PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A synthesis of qualitative research studies regarding the factors surrounding UK critical care trial infrastructure
AUTHORS	Pattison, Natalie; Arulkumaran, Nishkantha; O'Gara, Geraldine; Connolly, Bronwen; Humphreys, Sally; Walsh, Tim; Hopkins, Philip; Dark, Paul

VERSION 1 – REVIEW

REVIEWER	Christina Boncyk Vanderbilt University Medical Center, USA
REVIEW RETURNED	19-Jun-2019

GENERAL COMMENTS	This well-conducted qualitative study describes scientifically what is intuitive to research: centers conducting research with institutional support (financially and via supportive infrastructure) and provider buy-in are more productive. The identification of key themes to address hurdles and formulate such a system, however, are unique to this study and provide insight from which future projects can be implemented for quality improvement and systems change. Improvements to Table 1 will assist in describing centers involved. This is a well-written qualitative synthesis of two datasets in the United Kingdom collected between 2015 and 2017 including critical care consultants, nurses, physicians, and trial coordinators seeking to identify barriers and facilitators to critical care research implementation and design. This is an important focus aimed to improve study collection and generalizability of research findings across care settings. *Major Critiques*: 1. Table 1 cut off so unable to read column “8. De…” on. *Minor Critiques*: 1. In Methods, data collection describes an evolving interview process. Although the authors state this as a positive, enhancing the dependability and credibility of the transcripts, this could have introduced a bias with changes in interview structure over time. 2. In Methods, settings/sample does not include how many different centers were sampled. This information is in Table 1 should the reader wants to count hospitals, but would be helpful to have quantified in this section. 3. In Human and Unit resources, “on” should be removed so

	sentence reads: "Staffing was a factor impacting research delivery". 4. In Human and Unit resources, please define or clarify "line management". 5. In Table 1, column 1 needs a "/" between profession and area throughout. 6. In Table 1, please clarify "3/2 beds". 7. In Table 1, do not need 1, 2, 3, ect. numbering in columns. 8. In Table 1, columns not lined up between "2." and "3." sections. 9. In Table 1, under "4. Research staff numbers", please address "1 (was 4)". 10. In Table 1, under "6. Research team working patterns", please clarify "8-8pm days/week +5 on". 11. In Table 1, please clarify "working patterns" in column "7. Consultant numbers and working patterns." 12. In Table 1, please define acronym "WTE". 13. In Table 1, please define "band" and res", unclear what is being reported. 14. In Table 1, column "6. Working patterns", please use wither "days a week" or "days/week" consistently.

REVIEWER	Dr Nicola Power Lecturer in Psychology, Lancaster University, UK
REVIEW RETURNED	04-Jul-2019

GENERAL COMMENTS	Thank you for providing me with the opportunity to review this paper. It is an interesting and important paper that addresses a much-needed research question about the challenges to critical care research. I have provided a number of suggestions below that I hope help to strengthen the manuscript. They mainly refer to: tightening up some of the methodological points related to grounded theory/thematic analysis; clarifying the definitions of your sub-themes; providing quotes as evidence; and making your solutions more concrete and action-oriented. I hope that you find these suggestions useful. Abstract: - Please include n for each type of participant and clarify these participants are from 'less research active units' as mentioned later - It's not entirely clear what your data set is. Is it just the interviews or did you also conduct some kind of audit/observations? And is the n for participants for your new interviews or secondary interviews? - I'd remind the reader of what your aim was in your findings i.e., "The thematic analysis yielded six themes to explain the barriers to critical care research…" - How is your overarching core theme distinct from the six themes you've already listed? A thematic analysis should have main themes and related sub-themes Methods - Even if dataset 1 is reported in detail elsewhere, it would be useful to summarise this source to the reader. - Is 27 the total n across both interviews or are the 17 in addition? It might also be helpful to remind the reader that these participants work in less research active units, as this is an important point for

