

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Maternal and perinatal outcomes by planned place of birth in Australia 2000 – 2012: A linked population data study
AUTHORS	Homer, Caroline SE; Cheah, Seong L; Rossiter, Chris; Dahlen, Hannah G; Ellwood, David; Foureur, Maralyn Jean; Forster, Della Anne; McLachlan, HL; Oats, Jeremy JN; Sibbritt, David; Thornton, Charlene; Scarf, Vanessa

VERSION 1 – REVIEW

REVIEWER	Marit L. Bovbjerg Assistant Professor, Epidemiology Oregon State University USA
REVIEW RETURNED	24-Apr-2019

GENERAL COMMENTS	<p>This is a retrospective, population-based cohort study using linked registry data from Australia to study outcomes following planned community births vs. planned hospital births. The manuscript is well written, and the authors demonstrate an excellent understanding of the nuances of studying birth location. They correctly use an intention-to-treat analysis, acknowledging that their assessment of exposure (planned birth location) is not ideal, as for some women this occurred earlier in pregnancy than at the onset of labor. Below I provide specific suggestions (including, potentially, new analyses) that I believe would strengthen the manuscript.</p> <p>Introduction:</p> <ul style="list-style-type: none"> • Given the meta analysis of birth place, written by some of these same authors, why do we need this study (and why should it be published in an international journal)? Explain what about Australia is so different that those other results wouldn't apply. • As the aim is to study 'uncomplicated pregnancies', some discussion of pregnancy risk factors and the extent to which they do or do not (or we don't know) affect outcomes for community births is warranted. Need to justify the study population; I should know what 'uncomplicated' means in this context by the time I get to the Aim. (ETA: after reading the methods, it sounds like Australia has set a definition for 'low risk'? Is that the same as uncomplicated? And regardless, make it clear in the intro that these are rules set by Australia; otherwise readers could quibble about some of them) <p>Methods</p> <ul style="list-style-type: none"> • If excluding precipitous labors for hospitals and birth centers, should also exclude precipitous labors at home—perhaps those who delivered before the midwife arrived?
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- Other thoughts about exclusions:
 - o only breech? what about transverse? (could say “non-vertex” instead?)
 - o what about planned cesareans that aren’t scheduled? so they’re not pre-labor per se, but nonetheless the woman and the OB both know she’s having a cesarean when she shows up in labor
 - o what is the definition of prolonged ROM? ap hemorrhage? (do they have definitions for your study other than the ICD-10 code was indicated in the record? how are coders trained in Australia? what are usual diagnostic criteria?)
 - o what are “other relevant pregnancy complications”?
 - o The list of ICD-10 codes does not list all of the items from the list (breech, elective repeat cesarean), and then lists extra ones not discussed first (multiples). Please clarify how these exclusions were applied.
 - o line 338 suggests that both pre and postterm pregnancies are excluded; this does not appear in box 1?
 - for community births, does any admission for mom or baby count as a ‘readmission’? there are pros and cons to this approach (conservative criteria for transfer makes them not quite comparable to a readmission after initial hospital discharge...but on the other hand, you’ll be missing some potentially important outcomes if successful community births followed by a hospital transfer for mom or baby genuinely require then a re-admission to “count”)
 - suggest combining the 3 fetal/neonatal death variables to increase power. yes, etiologies (and thus prevention strategies) likely differ; however the goal for this manuscript is to assess safety of planned community birth, and thus the important outcome is whether the baby is alive or not, regardless of when the death occurred. Parents (and midwives!) don’t care, particularly, when; it’s arguably more informative for shared decision making if they are presented with an overall risk of death, rather than 3 separate ones.
 - Is parity dichotomized into primip/multip? If not, suggest doing so to increase precision in your models
 - Why use $\alpha < 0.01$? This is not standard, so must be justified
 - I have absolutely no idea what this sentence means: “For simplicity, percentages were computed for incidence of events at each birth setting instead of examining the corresponding sphericities and specificities of the data.” Please explain sphericities/specificities. Specificity is an epidemiology term, but I think you are using it differently here. I have never seen the word “sphericity” before.
 - Imputation could be used to address the demographic variables that are inconsistently recorded across states. I strongly urge you to do this, as the variables that you list as “unavailable bc missing” are important for the study question.
 - Other variables, ok not to impute, since there isn’t much missing data (<1%! I would love a dataset like that). But, suggest saying so in the methods section, because my first thought was “well if they have missing data, why not use multiple imputation?”
 - Please provide some discussion of why those confounders were chosen, and whether you assessed the extent of confounding when building the multivariable models, or whether all were decided a priori

