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)	Is Fascia Iliaca Compartment Block administered by paramedics for suspected hip fracture acceptable to patients? A qualitative study
AUTHORS	Evans, Bridie; Brown, Alan; Fegan, Greg; Ford, Simon; Guy, Katy; Jones, Jenna; Jones, Sian; Keen, Leigh; Khanom, Ashrafunnesa; Longo, Mirella; Pallister, Ian; Rees, Nigel; Russell, Ian; Seagrove, Anne; Watkins, Alan; Snooks, Helen

VERSION 1 – REVIEW

REVIEWER	Iain Moppett University of Nottingham, UK
REVIEW RETURNED	14-Aug-2019

GENERAL COMMENTS	The authors describe a qualitative study of patient and carer perception of paramedic delivered FICB in the context of a clinical trial. In general this is an interesting paper. It is limited by relatively small numbers - I'm not a qualitative expert, but saturation generally needs a few more participants than this. I appreciate that the sample size is what it is though. The methods and findings are appropriate and sensible. My personal opinion would be that the authors could make more of the discussion about what consent for research means in this context. This a complex area where researchers, potential participants, rule-writers and rule-enforcers have divergent, and often non-evidence based views. This study adds a bit more hard evidence to that discussion. Some comments for the authors to consider. Summary: I'm slightly confused by the n=13 in the participants section. Reading the rest of the paper, I think this is the total number of FICB participants. Introduction: This is being a bit pedantic, but the evidence is that surgery delayed beyond 48 hours is associated with a worse outcome. The jury is still out on cause and effect.

	The references for mortality are a bit out of date. Given that this is a UK based study it would seem sensible to use the NHFD data - which report a mortality of around 7% at thirty days. Complications of morphine: these are true but not really a cause of delay to surgery. Opiates vs opioids - I would suggest the authors stick to opioids which covers all of the relevant drugs. Page 7: '...Although FICB procedure may provide effective analgesia in the prehospital setting [30] as well as reduce morphine,...' Should this be '...Although FICB may provide effective analgesia in the prehospital setting [30] as well as reducing morphine use,...' Methods I'm sure it was done, but I can't see mention of written, informed consent. Maybe I've missed it. Perhaps add the word written in the Ethical Approval section on p 17. General wording: pain relief injection / injection in the groin / FICB are used at different times. Is this deliberate? Discussion: 'Elderly' Generally there is a move towards talking about older people. There is no mention of the number of participants as a limitation. The authors state that the participants were representative of the hip fracture population - but it would appear they all had capacity - whereas c.30% of hip fracture patients are confused on admission. As always these are simply my opinions. The authors may disagree.

REVIEWER	Steven Faux St Vincent's Hospital Sydney University of NSW Australia
REVIEW RETURNED	15-Sep-2019

GENERAL COMMENTS	Excellent article and needed in terms of acknowledging the feasibility to undertake research in the prehospital space. Some areas that need to be addressed prior to publication, however include: 1. more detail in the demographic table to include time to arrival at the scene from the call (this may affect development of delirium and hence memory for the event), rural or metropolitan, number of ficbs previously done by the paramedic who attended, also the number of comorbidities that the patient had. 2. the word methologists may be coined, I suggest an alternative term and an explanation of what a "methodologists" is or does 3. Would like you to comment on the cases (number and/ or biases) of those who were given the ficb but did not have a fractured hip (? those with fractured pelvis or fractured pelvis or soft tissue injury). Also some information on those who refused the fib (age gender ?comorbidities)

	3. The case of the man who had to be transported through the window is interesting and underlines the importance of the pain relief at the time. I would suggest that a case study of this extraction be offered as an appendix as it illustrates the importance of the paramedic being able to have the skill to undertake the FICB - 4. In the limitations comment need to be made of the poor memory of the event as this puts in question the decision by the ethics board of acknowledging that the patient consent for treatment may need to be additionally obtained by the person responsible (next of kin) if one is present. If not the question about the human right to analgesia may need to be alluded to (see WHO statement and IASP statement on the human right to access analgesia). 5. In the limitations comment needs to be made regarding patient's capacity to remember pain and offer pain scores in retrospect. This has been shown not always to be accurate and needs to be mentioned in the limitations. Otherwise I would like to congratulate authors and advisors for undertaking a piece of research that is highly valuable and is likely to encourage better understanding of the prehospital experience of patients in a variety of conditions.

