more resistant to this, given the evidence base protocols/ bundles of care. I personally don't like the use of the ~ symbol - - would be better to write approximately, aim for a sample between...

REVIEWER	Simone van Dulmen Radboudumc, Nijmegen, the Netherlands
REVIEW RETURNED	26-Aug-2019

GENERAL COMMENTS	The authors report on a study protocol of a mixed-methods exploratory study of low-value care practices in Canadian intensive care units. It is known that de-adoption of low-value care practices is challenging and tailor made interventions targeted on specific barriers and facilitators is of importance. Identifying specific barriers and facilitators on low-value care practices in ICU practice might help to develop those strategies. Therefore, this research is relevant. The protocol is well written. I do have some issues that need to be clarified. 1. There is no description when this study will be conducted. The approval of funding is provided in 2017. This needs to be clarified. 2. In the abstract it is stated that implementing evidence in clinical practice can result in inappropriate, ineffective, inefficient and unsafe care. In the introduction these terms are not clarified. And in the introduction the categorization in overuse, underuse and misuse is described. On page 5 line 14-16 there is only a categorization in ineffective and harmful with a short definition. I think this need to be clarified more appropriate and how these categorizations might interact. 3. On page 4 line 32-34 it is stated that this work builds on an in progress systematic review. It is unclear how the results of this study will be integrated in research strategies of phase 1 and 2 and the deliverables described on page 8. 4. And how (especially project nr 3) and when the future de adoption strategies as described on page 8 line 43-56 will be performed. Concerning the methods I have a few comments: Phase 1 5. Patient and public involvement page 5: the inclusion of patient and family partners is unclear. At what time points are they invited and what is the aim of their participation? Is it a form of a focus group interview with the aim to receive input of barriers-facilitators that patients perceive? Or do you want to inform patients and

	family partners on the results by discussing the themes> And how many patients and family partners do you want to involve and how are they being recruited? How do you integrate the results of the meetings in the deliverables? 6. Sampling and recruitment (page 5): this could be clarified more in detail. There is a list that may no longer be representative given the reference to an article published in 2015. This might be a problem? And could you give more detailed information on the snowballing: are you going to ask the medical directors and unit managers to provide names of the physicians and nurses or do you use another approach? Phase 2 7. Sampling and recruitment (page7): this needs to be described more in detail. How do you perform the snowball sampling? And how does that lead to the diverse representation on different elements? 8. Data analysis (page 8): the target response rate is 70%. That is high given the average response rate of surveys published in the literature. Is 70% realistic?

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer 1 – Comment #1

My main comment relates to identification of either ineffective or harmful ICU therapies in action. PPIs might be a good example - recent evidence (NEJM RCT) suggests reduction in bleeding but increase in infectious complications. You could potentially interpret the practice result of this in two ways. You point to use of albumin in resuscitation - which might not be beneficial, but is not harmful except in head injury (although in some jurisdictions it may be more expensive than crystalloid). So I think an explicit framework for how things are deemed inappropriate would be good - ie cost-effectiveness, clinical effectiveness, etc. and determining these from the outset (based on current evidence and perhaps a Canadian Delphi process would be important. It would be important to also understand the prevalence of outdated therapies - ie tight glycaemic control is unlikely to be widespread in practice anymore.

The problem with just surveying people, is you don't actually know what is happening - ie director might say - yes we have improved our ventilation strategies and only ventilate with low tidal volume, but unless they have measured their practice, you don't know how successful or not they are.

Will you only be using Choosing Wisely items or do you have other methods of identifying the "de-adoption" items?

Authors Response:

Thank you for this feedback. The focus of this study is to map the structure (i.e. context), process (i.e. interactions between stakeholders) and outcomes related to de-adoption (i.e. impact of deadoption efforts) in Canadian ICUs. The actual identification of low-value care items or practices that could be considered for removal or reduction in ICUs is not a focus of this study. We are interested in identifying the processes, context, circumstances, structures and outcomes that result through particular efforts that stakeholders put into action based on current evidence or best practices, such

as those recommended by Choosing Wisely. Identification of specific low-value care practices may occur through the interviews; however, this is not our current focus.