Results

- pregnancies between 2000 and 2012: does that mean that the BIRTH happened Jan 2000 – Dec 2012, and therefore you have data from 1999 (for some of those pregnancies) and 2013 (for the postpartum follow-up)? Please clarify.
 - Table 2 and 3 are in the wrong order, and I think table 3 was cut off? Would be nice to see all of table 3! Though I assume the home birth c/s rate was similar to birth center.
 - when you say “adjusted for parity” is that primip vs. multip? or as an ordinal variable?
 - Suggest reporting the incidence of normal labor & birth—nearly 80% in the hospital!! That’s definitely not the global norm; in the US we have 80% of women having epidurals. Sad but true.
 - Also suggest reporting the incidence of cesarean in all three locations in the main text as well; in fact, for both the table 2 and 3 discussions, reporting the incidences, rather than the aORs, would be more informative. Half as likely...ok, but does that mean 30% vs. 15%? Or 10% vs. 5%? The latter are more useful, I think, and then readers can refer to the tables for the rest of the numbers. Again, 8% cesareans in the hospital, even for low-risk women...this is not what we see in other countries.
 - Suggest expanding on the interventions that would only be available in hospitals (so, after an ip transfer from community setting)—of course they’re less common in planned community births, but a more interesting question would be are they less common if you limit the community birth sample to those who ended up in the hospital while they were still in labor, and therefore were actually at risk of these interventions? (I think this doesn’t apply to cesarean, as that’s sometimes a necessary thing (especially if it’s happening at such a low rate), whereas epidurals are more squishy. ALSO, suggest dropping women who had a cesarean from the analysis of epidurals (assuming that is the anesthesia of choice for cesareans in Australia), because some women probably got the epidural just because they were headed for a cesarean. I think what’s more interesting is the rest of the epidurals. (ETA: I see from the limitations section that you can’t identify ip transfers. suggest, then, dropping this section entirely)
 - women who had cesareans should be dropped from the hemorrhage analysis
 - Same comments re: reporting for the postpartum complications section. Incidences are more interesting than aORs
 - strongly urge you to drop the bit about stratifying deaths by parity. there aren’t enough deaths even for the main analysis, no sense having even smaller cells. I realize that the Birthplace in England study had that finding about parity...but you don’t have enough events (which...is not a bad thing?), and it would be easy for someone to take your numbers out of context, without all the caveats.
- Discussion
- line 426—please say “were slightly older”—two years is statistically significant when you have over a million people, but probably doesn’t matter too much clinically, given that mean age for all groups was 30-ish
 - lines 429-441—see above re: parity.
 - re: NICU. In the US, depending on the hospital, we sometimes see ALL community birth transfers going to the NICU, and anecdotally this is sometimes punitive if that hospital or the on-call OB doesn’t “believe” in community birth. Australia is very different than the US on lots of things, but might this be part of why we see increased NICU for birth centers? Then not for home bc

	<p>low events □ no power? Maybe not, since you limited to NICU stays of at least 48 hours. But something to think about.</p> <ul style="list-style-type: none"> • lines 460-464: suggest substantially expanding this section. (Or putting this info in the introduction? It seems more like justification than discussion, but depends on how you structure the rest). As currently written, this feels like a throw-away comment, when really it's the meat of the whole thing. • what proportion of women move during the 21 months they would be followed for this study? this has implications for completeness of data, if you can't link across states. please address in limitations. • line 494—not adjusting for confounders increases confounding, not selection bias • Your limitations section absolutely needs a section on power, as you had very little for the death outcome. Suggest even a post-hoc power analysis. <p>Minor points:</p> <ul style="list-style-type: none"> • Do available care options in Australia vary by hospital, or by state? • line 177-178: please clarify the roles for these practitioners. are both present for the birth? is the OB ever there for the labor? • suggest using the phrase “community birth”, rather than “home and birth center” or “out-of-hospital”. • line 286—“doctors”—all obstetricians? or do family practice docs (GPs) attend births in Australia? • line 309—perinatal outcomes should be a new paragraph • paragraph starting on line 330—define the states in the text. it is not sufficient just to define them in the footnote to the table. • what's the difference between a box and a table? • Line 354: tables should be numbered in the order that they appear in the text; these should therefore be tables 1 and 2 • Since you are presenting data on outcomes of birth, suggest using “primiparous” rather than “nulliparous”, as they've had that baby now. But, I know some journals care one way or the other, so go with the author guidelines. • I think the unadjusted OR columns are unnecessary • line 380—this is not “conversely”—you just said community birth settings were associated with more normal labor and birth. Therefore of course they are associated with FEWER interventions.
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REVIEWER	Dr Rachel Rowe National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford United Kingdom
REVIEW RETURNED	09-May-2019

