Reviewer’s report

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

Version: 1 Date: 04 Jan 2019

Reviewer: Tatyana Mollayeva

Reviewer's report:

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.

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.

- 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.

- 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 cite, 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.

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.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

No

**Are the conclusions drawn adequately supported by the data shown?**
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