

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Cohort profile: The Aboriginal Families Study: a prospective cohort of Aboriginal children and their mothers and caregivers in South Australia
AUTHORS	Glover, Karen; Leane, Cathy; Nikolof, Arwen; Gartland, Deirdre; Cahir, Petrea; Mensah, Fiona; Giallo, Rebecca; Reilly, Sheena; Middleton, Philippa; Makrides, Maria; Francis, Theresa; Collins-Clinch, Amanda; Clark, Yvonne; Brown, Stephanie; Gee, Graham

VERSION 1 - REVIEW

REVIEWER NAME	Ryder, Courtney
REVIEWER AFFILIATION	Flinders University, Injury Studies
REVIEWER CONFLICT OF INTEREST	No competing interests
DATE REVIEW RETURNED	08-Dec-2023

GENERAL COMMENTS	I have been provided with the opportunity and pleasure to review your Cohort profile manuscript addressing Aboriginal children and their mothers. I thoroughly enjoyed reviewing this piece of work and feel strongly that this is a significantly important project, especially given the exception community leadership and engagement. It was wonderful and refreshing to review a piece with Aboriginal leadership and authorship, which is so important in terms of knowledge ownership. I do however have some concerns with the overall structure and flow of the piece and feel strongly that this needs extensive review before it can be considered for publication. To provide some context to authors on my standpoint as part of this review, I have approached this as an Aboriginal researcher in Australia working closely with community in epidemiology and community co-design projects. I have broken this feedback into headings for ease of review and I hope this feedback will assist you in your future work. Manuscript Structure I have no doubt that you reviewed the structure and main headings of Cohort Profiles submitted to the BMJ for publication. However, I feel strongly that the format and flow in its current form, does not provide an overall appreciation of the depth and breadth of this study. In areas there is confusion, duplication and missing information in areas. This needs extensive review, in terms of the overall flow and subheadings of the manuscript. For instance, the Cohort Profile from: Jamieson LM, Hedges J, Ju X, et al. Cohort profile: South Australian Aboriginal Birth Cohort (SAABC)—a prospective longitudinal birth cohortBMJ Open 2021;11:e043559. doi: 10.1136/bmjopen-2020-043559 (https://bmjopen.bmj.com/content/11/2/e043559) provides a very clear road map of the study and where things are at for them. I would suggest starting with these overall headings but then placing in important headings which are appropriate for your study i.e. Aboriginal Governance and Capacity Building, Data Management and Analysis, etc.
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	Strengths and Limitations These could be strengthened further to highlight the importance and early outcomes of this program of work. Introduction The introduction really appears to be missing the essence and significance of this project. I kept on wondering, but why? Why this project? Why right now? While you have mentioned robust evidence is missing this needs to be built upon and appraised further i.e. the deficit narrative and discourse which surrounds information in this area, the lack of connection to Indigenous knowledges etc. Connection and contract to the Footprints in Time study would add some strength here as well, setting aside how this is different. The second paragraph in the introduction is methods and should not be there. Next should be Methods There was no methods heading for the cohort study. Also missing was the methodology which informs the overall program of research. I assume this focusses on Indigenous research methodologies i.e. Indigenist, Decolonisation, etc? This was not clear and could add strength to the paper. In the methods you could have subheadings of Project Governance, Community & Public Involvement, Study Design and also statistical analysis. I note that no statistical analysis approach was provided, even is this is general descriptive statistics this information is important. This information can easily be drawn from your statistical analysis plan, which should cover how you are cleaning and maintaining data. You can also include a Table with all of the Ethics Committee approvals here. It felt rather odd reading that all at the end. Cohort Description This would be better rendered in the example provided by Jamieson. You can then include that there are 2 waves to the study and the overall wave design, data collection processes, etc. You can also have an area on measures where you unpack each of the measures used in the waves which have been psychometrically assessed with community, which have not and processes you used in these cases. Include your Pilot Study approach in here as well, which appear to have been used to trial study measures. Table 2 would be better as supplementary material as it just provides details on the measures used. Data Collection This should be Results to Date. You can then break it into each of the headings required. All results which you have included in the other sections i.e. introduction, cohort description, pilot study outcomes, etc should go here. Study Governance There is a bunch of information which does not need to be here. Generally you do not need to discuss applying for the grant application or the MIAs which were established for the project. Try to keep this focussed to Indigenous Governance of Data – the project, etc. Also the CI steam who they were their roles, etc. This should go in the methods section. Findings to Date
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	This needs to be combined with the data collection section. If Aims 6, & and 8 do not have data yet, best to say data collection or analysis is ongoing, translation activities will occur. Strengths and Bias Further thought and consideration needs to be given here. For example in one section when there are tools which do not have validation with community it is mentioned 'and/or measures that were less likely to introduce cultural bias' the question is how? How did this occur? What process? It needs this support else it appears as a generalisation.
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REVIEWER NAME	Zhao, Yuejen
REVIEWER AFFILIATION	Health Gains Planning, Department of Health
REVIEWER CONFLICT OF INTEREST	None 11-Dec-2023
DATE REVIEW RETURNED	This is a report on study protocols with preliminary results for an important research project on Indigenous population health funded by NHMRC in Australia. This study will provide valuable longitudinal data of Indigenous child health and development. This data will be potentially useful to inform policy and practice to address Indigenous health gap in Australia. The study is specifically designed for Indigenous population. The sample size is modest. The research is progressing well. However, it still needs significant revisions before publication. Please revise to address the following points: • The paper is long. Can the authors shorten it without losing all the crucial information. It is difficult to summarise by readers themselves for a good understanding of the project. • Specific study elements unique for Australia need more explanations for international readership. • There is a lack of non-Indigenous controls in this study. How do you compare your results with non-Indigenous population. If this study is designed specifically for Indigenous population, how do you maintain comparability with non-Indigenous results. • There is a lack of justification that the study sample size is sufficient, and the sample is representative for South Australia or Australia as a whole.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1	Response
I thoroughly enjoyed reviewing this piece of work and feel strongly that this is a significantly important project, especially given the exception community leadership and engagement. It was wonderful and refreshing to review a piece with Aboriginal leadership and authorship, which is so important in terms of knowledge ownership.	Thank you for this acknowledgement