Reviewer 1 – Comment #2

Secondarily, do you think your sampling will truly tell you what is happening in Canadian ICUs? 2 ICUs from all available in each province, especially between teaching, metro, rural etc, may actually lead to reflection of scattered variation in practice. Would it be possible to increase the sampling, perhaps in your province?

Authors Response:

Thank for raising this question in regards to our sampling. We believe this comment is in reference to our sampling strategy discussed for Phase 1, which involves interviews with stakeholders. In addressing this comment, it is important to point out that the sampling strategy used for Phase 1 is purposive, which is commonly used in qualitative research and involves selection of participants who can provide data that is considered 'information-rich'. Our sampling frame is considered hetereogeneous as it involves sampling with stakeholders in different roles across five geographic regions in both academic and non-academic hospital settings. Use of a sampling frame such as this is intended to have high variation across a diversity of participants to gain breadth, which we felt was a key strength of this study. Having a diverse representation of experiences and perspectives will help us develop a more comprehensive understanding of potential facilitators, barriers, and potential knowledge translation strategies pertaining to de-adoption. We do however recognize the concern raised by the reviewer and appreciated their suggestion to our sample size for our home province, so we have increased our sampling size for Alberta. We will now recruit an additional 2 ICUs in Alberta and will plan to conduct interviews here first to ensure our study design will capture the diversity we are aiming for (see page 6). We also hope to further address the issue of obtaining a true representation of what is happening in Canadian ICUs through Phase 2 of our study, which involves stakeholder surveys and a much larger sample size across all Canadian ICUs.

Reviewer 1 – Comment #3

Finally, I have read the paper several times, and still struggle to define the outcome variables you will be reporting on. I think it would be worthwhile really trying to write out what your primary and secondary outcomes will look like:For example: ie we will report the items that - are most agreed on that are possible to de-adopt, that would provide the most patient benefit to de-adopt (risk), that would provide the most cost-benefit to de-adopt (ie not beneficial but costly), that have already been de-adopted. Secondary outcomes will be the composition of the teams and resources (education, decision support etc) required to achieve this.

Authors Response:

Thank you for your question regarding outcome variables. There is currently a lack of literature on processes, structures and outcomes pertaining to de-adoption of low-value care practices. Using a mixed-methods sequential exploratory design will allow us to explore this gap, including key outcome variables further. Through conducting the qualitative portion of this study first, we hope to identify key outcome variables, which will then be incorporated into the design of Phase

2. Furthermore, qualitative studies don't typically identify outcome variables as the goal is largely to gain depth and understanding to generate theory (see Jones, Torres & Arminio, 2013 – Negotiating the complexities of qualitative research in higher education for more information). In this design, we are hoping to use the theoretical insight we obtain through our Phase 1 findings to guide the design of Phase 2.

Reviewer 1 – Comment #4

Minor edits: Intro: "This is particularly. problematic in Intensive Care Units (ICUs)" - what evidence do you have for this statement? ICUs are probably more resistant to this, given the evidence base protocols/ bundles of care.

I personally don't like the use of the ~ symbol - - would be better to write approximately, aim for a sample between...

Authors Response:

Thank you for pointing out the problem with the statement listed above. We were aiming to be concise and could not include any references, as this statement was in the abstract section of the manuscript. We do agree with the reviewer comments that this statement is problematic without additional explanation or context and have removed it from the abstract. We have also removed the ~ symbol and have revised sections where this symbol was used.

Reviewer: 2 – Comment #1

1. There is no description when this study will be conducted. The approval of funding is provided in 2017. This needs to be clarified.