GENERAL COMMENTS	This paper reports an important study aiming to compare maternal and perinatal outcomes for 'low-risk' women planning birth in different settings in Australia over the period 2000-2012. I am pleased to have the opportunity to review it. This has clearly been a complex and challenging study to carry out, involving the use of linked routine data from all eight Australian states and territories, and the authors have appropriately referred to some of the consequent limitations. There are, however, some changes I would like to see before the paper is considered suitable for publication.
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These include: more detail in relation to aim and objectives; more clarity and information in relation to several aspects of the methods; the correction of a small number of errors; and attention to ensure that all potential limitations are considered and appropriately qualified conclusions are drawn, particularly in relation to perinatal outcomes.

My detailed comments are as follows:

1. Title:

i. I wonder if the title could be improved to make it more informative by adding the words “Maternal and perinatal” at the beginning.

2. Abstract:

i. Normal labour and birth should be included under outcomes, particularly given that it is the main result reported in the abstract.

ii. Given the findings relating to perinatal mortality in babies of nulliparous women planning birth at home, and the very small numbers of women planning birth at home, the conclusions should refer more explicitly to uncertainty about safety for babies in this group.

3. Background:

i. The first couple of paragraphs give a helpful introduction to the organisation of maternity care in Australia. It would be helpful to know what proportion of births take place in the public vs private sector. I think, for a general medical journal, it would also be helpful to have a brief description of what a “midwife-run birth centre” is. I would also like to see a brief explanation of the extent to which birth centre and home birth services are integrated with hospital-based services, e.g. in relation to transfer, as this has the potential to impact on outcomes.

ii. I’m not quite sure what the final sentence of paragraph one refers to – what are these differences? If this sentence is to remain I think more explanation is required.

iii. The background section is quite long. The summary of evidence on planned place of birth and outcomes, in Australia and elsewhere, is a bit jumbled and could probably be shortened. I wonder if it would be clearer to restructure this and present evidence on maternal outcomes, which is fairly consistent, separately from that on perinatal outcomes, where there is more variation and uncertainty/evidence of adverse outcome, particularly for women planning a first birth at home.

iv. The statement that “place of birth... [is] controversial in Australia” needs supporting evidence / a citation.

v. The aim of this study is clearly outlined at the end of the background. I would also like to see more specific objectives or research questions here, relating to the particular outcomes examined in this study.

4. Methods:

i. Under “Study design” the authors say that “homebirth and birth centre options are mostly restricted to women who meet low-risk criteria”. Later on the same page they refer to eliminating women with “complicating conditions” from the dataset and on the next page there is a definition of “low-risk pregnancy” with more information in Box 1. Box 1 contains a list of medical conditions and pregnancy complications, plus “any other relevant pregnancy complications”. It would be helpful to have more clarity and consistency of terminology in relation to the creation of their ‘low-risk’ sample. How was the list of medical conditions/complications