I do however have some concerns with the overall structure and flow of the piece and feel strongly that this needs extensive review before it can be considered for publication. To provide some context to authors on my standpoint as part of this review, I have approached this as an Aboriginal researcher in Australia working closely with community in epidemiology and community co-design projects.	Thanks for this context. We had approached telling the story of the study more historically. We appreciate your feedback and have revised the manuscript accordingly.
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<u>Manuscript Structure</u> I have no doubt that you reviewed the structure and main headings of Cohort Profiles submitted to the BMJ for publication. However, I feel strongly that the format and flow in its current form, does not provide an overall appreciation of the depth and breadth of this study. In areas there is confusion, duplication and missing information in areas. This needs extensive review, in terms of the overall flow and subheadings of the manuscript. For instance, the Cohort Profile from: Jamieson LM, Hedges J, Ju X, et al. Cohort profile: South Australian Aboriginal Birth Cohort (SAABC)—a prospective longitudinal birth cohortBMJ Open 2021;11:e043559. doi: 10.1136/bmjopen-2020-043559 (https://bmjopen.bmj.com/content/11/2/e043559) provides a very clear road map of the study and where things are at for them. I would suggest starting with these overall headings but then placing in important headings which are appropriate for your study i.e. Aboriginal Governance and Capacity Building, Data Management and Analysis, etc.	We have revised the structure as recommended. The Methods section now includes the following sub-headings: • Study design and approach • Study aims • Sample size • Aboriginal governance • Capacity building and knowledge exchange • Patient and public involvement This is followed by a section describing the Cohort, with sub-headings: • Who is in the cohort? • What has been measured? • Collaboration. This is followed by sections on Findings to date, and Future plans.
<u>Strengths and Limitations</u> These could be strengthened further to highlight the importance and early outcomes of this program of work.	The Author Guidelines specify no more than five dot points in this summary section. We have included the major methodological strengths and limitations.

