

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)	Strategies to enhance recruitment and consent to intensive care studies: qualitative study with researchers and patient-public involvement contributors
AUTHORS	Paddock, Katie; Woolfall, Kerry; Frith, Lucy; Watkins, Megan; Gamble, Carrol; Welters, Ingeborg; Young, Bridget

VERSION 1 – REVIEW

REVIEWER	Natale, Patrizia University of Bari
REVIEW RETURNED	31-May-2021

GENERAL COMMENTS	<p>The manuscript of Dr Paddock et al is entitled “Strategies to enhance recruitment and consent to intensive care studies: qualitative study with researchers and patient-public involvement contributors”. The authors aims to identify strategies to enhance recruitment and consent to intensive care units (ICU) studies. The need for the study is well made, and the manuscript is easy to read. I congratulate with authors for their great work and efforts. Participants selection is clear and themes and subthemes are clearly reported. Results are clearly reported. Discussion is coherent with the manuscript. Since the study was performed in the UK, the generalisability of the findings is not warranted. However, some minor revisions should be addressed:</p> <p>ABSTRACT:</p> <ul style="list-style-type: none">• It is not completely clear from the abstract how many themes emerged from the interviews? Maybe could be helpful for the reader to add which themes were identified during the interviews. <p>BACKGROUND:</p> <ul style="list-style-type: none">• Do you know what is the proportion of trials that archive adequate recruitments rate in ICU studies, basing on the available literature on thi topic?• The author addressed properly the issue related to recruitment in ICU studies but I wonder if retention in ICU studies could be also an interesting point do discuss.• Recruitments barriers and strategies to improve recruitment in clinical trials have been addressed in the paper of Natale et al, Transparency, trust and minimizing burden to increase recruitment and retention in trials: a systematic review, J Clin Epidemiol 2021• Information regarding potential barriers in recruitment in ICU studies are reported somehow. Are there any strategies used to increase recruitment in ICU studies?
-------------------------	--

	<p>DISCUSSION:</p> <ul style="list-style-type: none"> • It is not completely clear what this study adds to the previous knowledge in this filed. What are the key findings that add something new to this topic? I think that this point should be clarified.
--	--

REVIEWER	Hwang, David Y Division of Neurocritical Care and Emergency Neurology, Yale School of Medicine
REVIEW RETURNED	11-Jun-2021

GENERAL COMMENTS	<p>For this qualitative study, the authors interviewed 17 UK critical care researchers and 8 patient-public involvement (PPI) contributors to critical care research design re: regulatory challenges to conducting critical care clinical research. The paper outlines challenges that researchers run into when working with research ethics committees on obtaining protocols without prior consent, including staffing levels needed to enroll patients in studies with acute time windows and challenges with consenting surrogates who may be in a state of shock. It also gives an honest perspective on how PPI members of study protocol may or may not contribute significantly to research design.</p> <p>I genuinely enjoyed reading this paper and thought that it was very well organized, given that it covered a tremendous number of topics. The writing is clear, and the findings from the interviews were insightful. While many papers have been written with regards to some of the themes that were uncovered by the study, I do think the paper could be impactful in terms of providing empiric data for ICU researchers to take to the research committees at their institution and enhance conversations with those committees about how best to facilitate ICU research while respecting patient autonomy.</p> <p>Minor question—when recruiting PPIs, how many PPIs responded to the advertisement that was released?</p>
-------------------------	--

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comment: The manuscript of Dr Paddock et al is entitled “Strategies to enhance recruitment and consent to intensive care studies: qualitative study with researchers and patient-public involvement contributors”. The authors aims to identify strategies to enhance recruitment and consent to intensive care units (ICU) studies. The need for the study is well made, and the manuscript is easy to read. I congratulate with authors for their great work and efforts. Participants selection is clear and themes and subthemes are clearly reported. Results are clearly reported. Discussion is coherent with the manuscript. Since the study was performed in the UK, the generalisability of the findings is not warranted. However, some minor revisions should be addressed:

Author response: Thank you for taking the time to provide your feedback and suggestions for our paper.