	<p>arrived at? Box 1 refers to the exclusion of unplanned births at home (i.e. BBAs) – how were these identified?</p> <p>ii. The data sources used for this study are in the main well described. I was not clear what the “immediate postpartum period” (line 256 page 9) meant.</p> <p>iii. While some of the relevant information is contained in the “Definitions” section, it would be clearer if all the outcomes examined in this study were clearly listed and described in a separate section. The combined perinatal mortality data, for example, is not listed on page 11 and it’s generally not clear if this is a complete list of outcomes considered or an indicative selection. From the way the results section is written it appears as if normal labour and birth is the main outcome, but this isn’t described elsewhere so it’s not clear.</p> <p>iv. The normal labour and birth definition as described in this section and elsewhere does not exclude caesarean section, which I assume is an error.</p> <p>v. The sentence “We also stratified combined perinatal mortality data by parity” on line 312, page 11 relates to analysis, not definitions/outcomes. This section also refers to “other specific definitions” in tables. All relevant definitions/categorisation/outcomes should be described in the methods section, not just in footnotes to tables, e.g. the sentence in the footnote to Table 3 which explains that variables on mode of birth and intervention are all as defined by each state or territory should be in the methods section.</p> <p>vi. A flow chart would be helpful, if possible, to illustrate the data obtained from different sources, and the derivation of the analysis sample, indicating numbers of women excluded with risk factors etc.</p> <p>vii. The section on data analysis would benefit from more structure, clarity and detail and should simply describe all analyses that were carried out.</p> <p>i. The sentence on lines 349-50 about “sphericities and specificities of the data” will be impenetrable to most people. I assume this is a reference to the fact that there are likely to be ‘repeated measures’ of some sort in the dataset, i.e. women who appeared more than once, but that analyses did not take account of this. This needs to be explained more clearly, with rationale (not just “for simplicity”), and any limitations of this approach considered in the discussion.</p> <p>ii. The analyses using chi-squared test and ANOVA appear to relate to comparison of demographic characteristics across planned birth settings (and presumably chi squared test may have been used for initial exploration of outcomes), but the sentences describing these initial analyses are separated by several other sentences. Were the continuous variables categorised in the multivariable modelling (using the same categories as presented in Table 1) or included as linear variables?</p> <p>iii. It is sufficient in the methods section to explain that associations between planned place of birth and outcomes were adjusted for those clinical/demographic factors which were available across all linked datasets (listing those factors that were included in the multivariable logistic regression). Would it have been possible to carry out any sensitivity analyses, using data from one or more states which have more data on demographic factors, to explore the effect of this further adjustment?</p> <p>iv. What was the rationale for stratifying by parity only for the normal labour and birth outcome and the combined perinatal</p>
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	<p>mortality outcome? Was this pre-specified? Were any formal tests of interaction carried out?</p> <p>v. The approach to missing data seems broadly appropriate, although there is a curiously worded footnote to Table 3 which I don't understand - "No imputation was implemented to avoid data contamination. However, noises from data was unavoidably retained". Again, new information should not appear only in table footnotes. I am also puzzled by the statement that "wherever necessary" missing data was reported. It would be helpful to know how much missing data there was in relation to outcomes and whether those women who were excluded from analyses for this reason are likely to have been different in any way. In Table 3 the outcome "Mode of birth not stated" is also included, but this is not referred to anywhere. Is there a difference between 'missing' and 'not stated' in Table 1?</p> <p>vi. The final sentence of the data analysis section explains that cells with less than five women will not be reported in the paper, but in Table 5 there are three cells where there are less than five women, e.g. four nulliparous women who planned birth at home and had a stillbirth or early neonatal death. If this sentence is correct, which I assume it is since this is standard practice, I would not expect to see absolute numbers of deaths or incidence (since absolute numbers can be calculated from incidence) reported in Table 5 for these outcomes.</p> <p>5. Results:</p> <p>i. The sentence at the top of page 14 (lines 369-71) states that women planning to give birth in hospital labour wards were more likely to be Australian born – this is not what the data in Table 1 show.</p> <p>ii. Table 2 appears in the middle of Table 3</p> <p>iii. Tables 2-5 would be easier to read if the number of events and number of births were in separate columns and the Totals for each outcome were at the bottom of each cell rather than at the top.</p> <p>iv. Another level of subheading separating maternal and perinatal outcomes would be helpful so that it is clear that postpartum complications relate to the mother.</p> <p>v. In relation to the perinatal outcomes, it would be better to more clearly highlight that the absolute risks and relative increase in the odds were higher in the planned home birth group, although not statistically significant, and that overall numbers were small, rather than simply stating that there were no significant differences. Although there is considerable uncertainty, because of the small number of events, the direction of effect is the same for all mortality outcomes in the planned home birth group, irrespective of parity and I would like to see the results presented in a way which more clearly expresses this.</p> <p>vi. As referred to above, I am concerned that the small numbers in some cells in Table 5 mean that some women are potentially identifiable, e.g. four women planned birth at home and had a stillbirth, one woman planned birth in a birth centre and had a baby who died in the first 28 days of life. In my view, to comply with ethics approvals, these numbers and event rates should be suppressed and odds ratios presented alone.</p> <p>vii. In Table 5 for early neonatal death there are two asterisks in the table which are not explained in the footnotes.</p> <p>6. Discussion & conclusions</p> <p>i. The discussion of findings relating to perinatal mortality appropriately expresses some of the uncertainty around these</p>
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	<p>findings, particularly in relation to planned home birth. The Birthplace study results are not quite represented accurately here (lines 439-40). The primary outcome for Birthplace was a composite of perinatal mortality and selected early neonatal morbidities, not just perinatal mortality as is reported in this paper. I would also like to see some brief consideration of the context for planned home births in Australia, for example, the very low numbers of women planning birth at home, the extent of publicly funded maternity services for home birth, and the integration, or lack of it between, home birth services and hospital-based maternity care, particularly important to ensure seamless transfer.</p> <p>ii. Although there is a thoughtful discussion of the potential limitations of this study, I would like to see more explicit consideration of the possible impact of selection bias on the results of the study. It is also likely that there is some residual confounding – women planning birth in birth centres, and particularly home birth given the very small numbers, are likely to be different from those planning hospital birth in a number of ways, for example in their attitudes to intervention and approach to birth, which are not measureable and which are likely to impact on the findings in relation to interventions and outcomes.</p> <p>iii. The authors also refer to the difficulties they experienced identifying transfers. However their consideration of this aspect of the study is relatively brief and limited to an explanation that they were unable to report transfer rates. Given that they were not able to accurately identify transfers during labour, how confident are they that they were able to correctly identify intended place of birth? Is there a possibility that some planned birth centre/home births were erroneously classified as planned hospital births? This needs considering and explaining.</p> <p>7. In the STROBE checklist the section on participants is not strictly speaking appropriately completed. A flow diagram illustrating the derivation of the study sample would be helpful. The study size question has not been completed.</p>
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VERSION 1 – AUTHOR RESPONSE