Authors Response:

Thank you for raising this point. Our funding was obtained in April, 2017 at the same time that that the PI (Parsons Leigh) was about to begin a year of maternity leave so our work was put on hold for one years' time (until April 2018). The funding provided also included the systematic review portion of this work which was initiated in 2018 and is just recently finished. The protocol included in this manuscript is informed by the results of the systematic review, which also included members of the team involved with this manuscript (Parsons-Leigh, Niven and Stelfox). For example, results of the systematic review has revealed that many of the identified barriers to de-adoption were related to contextual factors (e.g. entrenched norms, clinician resistance), which we plan to explore further in Phase 1. We faced some delays in completing the systematic review, hence why we are starting the subsequent phases now. Phase 1 will start in October 2019, followed by Phase 2 which will start in June 2020. We have also incorporated a couple points in the manuscript (in the 'Overall Objective' section on page 4) to address this concern.

Reviewer: 2 – Comment #2

2. In the abstract it is stated that implementing evidence in clinical practice can result in inappropriate, ineffective, inefficient and unsafe care. In the introduction these terms are not clarified. And in the introduction the categorization in overuse, underuse and misuse is described. On page 5 line 14-16 there is only a categorization in ineffective and harmful with a short definition. I think this need to be clarified more appropriate and how these categorizations might interact.

Authors Response:

Thank you for identifying the discrepancy in our terminology. We have clarified our definition of low-value care practices (under 'introduction' page 3) and have adjusted the abstract (page 2) and our categories (page 5) to be more consistent.

Low-value care practices, as defined by Elshaug and colleagues (2017 - Levers for addressing medical underuse and overuse: achieving high-value health care) include, “interventions in which evidence suggests it confers no or very little benefit for patients, or risk of harm exceeds probable benefit, or, more broadly the added costs of the interventions do not provide proportional benefits” (p. 192).

Reviewer: 2 – Comment #3

3. On page 4 line 32-34 it is stated that this work builds on an in progress systematic review. It is unclear how the results of this study will be integrated in research strategies of phase 1 and 2 and the deliverables described on page 8.

Authors Response:

Thank you for raising this concern. The systematic review has just recently been completed and also involved members of the team who contributed to this manuscript (Parsons-Leigh, Niven and Stelfox). Initial findings from this systematic review has been used to guide the development of the interview guide in Phase 1 and will also be used to develop the survey questions in Phase 2. The results from the systematic review will be integrated into our final deliverable (inventory of key factors, barriers, facilitators and proposed implementation strategies to guide the de-adoption), alongside the results from Phase 1 and Phase 2 discussed in this manuscript. We agree with the reviewer comment that we do not address this clearly and have addressed this on page 5 (under section Phase 1 - Design), on page 7 (Under Phase 2 – Design) and on page 8 (under section the entitled ‘Mapping the structure, process and outcomes in de-adoption’).

Reviewer: 2 – Comment #4

And how (especially project nr 3) and when the future de adoption strategies as described on page 8 line 43-56 will be performed.

Authors Response:

Thank you for this feedback. We do not anticipate starting any future work as listed in page 8 until the work described in this manuscript is complete toward the end of 2020. The ideas listed for future work (in particular, project #3) are based on previously identified gaps in the literature related to de-adoption. For example, a scoping review completed by two members of our team (Niven and Stelfox) identified challenges to de-adoption exist beyond the critical care context. Prior to testing any de-adoption strategies identified through this work outside of critical care, we would consult with teams from other hospital units to determine the potential relevance of such strategies.

Reviewer: 2 - Concerning the methods I have a few comments:

Phase 1

5. Patient and public involvement page 5: the inclusion of patient and family partners is unclear. At what time points are they invited and what is the aim of their participation? Is it a form of a focus group interview with the aim to receive input of barriers-facilitators that patients perceive? Or do you want to inform patients and family partners on the results by discussing the themes> And how many patients and family partners do you want to involve and how are they being recruited? How do you integrate the results of the meetings in the deliverables?

Authors Response:

The aim of the participation of patient and family partners in this study is to help with design of contextual questions related to healthcare providers’ perceptions of patient and public involvement in de-adoption, and to keep them informed and updated on study results. We have a group of dedicated

patient and family partners (compensated for their time) that work with our group and provide feedback on all of the studies we conduct. We consult them from inception of a new idea to dissemination of the results for almost every project. In this particular study, we are not interviewing or soliciting participation of patients and families outside of our already existing network of patient and family partners as the purpose of the study is really to identify contextual factors in the clinical space. We have updated the manuscript to indicated that patient and family involvement is from pre-existing partners and not with members of the general public.