	your data. - Was the interview schedule semi-structured? Can you also provide an example of the types of questions that were asked? Or the themes you based your questions on? What was the range and mean average length of interviews? - What is “NP”? - Grounded theory is an analytic approach, not a recruitment strategy. It is when you analyse the data in order to generate a theory that you infer has application to the wider population (rather than your specific sample – thematic analysis seeks to generate themes in the specific data set you are analysing). I’m not clear how you have used the ‘principles of grounded theory’ in order to inform your sampling strategy. A common approach in qualitative research is to collect data until the point of ‘data saturation’ (i.e., when interviewees are not generating any new information). - Similarly, you seem to merge thematic analysis and grounded theory in your analysis section, but these are distinct techniques that must be distinguished – see Glaser, B.G., & Strauss, A.L. (1967). The Discovery of Grounded Theory: Strategies for Qualitative Research. New York: Aldine de Gruyter, and Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology, 3(2), 77-101. In a nutshell – thematic analysis is useful for identifying ‘themes’ in the dataset, whereas grounded theory is about generating a theory that explains the data with reference to your research question. Both these analytic approaches should have separate research questions. You can use both techniques to answer two research questions from the same data set, and this would be termed a pluralistic analysis – for an example of how these two techniques can be used to analyse the same data set (different research field, but please see ‘data analyses’ section in methodology) please see Power, N., & Alison, (2017). Redundant deliberation about negative consequences: decision inertia in emergency responders. Psychology, Public Policy & Law, 23(2), 243-258. Findings/Discussion - The distinction between your overarching theme and sub-themes is clearer in your overview section – I’d try and mirror this in your abstract i.e., overarching theme first, then related sub-themes (this follows the structure of a thematic analysis) - Why is “resource issues” not a theme of its own if it’s important (or how is it distinct from organisational)? It would also help to briefly define each of your sub-themes in the ‘overarching findings from synthesis’ section to be clear on what they are before going into detail on other levels (e.g., teams/individuals) as it’s not clear if they are separate to your sub-themes (if so, why?) or if they’re meant to fit within some of your thematic categories. - Organisational Factors – I thought you only looked at less research-active sites? I’d also be interested to hear about ‘what’ additional support sites received from academia, as these links can also bring with them lots of issues (e.g., different ethics requirements, sufficient buy-out time for academics, working to different time scales… etc.) - You report a lot of findings in your sub-themes, but you only back a few up with quotes. I realise this is to do with space-saving, but I’d suggest putting your quotes in a table to show you actually have evidence (from a very rich data set!), rather than just asking the reader to trust your interpretation. An example of how this could be done can be seen in Power, N., Plummer, N.R., Baldwin, J., James, F.R., & Laha, S. (2018). Intensive care decision-making: Identifying

	challenges and generating solutions to improve inter-specialty referrals to critical care. Journal of the Intensive Care Society, 4(19), 287-298. - Table 2 provides a useful overview of recommendations, but I'm surprised that they don't directly map onto your sub-themes. Why is this? - I think some recommendations need clarifying and/or should be made more concrete e.g., 'create more career structures…' – what do you mean by a career structure? Who should attend senior nurse meetings? How would you suggest that sites negotiate leveraged funding? It's good to identify solutions, but it would be helpful to have more concrete recommendations that explain HOW to action them. - I don't think you need both table 2 and figure 1, unless there is a key difference I can't see? (Figure 1 is better) - Table 1 seems like unnecessary/overly detailed information about demographics. Could you reduce this by site? Or are they all different sites? Or order information in a way that makes more sense? Or reduce/cut?

VERSION 1 – AUTHOR RESPONSE

Thank you for providing me with the opportunity to review this paper. It is an interesting and important paper that addresses a much-needed research question about the challenges to critical care research. I have provided a number of suggestions below that I hope help to strengthen the manuscript. They mainly refer to: tightening up some of the methodological points related to grounded theory/thematic analysis; clarifying the definitions of your sub-themes; providing quotes as evidence; and making your solutions more concrete and action-oriented. I hope that you find these suggestions useful.