Response to reviewer 1

Reviewer 1	Response
<p>This is a retrospective, population-based cohort study using linked registry data from Australia to study outcomes following planned community births vs. planned hospital births. The manuscript is well written, and the authors demonstrate an excellent understanding of the nuances of studying birth location. They correctly use an intention-to-treat analysis, acknowledging that their</p>	<p>Thank you for your thoughtful and thorough review of our paper. We will address all your comments in the table below.</p>

<p>assessment of exposure (planned birth location) is not ideal, as for some women this occurred earlier in pregnancy than at the onset of labor. Below I provide specific suggestions (including, potentially, new analyses) that I believe would strengthen the manuscript.</p>	
<p>Introduction</p>	
<p>Given the meta analysis of birth place, written by some of these same authors, why do we need this study (and why should it be published in an international journal)? Explain what about Australia is so different that those other results wouldn't apply.</p>	<p>We believe that this study is unique and important. It is the first time a national study has been conducted in Australia. The situation in Australia is different to other countries as the health system is funded across both national and state systems and the geography is very different to other places in terms of rural and remote settings. Homebirth is highly contentious in Australia and publishing this in an international journal is important to highlight the context and the issues.</p> <p>The study was funded by the National Health and medical Resaerch Council showing it's national significance.</p>
<p>As the aim is to study 'uncomplicated pregnancies', some discussion of pregnancy risk factors and the extent to which they do or do not (or we don't know) affect outcomes for community births is warranted. Need to justify the study population; I should know what 'uncomplicated' means in this context by the time I get to the Aim. (ETA: after reading the methods, it sounds like Australia has set a definition for 'low risk'? Is that the same as uncomplicated? And regardless, make it clear in the intro that these are rules set by Australia; otherwise readers could quibble about some of them)</p>	<p>We have added a clarification of uncomplicated when it is first mentioned in the Introductory paragraph.</p> <p>We have moved the definition of uncomplicated to be with the aim to help clarity.</p> <p>We see that using both terms is confusing – we have endeavored to use uncomplicated unless the authors of the papers we refer to use otherwise.</p>

Methods	
<p>If excluding precipitous labors for hospitals and birth centers, should also exclude precipitous labors at home—perhaps those who delivered before the midwife arrived?</p>	<p>It is possible that some women gave birth at home before the midwife arrived but the data systems do not collect this across the country so it is not possible to know.</p>
<p>Other thoughts about exclusions:</p> <ol style="list-style-type: none"> 1. only breech? what about transverse? (could say “non-vertex” instead?) 2. what about planned cesareans that aren’t scheduled? so they’re not pre-labor per se, but nonetheless the woman and the OB both know she’s having a cesarean when she shows up in labor 3. what is the definition of prolonged ROM? ap hemorrhage? (do they have definitions for your study other than the ICD-10 code was indicated in the record? how are coders trained in Australia? what are usual diagnostic criteria?) 4. what are “other 	<p>We have added non-vertex</p> <p>It is not possible to determine planned caesareans that aren’t scheduled in our data systems. Mostly women are recorded as being planned or unplanned.</p> <p>Definitions are only those provided by ICD-10-AM coding – so in line with this if a woman has PROM recorded in her medical record then her record will be coded as PROM by the coders. Medical records are written by trained medical and nursing/midwifery staff only so standard definitions are utilized.</p> <p>Coders have national training in Australia and this is consistent. It seems beyond the scope of this paper to go into detail about their training or diagnostic criteria. We have no reason to believe that there would be a bias in the coding, regardless of the setting..</p> <p>We didn’t include pre-pregnancies and examined maternal mortality within 42 days or readmission within 28 days.</p> <p>We defined uncomplicated pregnancy as a singleton fetus in cephalic presentation between 37 and 41 completed weeks’ gestation. We have added the extremes to this to Box 1.</p>