6. Sampling and recruitment (page 5): this could be clarified more in detail. There is a list that may no longer be representative given the reference to an article published in 2015. This might be a problem? And could you give more detailed information on the snowballing: are you going to ask the medical directors and unit managers to provide names of the physicians and nurses or do you use another approach?

Authors Response:

Thank you for raising this point. We have added more detail into the sampling recruitment section for Phase 1 (page 5-6). In regards to the list we have from a previous study, we are using it as a guide only and it will be checked for accuracy based on publically available information before contacting anyone. With the snowball sampling strategy, we will be approaching medical directors/ unit managers and asking them to participate in an interview and for their help in sharing the details of the study with physicians and nurses in their ICU.

Phase 2

7. Sampling and recruitment (page7): this needs to be described more in detail. How do you perform the snowball sampling? And how does that lead to the diverse representation on different elements?

Authors Response:

Thank you for this feedback. We have added more details to the sampling and recruitment section for Phase 2 (page 7). Snowball sampling will be performed by initially contacting medical directors and unit managers across all ICUs in Canada. We will ask the medical directors and unit managers to fill out the survey and then forward it to other front-line providers in their ICU, including physicians and nurses. We anticipate that a large sample size that targets all ICUs in Canada will capture a diverse range of participants. We will include a number of demographic questions to help identify differences in perceptions based on age, gender, number of years working in critical care, academic/ non-academic hospital setting, etc. (see 'procedure' on page 7 for more details on demographic variables). While we will aim to capture a diverse representation of stakeholders, we acknowledge that a limitation of this study is the use of a snowball sampling strategy, which may limit our ability to achieve true representation of the population (we have acknowledged this in the strengths and limitations section).

8. Data analysis (page 8): the target response rate is 70%. That is high given the average response rate of surveys published in the literature. Is 70% realistic?

Authors Response:

Thank you for identifying this issue. Based on an earlier study with a similar design completed by members of our team (see Stelfox, Niven, Clement, et al., 2015 - Stakeholder engagement to identify

priorities for improving the quality and value of critical care), we have revised our target response rate to 62% (page 8). We have also referenced this study (see page 12, reference #38).

VERSION 2 – REVIEW

REVIEWER	Matthew Anstey Sir Charles Gairdner Hospital Australia
REVIEW RETURNED	02-Oct-2019

GENERAL COMMENTS	Thanks to the authors for revising the manuscript. A few comments: 1. You talk about the outcomes for phase 1 being based on exploring the structure,, process and outcomes for de-adoption. Yet you still don't really explain anywhere what that means. Outcomes I assume are examples of de-adoption, but could you provide examples of what you would be looking for in the structure and process? Equally, if this is a protocol paper, then an outline of the themes of your semi-structured interviews would be important. 2. I couldn't find any mention of capturing of the organisational elements that might promote (or not) quality improvement activities and de-adoption. ie a site that has project officer support, or QI clinical director. Hypothesis being that larger sites might have more staff available to tackle these initiatives. 3.A response rate of 62% remains aspirational. Anything above 40% will be an excellent result.

REVIEWER	dr. Simone van Dulmen Radboud university medical center, Nijmegen, the Netherlands
REVIEW RETURNED	21-Oct-2019

GENERAL COMMENTS	I have no further comments. The authors responded adequately on my previous comments.

VERSION 2 – AUTHOR RESPONSE

1. You talk about the outcomes for phase 1 being based on exploring the structure,, process and outcomes for de-adoption. Yet you still don't really explain anywhere what that means. Outcomes I assume are examples of de-adoption, but could you provide examples of what you would be looking for in the structure and process? Equally, if this is a protocol paper, then an outline of the themes of your semi-structured interviews would be important.