We thank the reviewers for their thoughtful suggestions and we have amended accordingly.

Abstract:
- Please include n for each type of participant and clarify these participants are from 'less research active units' as mentioned later **- thank you, we have amended to include numbers, word count won't allow us to include the number from less research active units, but this is described later in the methods.**
- It's not entirely clear what your data set is. Is it just the interviews or did you also conduct some kind of audit/observations? And is the n for participants for your new interviews or secondary interviews?

Thank you, these were all new interviews – we have clarified this

- I'd remind the reader of what your aim was in your findings i.e., "The thematic analysis yielded six themes to explain the barriers to critical care research…" **Thank you, we have amended.**
- How is your overarching core theme distinct from the six themes you've already listed? A thematic analysis should have main themes and related sub-themes. **This was a thematic synthesis of previous thematic analyses, sub themes are presented but an overarching core theme to represent the main essence of the themes is presented to exemplify the core issue raised in the synthesis**.

Methods
- Even if dataset 1 is reported in detail elsewhere, it would be useful to summarise this source to the reader. **Thank you, we have now added in this information.**
- Is 27 the total n across both interviews or are the 17 in addition? It might also be helpful to remind the reader that these participants work in less research active unts, as this is an important point for your data. **We have clarified this – thank you**
- Was the interview schedule semi-structured? Can you also provide an example of the types of questions that were asked? Or the themes you based your questions on? What was the range and

mean average length of interviews? **We have now provided this, thank you**
- What is “NP”? **The author initials indicating which author undertook that element of the work (as per journal style)**
- Grounded theory is an analytic approach, not a recruitment strategy. It is when you analyse the data in order to generate a theory that you infer has application to the wider population (rather than your specific sample – thematic analysis seeks to generate themes in the specific data set you are analysing). I’m not clear how you have used the ‘principles of grounded theory’ in order to inform your sampling strategy. A common approach in qualitative research is to collect data until the point of ‘data saturation’ (i.e., when interviewees are not generating any new information). **Thank you, we have reworded to make it clear we were using the principles of theoretical sampling (from GT), in order to build up a picture of the landscape of UK trials.**
- Similarly, you seem to merge thematic analysis and grounded theory in your analysis section, but these are distinct techniques that must be distinguished – see Glaser, B.G., & Strauss, A.L. (1967). The Discovery of Grounded Theory: Strategies for Qualitative Research. New York: Aldine de Gruyter, and Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology, 3(2), 77-101. In a nutshell – thematic analysis is useful for identifying ‘themes’ in the dataset, whereas grounded theory is about generating a theory that explains the data with reference to your research question. Both these analytic approaches should have separate research questions. You can use both techniques to answer two research questions from the same data set, and this would be termed a pluralistic analysis – for an example of how these two techniques can be used to analyse the same data set (different research field, but please see ‘data analyses’ section in methodology) please see Power, N., & Alison, (2017). Redundant deliberation about negative consequences: decision inertia in emergency responders. Psychology, Public Policy & Law, 23(2), 243-258. **Thank you for the comment, we have amended to remove reference to GT in order not to confuse. However, GT and TA can arguably be used concurrently, as Boyatzis describes in his seminal work (the precursor to the Braun and Clark’s application of TA) and we have also published previously using this approach. We have added in Boyatzis’ ref to substantiate this.**

Findings/Discussion
- The distinction between your overarching theme and sub-themes is clearer in your overview section – I’d try and mirror this in your abstract i.e., overarching theme first, then related sub-themes (this follows the structure of a thematic analysis) **Thank you, we have amended the abstract**
- Why is “resource issues” not a theme of its own if it’s important (or how is it distinct from organisational)? **Resource issues could not simply be abstracted out to an organisational level, since there were resource implications that were within individual’s power to influence; it did not necessarily mean that the organisation could influence every element of these resource issues. We have added in a line to reflect this.**