Introduction ██████████ The introduction really appears to be missing the essence and significance of this project. I kept on wondering, but why? Why this project? Why right now? While you have mentioned robust evidence is missing this needs to be built upon and appraised further i.e. the deficit narrative and discourse which surrounds information in this area, the lack of connection to Indigenous knowledges etc. Connection and contract to the Footprints in Time study would add some strength here as well, setting aside how this is different. The second paragraph in the introduction is methods and should not be there.	We have added some additional commentary about the legacy of deficit-based approaches and the significance of the study in this section of the paper. We are conscious that the second reviewer recommended shortening the paper and have taken this into account in the length of our response to these queries. We have moved this paragraph to the methods section of the paper.
Next should be Methods ████████████████████ There was no methods heading for the cohort study.	We have revised the structure as recommended.
Also missing was the methodology which informs the overall program of research. I assume this focusses on Indigenous research methodologies i.e. Indigenist, Decolonisation, etc? This was not clear and could add strength to the paper. In the methods you could have subheadings of Project Governance, Community & Public Involvement, Study Design and also statistical analysis.	We have also added additional detail regarding the alignment of study methods and approaches with NHMRC guidance and the SA Aboriginal Health Research Accord as follows: The research design and approach to community engagement, choice of study methods, selection of study measures, analysis methods, and processes for interpreting and reporting findings were informed by and consistent with values and ethics for Aboriginal and Torres Strait Islander health research outlined by the Australian National Health and Medical Research Council and

the South Australian Aboriginal Health Research Accord.(ADD REFS) This included a commitment to community consultation to inform the study protocol; detailed pre-testing of study procedures and study designed measures (undertaken prior to each wave of the study); and an overarching commitment to ensuring that the study would benefit Aboriginal communities in South Australia.

I note that no statistical analysis approach was provided, even is this is general descriptive statistics this information is important. This information can easily be drawn from your statistical analysis plan, which should cover how you are cleaning and maintaining data.

Given the wide-ranging aims of the paper and different types of data collected, it is not possible to provide a meaningful account of statistical analysis plans. This information is provided in papers reporting on findings.

You can also include a Table with all of the Ethics Committee approvals here. It felt rather odd reading that all at the end.

HREC approvals are reported in the text of the paper as per the journal’s standard practice.

Cohort Description

This would be better rendered in the example provided by Jamieson. You can then include that there are 2 waves to the study and the overall wave design, data collection processes, etc. You can also have an area on measures where you unpack each of the measures used in the waves which have been psychometrically assessed with community, which have not and processes you used in these cases. Include your Pilot Study

The paper has been restructured as suggested.

We have included further information about our approach to pilot testing in the section on Study Design and Approach as follows...

Pilot testing was undertaken using a variety of methods, including yarning circles and one-to-one interviews. Interviews and yarning circles – held in urban, regional and remote communities - were

approach in here as well, which appear to have been used to trial study measures.

used to seek verbal feedback about ways of asking about potentially sensitive issues in culturally acceptable and safe ways. Iterative testing of study procedures and potential study measures and approaches was undertaken, with each stage of testing integrating feedback from the previous