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1
Reviewer Name: Iain Moppett
Institution and Country: University of Nottingham, UK
Please state any competing interests or state 'None declared': None
Please leave your comments for the authors below
The authors describe a qualitative study of patient and carer perception of paramedic delivered FICB in the context of a clinical trial.
In general this is an interesting paper. It is limited by relatively small numbers - I'm not a qualitative expert, but saturation generally needs a few more participants than this. I appreciate that the sample size is what it is though.
The methods and findings are appropriate and sensible. My personal opinion would be that the authors could make more of the discussion about what consent for research means in this context. This a complex area where researchers, potential participants, rule-writers and rule-enforcers have divergent, and often non-evidence based views. This study adds a bit more hard evidence to that discussion.

Thank you for your interest in our paper. We recognise this was a small sample and have amended the strengths and limitations sections to acknowledge this in line with your observation. Please see pages 5 and 13. We are also grateful to you for highlighting the opportunity to further discuss the issue of consent for research in the prehospital context. Please see page 15.

Some comments for the authors to consider.
Summary:
I'm slightly confused by the n=13 in the participants section. Reading the rest of the paper, I think this is the total number of FICB participants.

You have correctly highlighted the confusing description of participants. We have amended this section to report the total number of participants in the interview study. Please see page 3.

Introduction:
This is being a bit pedantic, but the evidence is that surgery delayed beyond 48 hours is associated with a worse outcome. The jury is still out on cause and effect.
Thank you for pointing out the misleading nature of our statement which we have corrected as suggested. Please see page 6.

The references for mortality are a bit out of date. Given that this is a UK based study it would seem sensible to use the NHFD data - which report a mortality of around 7% at thirty days.
We have updated reference 4 as suggested.

Complications of morphine: these are true but not really a cause of delay to surgery.
We have clarified the sentence relating to complications of morphine in line with your observation. Please see page 6.

Opiates vs opioids - I would suggest the authors stick to opioids which covers all of the relevant drugs.
We have corrected our paper to consistent use of opioids. Please see page 6.

Page 7: '...Although FICB procedure may provide effective

analgesia in the prehospital setting [30] as well as reduce morphine,...' Should this be '...Although FICB may provide effective analgesia in the prehospital setting [30] as well as reducing morphine use,...'
Thank you for noting this. We have corrected the wording, as you indicate. Please see page 7.

Methods
I'm sure it was done, but I can't see mention of written, informed consent. Maybe I've missed it. Perhaps add the word written in the Ethical Approval section on p 17.
You are correct to highlight that we omitted to explicitly report that all consent was informed and recorded in writing. We have corrected this in the data collection section and also in the statement describing Ethical Approval and Consent to Participation at the end of the paper. Please see pages 8 and 18.

General wording: pain relief injection / injection in the groin / FICB are used at different times. Is this deliberate?
We have used these three terms throughout the paper so that readers who are not familiar with the procedure are reminded of its clinical name, that it is administered to provide pain relief and that administration is by is injection into the groin area. We felt this is helpful for the range of future readers.

Discussion:
'Elderly' Generally there is a move towards talking about older people.
Thank you for highlighting this. We have changed ‘elderly’ for ‘older’ throughout.

There is no mention of the number of participants as a limitation.
We agree the small sample size is a limitation which we should have acknowledged. We have now included this in the Strengths and Limitations sections on page 5 and 13.

The authors state that the participants were representative of the hip fracture population - but it would appear they all had capacity - whereas c.30% of hip fracture patients are confused on admission.
We have clarified that the participants were typical of a population who have capacity. Thank you for pointing this out. Please see page 13.

As always these are simply my opinions. The authors may disagree.

Iain Moppett
Nottingham, UK

Thank you for supportive remarks and constructive suggestions to improve our paper. We believe these changes strengthen the quality of our work.