Authors Response:

Thank you for this feedback. We have added additional descriptive language in both the abstract and manuscript body to ensure that the meanings of structure (i.e. healthcare context), process (i.e. actions or events in healthcare) and outcomes (i.e. effects on health status, quality, knowledge or behavior) is specifically stated (see pages 2 and 4). In addition, we have also included specific examples in the main body of the manuscript to help address this feedback (see page 5-6).

Our interview questions have been developed to explore factors related to structure, process and outcome in de-adoption. Our interview guide is structured around the following themes: 1) demographics; 2) familiarity with de-adoption; 3) critical care context; 4) examples of deadoption processes, including what indicators ICU stakeholders use to determine success of deadoption initiative and whether their efforts were sustainable (i.e. outcome); 5) barriers to deadoption, including differences between regional vs. urban hospitals (i.e. structure); and 6) deadoption processes, including how de-adoption initiatives are identified and implemented. We have included the interview guide as a supplemental file to ensure that this is well communicated to the reader.

Editorial comments:

2. I couldn't find any mention of capturing of the organizational elements that might promote (or not) quality improvement activities and de-adoption. ie a site that has project officer support, or QI clinical director. Hypothesis being that larger sites might have more staff available to tackle these initiatives.

Authors Response:

Thank you for this feedback. We anticipate that we will develop a better understanding of the organizational elements important for de-adoption initiatives to be successful and sustainable through the first phase of this research. Specifically, we hope to capture this through incorporating interview questions that focus on the structural elements of ICU in connection to facilitators and barriers to de-adoption. Interview questions that we have included to address this include asking participants to identify the number of different stakeholders available to be involved with de-adoption initiatives in their unit, as well as how contextual factors (e.g. being situated in an academic/ non-academic setting) influence the de-adoption process. We expect that potential responses from participants will include factors related to the number of different stakeholder groups involved; the challenge of mobilizing ICUs that may be larger in size; the supports provided by quality improvement support staff and other organizational structures that either help or hinder how de-adoption efforts are implemented. We have included a point to clarify this in the main document (see page 6).

Editorial comments:

3.A response rate of 62% remains aspirational. Anything above 40% will be an excellent result.

Authors Response:

Thank you for identifying this issue. We based our response rate of 62% on an earlier study with a similar design completed by members of our team (see Stelfox, Niven, Clement, et al., 2015 - Stakeholder engagement to identify priorities for improving the quality and value of critical care; page 12, reference #38). However, we do agree with this concern and have modified this to 40% to be more conservative as suggested by the reviewer above. This is addressed in the main document (see page 8).

VERSION 3 - REVIEW

REVIEWER	Matthew Anstey Curtin University, Australia
REVIEW RETURNED	25-Nov-2019

GENERAL COMMENTS	Thanks for the revisions. I am happy with the changes made.

	Two very minor comments. Institutional characteristics (size organisation etc) is important, but staff capacity is also important - ie whether the hospital or department has quality improvement capabilities or staff available. In changing the response rate, you have altered your outcome estimates, but haven't changed the sample size. I assume that is for reasons of feasibility and seems ok, but just wanted to check. thanks

VERSION 3 – AUTHOR RESPONSE

Reviewer comment:

1. Institutional characteristics (size organisation etc) is important, but staff capacity is also important - ie whether the hospital or department has quality improvement capabilities or staff available.

Authors Response:

Thank you for this feedback. We agree and have incorporated a point on quality improvement staff/ capacity as a factor to be explored through phase 1 of this research (see page 5 and see supplementary file – interview guide).

Reviewer comment:

2. In changing the response rate, you have altered your outcome estimates, but haven't changed the sample size. I assume that is for reasons of feasibility and seems ok, but just wanted to check. Authors Response:

The reviewer is correct, we have kept our sample size the same as a measure of feasibility. There are a total of 180 ICUs in Canada and 100% of administrators are already included in our sample. In addition, we do not believe that it is feasible to expect more than 12 individual survey responses per ICU on average, which our total sample size is based on.

VERSION 4 - REVIEW

REVIEWER	Matthew Anstey Curtin University Australia
REVIEW RETURNED	27-Nov-2019

GENERAL COMMENTS	Thanks for addressing my comments. Good luck on your research.