It would also help to briefly define each of your sub-themes in the ‘overarching findings from synthesis’ section to be clear on what they are before going into detail on other levels (e.g., teams/individuals) as it’s not clear if they are separate to your sub-themes (if so, why?) or if they’re meant to fit within some of your thematic categories. **We have now added in a description of each theme for each sub-theme (This was already in place for Clinician factors, so no further description added).**

- Organisational Factors – I thought you only looked at less research-active sites? I’d also be interested to hear about ‘what’ additional support sites received from academia, as these links can also bring with them lots of issues (e.g., different ethics requirements, sufficient buy-out time for academics, working to different time scales… etc.) **We included both, as explained in the methods, the synthesised dataset (dataset 1 and 2) included both research-active and non-research active**
- You report a lot of findings in your sub-themes, but you only back a few up with quotes. I realise this is to do with space-saving, but I’d suggest putting your quotes in a table to show you actually have evidence (from a very rich data set!), rather than just asking the reader to trust your interpretation. An example of how this could be done can be seen in Power, N., Plummer, N.R., Baldwin, J., James, F.R., & Laha, S. (2018). Intensive care decision-making: Identifying challenges and generating solutions to improve inter-specialty referrals to critical care. Journal of the Intensive Care Society, 4(19), 287-298.

We have added in some further quotes to exemplify. Thank you for the suggestion of tabulation, however we prefer not to tabulate the quotes as we strongly feel this detracts from reading the findings in context, supported by qualitative description and interpretation. We have published widely in over 50 qualitative papers as a group of authors, using this conventional approach, and feel this is the most appropriate for this particular study. We would like to take the editor's opinion on this.

- Table 2 provides a useful overview of recommendations, but I'm surprised that they don't directly map onto your sub-themes. Why is this? **We felt these didn't quite align however we have restructured this supplemental table to align better to the sub-themes, but now included this as a supplemental file (please see next response).**
- I think some recommendations need clarifying and/or should be made more concrete e.g., 'create more career structures…' – what do youean by a career structure? Who should attend senior nurse meetings? How would you suggest that sites negotiate leveraged funding? It's good to identify solutions, but it would be helpful to have more concrete recommendations that explain HOW to action them. **We have added in examples where appropriate.**
- I don't think you need both table 2 and figure 1, unless there is a key difference I can't see? (Figure 1 is better) **Figure 1 does not encompass all the recommendations, only the salient points, as the figure would be too difficult to read with all the recommendations on. Table 2 is a supplemental file for people who wish to understand more.**
- Table 1 seems like unnecessary/overly detailed information about demographics. Could you reduce this by site? Or are they all different sites? Or order information in a way that makes more sense? Or reduce/cut?

These are all distinct sites, the other reviewer has made suggestions to this table, please see below. We have simplified as per your comments.

This is a well-written qualitative synthesis of two datasets in the United Kingdom collected between 2015 and 2017 including critical care consultants, nurses, physicians, and trial coordinators seeking to identify barriers and facilitators to critical care research implementation and design. This is an important focus aimed to improve study collection and generalizability of research findings across care settings.

Major Critiques:

1. Table 1 cut off so unable to read column "8. De…" on.

This is a supplemental file, and on opening as a separate file it appears not to be a problem – we have removed it from within the main manuscript document.

Minor Critiques:

1. In Methods, data collection describes an evolving interview process. Although the authors state this as a positive, enhancing the dependability and credibility of the transcripts, this could have introduced a bias with changes in interview structure over time.

Thank you, we have added in a sentence to the limitations critique in the discussion to reflect this.

2. In Methods, settings/sample does not include how many different centers were sampled. This information is in Table 1 should the reader wants to count hospitals, but would be helpful to have quantified in this section.

Thank you, we have now added this in.

3. In Human and Unit resources, "on" should be removed so sentence reads: "Staffing was a factor impacting research delivery".

We have amended to affecting in order to read better.