Reviewer: 2
Reviewer Name: Steven Faux
Institution and Country:
St Vincent's Hospital Sydney
University of NSW Australia
Please state any competing interests or state 'None declared': nil
Please leave your comments for the authors below
Excellent article and needed in terms of acknowledging the feasibility to undertake research in the prehospital space.
We are grateful you agree that our work is relevant and useful to undertaking research and ultimately improving patient care in the prehospital environment. Thank you for your support.

Some areas that need to be addressed prior to publication, however include:
1. more detail in the demographic table to include time to arrival at the scene from the call (this may affect development of delirium and hence memory for the event), rural or metropolitan, number of ficbs previously done by the paramedic who attended, also the number of comorbidities that the patient had.
We accept that patient memory may be affected by their wait for emergency care. In the paper, patients reported that time to arrival on scene ranged between a half hour and six hours (page 10). We also state that the study took place in an urban area of south Wales (page 8). Some of the demographic data you mention can be found in our paper reporting overall study results (see Jones et al., 2019 https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-019-0454-1). However, we do not have these data at individual level so cannot provide them in this paper.

2. the word methologists may be coined, I suggest an alternative term and an explanation of what a "methodologists" is or does

Thank you for pointing this out. We have ensured use of the correct term 'methodologist' and added a short explanation on page 7.

3. Would like you to comment on the cases (number and/ or biases) of those who were given the ficb but did not have a fractured hip (? those with fractured pelvis or fractured pelvis or soft tissue injury). Also some information on those who refused the fib (age gender ?comorbidities)

In this qualitative paper, our aim is to report experiences of patients who received FICB for a diagnosed hip fracture. Our sampling criteria meant that we only interviewed patients who received the nerve block from an attending paramedic. We have reported all our study results in our paper Jones et al., 2019 (https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-019-0454-1) reference 19 on page 8 of our paper. We do recognise that the sample included in this interview study is small and selected and we acknowledged this in our strengths and limitations sections (please see pages 5 and 13).

3. The case of the man who had to be transported through the window is interesting and underlines the importance of the pain relief at the time. I would suggest that a case study of this extraction be offered as an appendix as it illustrates the importance of the paramedic being able to have the skill to undertake the FICB –

The man who recalled consenting to FICB reported that this avoided him being extracted by stretcher through a window. Having the nerve block relieved his pain sufficiently for the paramedics to sit him in a chair and wheel him through the door. Your comment has highlighted the misleading way in which we described the situation and we are very grateful to have the opportunity to correct the account. Please see page 10 for the amended version.

4. In the limitations comment need to be made of the poor memory of the event as this puts in question the decision by the ethics board of acknowledging that the patient consent for treatment may need to be additionally obtained by the person responsible (next of kin) if one is present. If not the question about the human right to analgesia may need to be alluded to (see WHO statement and IASP statement on the human right to access analgesia).

Both reviewers have highlighted the implications of our results for consent processes. Consent to treatment was taken as per normal practice and was out of the scope of the research ethics process. However, we recognise there is an opportunity to further discuss how limited recall illustrates the reduced capacity to consent to research at the time of emergency and we have included additional reflections on this on page 15.

5. In the limitations comment needs to be made regarding patient's capacity to remember pain and offer pain scores in retrospect. This has been shown not always to be accurate and needs to be mentioned in the limitations.
We have added this important point to the limitations section. Please see page 13.

Otherwise I would like to congratulate authors and advisors for undertaking a piece of research that is highly valuable and is likely to encourage better understanding of the prehospital experience of patients in a variety of conditions.

Thank you for your helpful comments on our draft paper which have enabled us to strengthen the reporting of our work.

VERSION 2 – REVIEW

REVIEWER	Iain Moppett University of Nottingham, UK
REVIEW RETURNED	15-Oct-2019

GENERAL COMMENTS	The authors have addressed my comments. Their new paragraph on consent is helpful and considered. One point about language though. Consent is given (or taken) we don't consent people. So when this is discussed it should be some variant of consent was sought, consent was given, consent was taken but never we consented people. Sorry to be a pedant but I think it is important to keep the language (and our behaviours) person-centred.