<p>relevant pregnancy complications”?</p> <p>5. The list of ICD-10 codes does not list all of the items from the list (breech, elective repeat cesarean), and then lists extra ones not discussed first (multiples). Please clarify how these exclusions were applied.</p> <p>6. line 338 suggests that both pre and post pregnancies are excluded; this does not appear in box 1?</p>	
<p>For community births, does <i>any</i> admission for mom or baby count as a ‘readmission’? there are pros and cons to this approach (conservative criteria for transfer makes them not quite comparable to a readmission after initial hospital discharge...but on the other hand, you’ll be missing some potentially important outcomes if successful community births followed by a hospital transfer for mom or baby genuinely require then a re-admission to “count”)</p>	<p>Women who gave birth at home and required transfer to hospital either during labour or after the birth are counted as an admission. We understand that there are limitations with this approach but it was the clearest given the data set.</p> <p>We have added this detail in the text.</p>
<p>Suggest combining the 3 fetal/neonatal death variables to increase power. yes, etiologies (and thus prevention strategies) likely differ; however the goal for this manuscript is to assess</p>	<p>The deaths are reported combined in Table 4.</p>

<p>safety of planned community birth, and thus the important outcome is whether the baby is alive or not, regardless of when the death occurred. Parents (and midwives!) don't care, particularly, when; it's arguably more informative for shared decision making if they are presented with an overall risk of death, rather than 3 separate ones.</p>	
<p>Is parity dichotomized into primip/multip? If not, suggest doing so to increase precision in your models</p>	<p>Yes – it is dichotomized. Additional clarity has been added including this statement:</p> <p>We present analysis stratified by parity (first baby versus other) for normal labour and birth and perinatal mortality.</p>
<p>Why use alpha < 0.01? This is not standard, so must be justified</p>	<p>We selected this to have a more precise conclusion due to large sample size. We have justified this now.</p>
<p>I have absolutely no idea what this sentence means: "For simplicity, percentages were computed for incidence of events at each birth setting instead of examining the corresponding sphericities and specificities of the data." Please explain sphericities/specificities. Specificity is an epidemiology term, but I think you are using it differently here. I have never seen the word "sphericity" before.</p>	<p>Thank you. We have now simplified this to <u>Percentages were computed for incidence of events at each birth setting.</u></p>
<p>Imputation could be used to address the demographic variables that are inconsistently recorded across states. I strongly urge you to do this, as the variables that you list as "unavailable bc missing" are important for the study question.</p> <p>Other variables, ok not to impute, since there isn't much missing data (<1%! I would love a dataset like that). But, suggest saying so in the methods section, because my first thought was "well if they</p>	<p>We choose not to undertake imputation given the size of the data set and the length of time as we felt the missing characteristics were unlikely to be so different as to alter the findings.</p>

<p>have missing data, why not use multiple imputation?"</p>	
<p>Please provide some discussion of why those confounders were chosen, and whether you assessed the extent of confounding when building the multivariable models, or whether all were decided <i>a priori</i></p>	<p>The decisions on the confounders to include were made <i>a priori</i> by the research team. We have added this in the paper.</p> <p>Please note that since we submitted this paper our methodology paper has been published. This does not have a flow chart but has more detail on the sample:</p> <p>Cheah SL, Scarf V, Rossiter C, Thornton C, Homer CSE. Creating the first national linked dataset on perinatal and maternal outcomes in Australia: Methods and challenges. Journal of Biomedical Informatics Volume 93, May 2019.</p> <p>Available from : https://www.sciencedirect.com/science/article/pii/S153204641930070X</p>
<p>Results</p>	
<p>pregnancies between 2000 and 2012: does that mean that the BIRTH happened Jan 2000 – Dec 2012, and therefore you have data from 1999 (for some of those pregnancies) and 2013 (for the postpartum follow-up)? Please clarify.</p>	<p>It is births from 1/1/2000 to 31/12/2012. We have rephrased that sentence to assist clarity.</p>
<p>Table 2 and 3 are in the wrong order, and I think table 3 was cut off? Would be nice to see all of table 3! Though I assume the home birth c/s rate was similar to birth center.</p>	<p>Table 2 is about normal labour and birth by planned place of birth and parity.</p> <p>Table 3 is about mode of birth and intervention rates by planned place of birth. We are not sure how they are in the wrong order?</p> <p>Table 3 goes across to the next page where epidural and spinal analgesia for labour is presented. I am sorry if something happened to the table for you.</p> <p>Home birth CS rate was similar to birth center as in the 4th row of Table 3.</p>
<p>when you say "adjusted for parity" is that primip vs. multip? or as an ordinal variable?</p>	<p>Yes - primip vs. multip. We have clarified this in the text.</p>