Table 2 would be better as supplementary material as it just provides details on the measures used.	stage. In wave 1, this phase of work took over 12 months and included development of a study designed measure of stressful events and social health issues. In wave 2, the pilot phase focused on development of a culturally adapted measure of Aboriginal women's experiences of partner violence (AEPVS), and development of study designed measures of Aboriginal ways of parenting, again taking over 12 months. Our preference would be for Table 2 to be included in the paper. However, we are happy for it to be included in supplementary material if this would fit better with journal requirements.
Data Collection ██████████ This should be Results to Date. You can then break it into each of the headings required. All results which you have included in the other sections i.e. introduction, cohort description, pilot study outcomes, etc should go here.	This section is now titled "What has been measured?" This aligns with the approach taken by Jamieson et al. Our preference is to retain the current separation of information on study measures (What has been measured?) and findings to date. All results are now reported in the section entitled "Findings to date".
Study Governance ██████████ There is a bunch of information which does not need to be here. Generally you do not need to discuss applying for the grant application or the MIAs which were established for the project. Try to keep this focussed to Indigenous Governance of Data – the project, etc.	The following text has been removed from the paper. _____ The study protocol for wave 1 was approved by the Board of the AHCSA in 2009, providing the basis for submission of the successful application to the Australian National Health and Medical

	Research Council for funding in 2011. Subsequently, two multi-institution agreements covering the first and second waves of data collection and analysis have been developed and signed by Aboriginal and non-Aboriginal study investigators, including a nominee of the AHCSA. The original project agreement and subsequent multi-institution agreements make provision for shared intellectual property in outputs arising from the study.
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Also the CI steam who they were their roles, etc. This should go in the methods section.	We have added a sentence describing the background skills and roles of CIs and AGG members as follows... Aboriginal investigators (KG, CL, YC, GG) and Aboriginal Governance Group members (CL, KG, AN, YC, TF, AC-C) bring community and policy knowledge, clinical experience in psychology, and research experience using Indigenous methodologies. Non-Aboriginal investigators (SB, DG, FM, RG, SR, PM, MM) and study staff (PC) bring experience in Aboriginal health research, epidemiological methods, biostatistics, psychology, child development, speech pathology and nutrition.
<u>Findings to Date</u> This needs to be combined with the data collection section. If Aims 6, & and 8 do not have data yet, best to say data collection or analysis is ongoing, translation activities will occur.	See comment in the section on 'Data collection' on page 4 (above)
<u>Strengths and Bias</u> Further thought and consideration needs to be given here. For example in one section when there are tools which do not have validation with community it is mentioned 'and/or measures that were less likely to introduce cultural bias' the question is how? How did this occur? What process? It needs this support else it appears as a generalisation.	We appreciate the reviewer's concern about this issue. We have included an additional example as an indication of our approach. However, detailed consideration of these issues is beyond the scope of this paper. Further information about our decision-making with regard to these study measures will be included in papers reporting findings drawing on these study measures.
Reviewer 2	Response
This is a report on study protocols with preliminary results for an important research	Thank you for acknowledging the significance of the study.

project on Indigenous population health funded by NHMRC in Australia. This study will provide valuable longitudinal data of Indigenous child health and development. This data will be potentially useful to inform policy and practice to address Indigenous health gap in Australia. The study is specifically designed for Indigenous population. The sample size is modest. The research is progressing well. However, it still needs significant revisions before publication. Please revise to address the following points:	We have addressed the reviewer's feedback below.
• The paper is long. Can the authors shorten it without losing all the crucial information. It is difficult to summarise by readers themselves for a good understanding of the project.	We have restructured the manuscript to avoid duplication and omitted some text for reasons of brevity.

• Specific study elements unique for Australia need more explanations for international readership.	We have provided as much additional information about study procedures and the context for these as is feasible without substantially adding to the word length.
• There is a lack of non-Indigenous controls in this study. How do you compare your results with non-Indigenous population. If this study is designed specifically for Indigenous population, how do you maintain comparability with non-Indigenous results.	The study was not designed for the purpose of comparison with non-Indigenous children and families. As noted in the paper, our primary focus was on 'within cohort' comparisons.
• There is a lack of justification that the study sample size is sufficient, and the sample is representative for South Australia or Australia as a whole.	We have added a brief section outlining the justification for the sample size, including reference to an earlier paper providing additional details. The sample is representative in terms of maternal age, infant birthweight and gestation. Women living in remote communities and women having their first baby were slightly over-represented (This information is reported in the paper on pages 12-13).