Author’s response to reviews

Title: Indigenous traumatic brain injury research: Responding to recruitment challenges in the hospital environment

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Author’s response to reviews:

The Editor-in-Chief
BMC Medical Research Methodology

Dear Editor,

Indigenous traumatic brain injury research: Responding to recruitment challenges in the hospital environment
Thank you for the opportunity to address the comments from reviewer 2 regarding the manuscript.

We would like to thank all the reviewers for their comments. We confirm that we have made the suggested amendments to the manuscript.

We trust these changes will be sufficient for you to consider final approval of the manuscript for publication.

Yours faithfully,

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Reviewer 2: I thank the authors for their responses and appreciate the effort that went into revision of this work. There remain points to be clarified and issues with conclusions to be resolved.

The major point of this work is to bring attention to challenges at multiple levels when recruiting Aboriginal and Torres Strait Islander patients with traumatic brain injury to participate in research in two hospitals in Australia. The authors argue for the need to simplify the research recruitment process, and with that maximize recruitment and reduce the amount of ethics amendments. In addition, authors suggest employing hospital staff as research project officers to minimize many of the described delays in recruitment and associated challenges. Finally, authors concluded that "Clinicians are the best measure for determining suitability for consent" as opposed to the Westmead posttraumatic amnesia scale

The main arguments for a simplified research recruitment process are as follows:

- Approximately 200 participants and their caregivers were planned to be recruited; of 62 eligible to participate, 24 participants (38%) were recruited. Note: distribution of patients with...
TBI and their caregivers out of those eligible were not provided. Likewise, timelines of recruitment were not provided, and main reasons for the failure to meet eligibility of 138 participants were not reported.

Information on sex distribution, severity of injury, age, as it concerned recruitment challenges were not presented. This information was not collected as per ethics approval protocol.

- "One in five patients (19.4%) identified as meeting eligibility criteria" were discharged against medical advice, and therefore were not approached by research staff to participate in the research project

- Patients under guardianship (9.6% of patients meeting the eligibility criteria) were most impacted by not being able to participate in research

- "Project and hospital staff identified that earlier contact with eligible patients was required to improve recruitment"

While I strongly agree that there is rationale for publishing works that concern recruitment challenges in patients with traumatic brain injury in general, and in Aboriginal and Torres Strait Islander patients in particular, the idea for simplification of the research recruitment process, as proposed by researchers, is not thoroughly thought out.

Author response: The authors of the manuscript thank the reviewer for thoughtful and constructive feedback. Please note we have added the following statement on page 8: “The recruitment period occurred between July 2016 and February 2018.”

1. The authors point to four major challenges they encountered, which they believe necessitate simplification of recruitment, and these points are problematic for numerous reasons:

- Challenges with recruitment of the Aboriginal persons that the researchers encountered could be related to the disproportional burden of morbidity, certain mechanisms of injury (assault and self-inflicted injury), inequitable access to health services, feeling isolated while in hospital, each of which may be related to first three arguments made by the researchers

Author response:

The reviewer makes an appropriate and important point regarding the challenges Indigenous patients may experience due to the mechanism of the injury and their poor experiences with clinicians in hospital.

In response to this comment, the following paragraph has been included on page 20 in the discussion of the manuscript:
Considering the hospital admission rates of TBI of Indigenous Australians [1, 2], the research team received a lower number of identified suitable patients during recruitment. The circumstances in which Indigenous Australians present to hospital for a TBI and the experiences they report while in hospital may have contributed to challenges in identifying them for the project. Compared to non-Indigenous Australians, Indigenous Australians are more likely to present to hospital with a traumatic brain injury following an assault [2]. Falls are the main cause of TBI among non-Indigenous Australians [2]. Following an assault, Indigenous patients may have a range of needs that require addressing following their hospital admission including access to housing, child-related responsibilities and assisting with police investigations surrounding the assault [29]. While in hospital, Indigenous patients report feelings of loneliness, difficulties engaging with treating clinician and feeling excluded from discussion relating to their health care and treatment [29]. The needs and experiences of Indigenous TBI patients while in hospital may mean some patients do not come to the attention of clinicians for the project. Patient access to treatment is paramount and research recruiting through hospitals should ensure they do not impinge upon patients’ rights to health care.

The first three recommendations are informed by our experiences recruiting Indigenous patients for this project and the challenges Indigenous patients may be experience due to the mechanism of their injury, the injury itself, and the hospital environment. We have attempted to provide greater clarification and detail for how each recommendation would apply to future projects.

Recommendation 1 relates to how the 24 hour admission criteria limited the project’s ability to recruit from certain wards in the hospital. It has been moved to recommendation 2.

Ensure proposed recruitment processes and eligibility criteria are appropriately described. Unnecessary criteria or description of recruitment processes in a study protocol may result in recruitment processes being unable to be implemented in some wards. For example, the >24 hour admission criteria reduced the hospital wards the project could implement recruitment processes. To make modifications to recruitment processes and patient eligibility criteria, the research team consulted the ethics committee and submitted ethics amendments in line with national research guidelines [36].