Reviewer 1 comment: It is not completely clear from the abstract how many themes emerged from the interviews? Maybe could be helpful for the reader to add which themes were identified during the interviews.

Author response: This has now been added to the abstract and results sections

Reviewer 1 comment: Do you know what is the proportion of trials that archive adequate recruitments rate in ICU studies, basing on the available literature on thi topic?

Author response: We have included a reference to the percentage of randomised clinical trials that do not meet their recruitment targets in the introduction. There is no clear, consistent evidence of the proportion of ICU studies specifically that do meet recruitment targets specifically.

Reviewer 1 comment: The author addressed properly the issue related to recruitment in ICU studies but I wonder if retention in ICU studies could be also an interesting point do discuss.

Author response: We agree that this would be interesting, but a discussion of retention to ICU studies is beyond the scope of this study.

Reviewer 1 comment: Recruitments barriers and strategies to improve recruitment in clinical trials have been addressed in the paper of Natale et al, Transparency, trust and minimizing burden to increase recruitment and retention in trials: a systematic review, J Clin Epidemiol 2021

Author response: Thank you for this suggestion. We have now added this reference to the introduction.

Reviewer 1 comment: Information regarding potential barriers in recruitment in ICU studies are reported somehow. Are there any strategies used to increase recruitment in ICU studies?

Author response: In Box 3 in the discussion section of the paper includes several factors that could benefit recruitment and consent to ICU studies in terms of increasing the numbers of patients recruited as well as enhancing the quality of the process. We feel this sufficiently meets the reviewer's comment.

Reviewer 1 comment: It is not completely clear what this study adds to the previous knowledge in this filed. What are the key findings that add something new to this topic? I think that this point should be clarified.

Author response: This paper adds robust empirical evidence to support existing informal understandings of issues relating recruitment and consent to ICU studies. We have added to the Discussion section to clarify this.

Reviewer 2 comment: For this qualitative study, the authors interviewed 17 UK critical care researchers and 8 patient-public involvement (PPI) contributors to critical care research design re: regulatory challenges to conducting critical care clinical research. The paper outlines challenges that researchers run into when working with research ethics committees on obtaining protocols without prior consent, including staffing levels needed to enroll patients in studies with acute time windows and challenges with consenting surrogates who may be in a state of shock. It also gives an honest perspective on how PPI members of study protocol may or may not contribute significantly to research design.

I genuinely enjoyed reading this paper and thought that it was very well organized, given that it covered a tremendous number of topics. The writing is clear, and the findings from the interviews were insightful. While many papers have been written with regards to some of the themes that were uncovered by the study, I do think the paper could be impactful in terms of providing empiric data for ICU researchers to take to the research committees at their institution and enhance conversations with those committees about how best to facilitate ICU research while respecting patient autonomy.

Author response: Thank you for taking the time to provide your feedback on our paper.

Reviewer 2 comment: Minor question—when recruiting PPIs, how many PPIs responded to the advertisement that was released?

Author response: We received communication from a further seven PPI contributors who were then not interviewed. Most due to lack of response to arrange an interview date, and two declined over concerns they would breach the confidentiality of the study they were involved in. We have included the number of PPI contributors who contacted us for an interview in the results section of the paper.

Reviewer: 1

Competing interests of Reviewer: none

Reviewer: 2

Competing interests of Reviewer: None.

I hope that we have provided satisfactory answers to the reviewers' comments and look forward to your response.

VERSION 2 – REVIEW

REVIEWER	Natale, Patrizia University of Bari
REVIEW RETURNED	11-Aug-2021

GENERAL COMMENTS	well done. I give my green light to go.
-------------------------	---

REVIEWER	Hwang, David Y Division of Neurocritical Care and Emergency Neurology, Yale School of Medicine
REVIEW RETURNED	26-Aug-2021

GENERAL COMMENTS	Thank you very much.
-------------------------	----------------------