<p>Suggest reporting the incidence of normal labor & birth—nearly 80% in the hospital!! That’s definitely not the global norm; in the US we have 80% of women having epidurals. Sad but true.</p>	<p>We have reported this in Table 2. We have added a sentence in text.</p>
<p>Also suggest reporting the incidence of cesarean in all three locations in the main text as well; in fact, for both the table 2 and 3 discussions, reporting the incidences, rather than the aORs, would be more informative. Half as likely...ok, but does that mean 30% vs. 15%? Or 10% vs. 5%? The latter are more useful, I think, and then readers can refer to the tables for the rest of the numbers. Again, 8% cesareans in the hospital, even for low-risk women...this is not what we see in other countries.</p>	<p>We have added some text to help explain this better.</p> <p>We feel it is too complex to add all the %’s as there are three groups in each outcomes and this is hard to easily express in the text.</p>
<p>Suggest expanding on the interventions that would only be available in hospitals (so, after an ip transfer from community setting)—of course they’re less common in planned community births, but a more interesting question would be are they less common if you limit the community birth sample to those who ended up in the hospital while they were still in labor, and therefore were actually at risk of these interventions? (I think this doesn’t apply to cesarean, as that’s sometimes a necessary thing (especially if it’s happening at such a low rate), whereas epidurals are more squishy. ALSO, suggest dropping women who had a cesarean from the analysis of epidurals (assuming that is the anesthesia of choice for</p>	<p>The interventions we have included are only available in hospitals and therefore women require transfer to receive them.</p> <p>We agree that the transfer rates are a problem and we have not included that data.</p>

<p>cesareans in Australia), because some women probably got the epidural just because they were headed for a cesarean. I think what's more interesting is the rest of the epidurals. (ETA: I see from the limitations section that you can't identify ip transfers. suggest, then, dropping this section entirely)</p>	
<p>Women who had cesareans should be dropped from the hemorrhage analysis</p>	<p>We would like to retain the comparison we have to make the reporting as complete as possible.</p>
<p>Same comments re: reporting for the postpartum complications section. Incidences are more interesting than aORs</p>	<p>Given the complexity of describing the percentages from three groups we would prefer not to report them all in text. They are all in the tables.</p>
<p>strongly urge you to drop the bit about stratifying deaths by parity. there aren't enough deaths even for the main analysis, no sense having even smaller cells. I realize that the Birthplace in England study had that finding about parity...but you don't have enough events (which...is not a bad thing?), and it would be easy for someone to take your numbers out of context, without all the caveats.</p>	<p>Our team feel that it better to report than to drop though the number is small and data analyses were not performed. Readers may wonder why deaths of small numbers are excluded. The Birthplace in England results has led to parity becoming an important consideration for obstetricians considering support for homebirth. Likewise there are homebirth models being introduced in Australia that excluded primiparous women based on the Birthplace in England study. Increasingly studies on homebirth are reporting parity and so ultimately more metanalysis can be done on parity in the future.</p>
<p>Discussion</p>	
<p>line 426—please say “were <i>slightly</i> older”—two years is statistically significant when you have over a million people, but probably doesn't matter too much clinically, given that mean age for all groups was 30-ish</p>	<p>We agree and have added this.</p>

<p>lines 429-441—see above re: parity.</p>	<p>Hopefully the clarity we have included above will assist this.</p>
<p>re: NICU. In the US, depending on the hospital, we sometimes see ALL community birth transfers going to the NICU, and anecdotally this is sometimes punitive if that hospital or the on-call OB doesn't "believe" in community birth. Australia is very different than the US on lots of things, but might this be part of why we see increased NICU for birth centers? Then not for home bc low events → no power? Maybe not, since you limited to NICU stays of at least 48 hours. But something to think about.</p>	<p>Yes. This is concerning information from the US. That is certainly not the case here in Australia.</p>
<p>lines 460-464: suggest substantially expanding this section. (Or putting this info in the introduction? It seems more like justification than discussion, but depends on how you structure the rest). As currently written, this feels like a throw-away comment, when really it's the meat of the whole thing.</p>	<p>Yes. We can see this and on reflection, given the primary aim of the study was not CS rates, we have removed this para.</p>
<p>what proportion of women move during the 21 months they would be followed for this study? this has implications for completeness of data, if you can't link across states. please address in limitations.</p>	<p>Each dataset has it's own PID, we can't track the move of the mothers/babies between states/territories. We have added this as a limitation.</p>
<p>line 494—not adjusting for confounders increases confounding, not selection bias</p>	<p>Thank you for pointing out this error. We have deleted this.</p>