4. In Human and Unit resources, please define or clarify “line management”. **We have added this in**

5. In Table 1, column 1 needs a “/” between profession and area throughout. **We have added this in**

6. In Table 1, please clarify “3/2 beds”. **Thank you, we have added in a footnote to define this**

7. In Table 1, do not need 1, 2, 3, ect. numbering in columns. **Thank you we have amended.**

8. In Table 1, columns not lined up between “2.” and “3.” sections. **Now amended**

9. In Table 1, under “4. Research staff numbers”, please address “1 (was 4)”. **Thank you, we have amended**

10. In Table 1, under “6. Research team working patterns”, please clarify “8-8pm days/week +5 on”. **Thank you, we have clarified what on call means**

11. In Table 1, please clarify “working patterns” in column “7. Consultant numbers and working patterns.” **We have combined this column with the PA column and removed reference to working patterns to simplify**

12. In Table 1, please define acronym “WTE”. **Now defined**

13. In Table 1, please define “band” and res”, unclear what is being reported. **Explanation has been given as a footnote for this.**

14. In Table 1, column “6. Working patterns”, please use wither “days a week” or “days/week” consistently. **Thank you, we have now amended this.**

VERSION 2 – REVIEW

REVIEWER	Nicola Power Lancaster University, UK
REVIEW RETURNED	13-Aug-2019

GENERAL COMMENTS	Thank you for revising your manuscript. I believe that it is now much improved and I only have a few, very minor, comments to be addressed. Abstract: - “Primary and secondary analysis of the two datasets was undertaken in the thematic analysis” – doesn’t make sense to me. Can you rephrase? Method: - Information about methodology is much clearer – thank you for clarifying. - What was your strategy for any disagreements in coding with your independent researcher? Did you code to consensus? Did you record any inter-rater reliability statistics (e.g., Cohen’s Kappa)? Findings: - Under ‘human and unit resources’ – which subthemes are you referring to when saying ‘these sub-themes’? and how were they closely aligned? Why not just treat as one sub-theme if they’re close to save confusion? - Thank you for adding in definitions and additional quotes in places. There are still a few places where I would expect/like to see a quote to support your interpretation (e.g., research staff with a clinical background in critical care found communication easier – quote to explain this/reasons why; Quotes to support some of the points

	made in the first paragraph under ‘study/trial factors’). Discussion: - Minor point – sometimes you put a full stop before your citations. - Can you explain what you mean by ‘moderatum generalisations’ and notions of transferability – might not be clear to someone unfamiliar with qualitative research.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2

Abstract:
- “Primary and secondary analysis of the two datasets was undertaken in the thematic analysis” – doesn’t make sense to me. Can you rephrase?

We have rephrased this slightly. These terms are not unusual to use in any type of research, so we believe the reader would understand this.

Method:
- Information about methodology is much clearer – thank you for clarifying.
- What was your strategy for any disagreements in coding with your independent researcher? Did you code to consensus? Did you record any inter-rater reliability statistics (e.g., Cohen’s Kappa)?

We have added in that we coded to consensus, as is usual in qual research, rather than using IRR.

Findings:
- Under ‘human and unit resources’ – which subthemes are you referring to when saying ‘these sub-themes’? and how were they closely aligned? Why not just treat as one sub-theme if they’re close to save confusion?

We have left this as six themes rather than treating as one combined sub-theme (five themes) as despite similarities in coding and category development, there were enough differences to warrant distinction. This was agreed during the analysis and we would be 'forcing a fit' at this stage to change it and it would not reflect the qualitative analysis.

- Thank you for adding in definitions and additional quotes in places. There are still a few places where I would expect/like to see a quote to support your interpretation (e.g., research staff with a clinical background in critical care found communication easier – quote to explain this/reasons why; Quotes to support some of the points made in the first paragraph under ‘study/trial factors’).

Thank you we have added further quotes as requested.

Discussion:
- Minor point – sometimes you put a full stop before your citations.

Vancouver style is cited after the full stop, as opposed to APA/Harvard.

- Can you explain what you mean by ‘moderatum generalisations’ and notions of transferability – might not be clear to someone unfamiliar with qualitative research.

Thank you we have added in a sentence to clarify.