Recommendation 2 has been expanded in detail and now appears as recommendation 3.

Engagement with patients, consent and data collection processes should be flexible. It is likely that in this environment, the completion of consent and data collection may require a researcher to meet with a patient on multiple occasions over multiple days. Consent and data collection processes need to include additional time to account for patient treatment, meeting with clinicians and hospital staff, other non-health needs (e.g accommodation needs), other meetings (e.g. contact with police), discharge planning, arrangement of interpreters, patient health (e.g...
fatigue, loneliness) and patient travel arrangements. In some circumstances, data collection may not be possible in the hospital.

Recommendation 3 has been expanded to and now appears as recommendation 1.

Ability to employ a hospital staff member as a centralized recruiter at each hospital site. As used in rehabilitation environments elsewhere [35], a centralized recruiter would act as a liaison between the research team and potential research participants. Based at on hospital grounds, a centralized recruiter could minimise many of the described delays in the identification, consent and data collection process. A centralised recruiter may be able to more readily access health system data and work across wards. Supporting research projects operating in the hospital would be the recruiter’s primary task and would therefore not be directly part of a patient’s treating team. remove any potential complexities surrounding clinicians and allied health staff being required to report information to authorities they may receive in a researcher role.

2. Ethics in clinical research, especially in disorders that are associated with cognitive challenges, as in traumatic brain injury, is a complex discussion which cannot be simplified just because of challenges during the recruitment process; it should be remembered that the main purpose patients with traumatic brain injury were in these two hospitals where recruitment took place, was to receive medical treatment. The reviewer suggests thinking of ethics in research, and Aboriginal bioethics, and reviewing their conclusions. Three guiding ethics principles for research are respect for persons (concerns the choices of autonomous/capable individuals be respected), beneficence (balance of potential benefits and harms), and justice (equitable distribution of the burden and benefits of research). These should be the focus of the paper, should the researchers feel simplification of the research process in supported by their findings.

Author response: The authors strongly agree with the reviewer’s comment regarding the three guiding ethical principles for research with patients. With this in mind, we have reviewed the first three recommendations and the discussion as a whole. As described above, we have rephrased the recommendations and provided additional details.

We have also revised the conclusion section of the abstract:

Based on our recruitment experiences, several recommendations are proposed for future TBI studies with Indigenous Australians. Indigenous TBI patients have a wide range of needs and priorities which must be addressed. Recruitment and data collection processes should ensure they do not impact upon the care and treatment Indigenous patients receive. Employment of a centralized recruiter at each hospital site may help to minimise the challenges researchers need to navigate in the hospital environment. To improve recruitment processes in hospitals, it is
essential for researchers examining other health or injury outcomes to describe their recruitment experiences.

3. Finally, issue with confidentiality is important to consider when proposing employment of hospital staff as research officers. This is very relevant in light of legal charges (police involvement) in certain situations. Clinicians' duty to disclose information under the law of fiduciary duty might be compromised if he/she acts as a researcher. Consequently, employment of hospital staff as research officers can be complex. In contract, position of Centralized Recruiter at each hospital site, as in the Toronto Rehabilitation Institute, might be a reasonable solution, to act as a liaison between researchers and potential research participants, in the recruitment process.

Author response: The reviewer highlights an important point about the complexities of employing hospital staff as research assistants. In line with the reviewer's comment, the following has been included in the manuscript:

Ability to employ a hospital staff member as a centralized recruiter at each hospital site. As used in rehabilitation environments elsewhere [35], a centralized recruiter would act as a liaison between the research team and potential research participants. Based at on hospital grounds, a centralized recruiter could minimise many of the described delays in the identification, consent and data collection process. A centralised recruiter may be able to more readily access health system data and work across wards. Supporting research projects operating in the hospital would be the recruiter's primary task and would therefore not be directly part of a patient's treating team. remove any potential complexities surrounding clinicians and allied health staff being required to report information to authorities they may receive in a researcher role.

4. In summary, conclusions of this research paper and discussion section should be revisited in light of the concerns described above. Taking into consideration the structure of research ethics, it is expected that the discussion is in line with the Belmont report, and if modifications are proposed, that an ethics board is consulted.

Author response: The recommendation regarding how recruitment processes are described relates to our inclusion of the 24-hour admission criteria. This was not was a recommendation of the ethics committee previously and limited the project’s ability to recruit from certain wards in the hospital. To remove it to extend our recruitment processes to other wards including short stay units required an ethics amendment. We have attempted to provide greater clarification of what this recommendation relates to:
Proposed recruitment processes should include specific detail on criteria for participation. Unnecessary criteria or description of recruitment processes in a study protocol may result in recruitment processes being unable to be implemented in some wards. For example, the >24 hour admission criteria reduced the wards the project could implement recruitment processes. To make modifications to recruitment processes and patient eligibility criteria, the research team consulted the ethics committee and submitted ethics amendments in line with research guidelines.