<p>Your limitations section absolutely needs a section on power, as you had very little for the death outcome. Suggest even a post-hoc power analysis.</p>	<p>We've provided the whole population sizes, not sample population sizes, so the power analysis is deemed unnecessary in linked data sets. We have addressed the small numbers of homebirths in the limitations.</p>
<p>Minor Points</p>	
<p>Do available care options in Australia vary by hospital, or by state?</p>	<p>Yes. This sentence is in the Introduction - There are some differences across Australia in the way care is provided, the local guidelines and the choices available to women.</p>
<p>line 177-178: please clarify the roles for these practitioners. are both present for the birth? is the OB ever there for the labor?</p>	<p>Yes – have added to clarify this.</p>
<p>suggest using the phrase “community birth”, rather than “home and birth center” or “out-of-hospital”.</p>	<p>Homebirth is the recognised term in Australia and other countries like the UK and New Zealand. We recognise community birth is a US term, and our understanding is that it is broader than just homebirth – i.e. that it also includes independently run community birthing centres as well. We would therefore prefer to retain the term.</p>
<p>line 286—“doctors”—all obstetricians? or do family practice docs (GPs) attend births in Australia?</p>	<p>Yes – we have added this: <u>... women are attended by midwives, obstetricians and/or general practitioner (GP) obstetricians.</u></p>
<p>line 309—perinatal outcomes should be a new paragraph</p>	<p>Thank you – done.</p>
<p>paragraph starting on line 330—define the states in the text. it is not sufficient just to define them in the footnote to the table.</p>	<p>We have tried to add the names of the 8 states and territories in the text but it reads in a very cumbersome way. We would prefer not to define these></p>
<p>what's the difference between a box and a table?</p>	<p>We used boxes when it was more textual and table when it included data/numbers. We are fine to alter this if the Editor requests.</p>
<p>Line 354: tables should be numbered in the order that they appear in the text; these</p>	<p>The order is correct.</p>

should therefore be tables 1 and 2	
Since you are presenting data on outcomes of birth, suggest using “primiparous” rather than “nulliparous”, as they’ve had that baby now. But, I know some journals care one way or the other, so go with the author guidelines.	We have changed this as requested.
I think the unadjusted OR columns are unnecessary	We would prefer to retain them if the Editor agrees.
line 380—this is not “conversely”—you just said community birth settings were associated with more normal labor and birth. Therefore of course they are associated with FEWER interventions.	Yes. We agree and removed this word.

Response to Reviewer: 2

Reviewer 2	Response
<p>This paper reports an important study aiming to compare maternal and perinatal outcomes for ‘low-risk’ women planning birth in different settings in Australia over the period 2000-2012. I am pleased to have the opportunity to review it. This has clearly been a complex and challenging study to carry out, involving the use of linked routine data from all eight Australian states and territories, and the authors have appropriately referred to some of the consequent limitations. There are, however, some changes I would like to see before the paper is considered suitable for publication. These include: more detail in relation to aim and objectives; more clarity and information in relation to several aspects of the methods; the correction of a small number of errors; and attention to ensure that all potential limitations are considered and appropriately qualified conclusions are drawn, particularly in relation to perinatal outcomes.</p>	<p>Thank you for the encouraging comments.</p>

Title	
I wonder if the title could be improved to make it more informative by adding the words “Maternal and perinatal” at the beginning.	Yes – now done.
Abstract	
i. Normal labour and birth should be included under outcomes, particularly given that it is the main result reported the abstract.	Yes – we agree and have added this
ii. Given the findings relating to perinatal mortality in babies of nulliparous women planning birth at home, and the very small numbers of women planning birth at home, the conclusions should refer more explicitly to uncertainty about safety for babies in this group.	We have added a phrase about the small numbers.
Background	
3. Background: i. The first couple of paragraphs give a helpful introduction to the organisation of maternity care in Australia. It would be helpful to know what proportion of births take place in the public vs private sector. I think, for a general medical journal, it would also be helpful to have a brief description of what a “midwife-run birth centre” is. I would also like to see a brief explanation of the extent to which birth centre and home birth services are integrated with hospital-based services, e.g. in relation to transfer, as this has the potential to impact on outcomes.	We have added a sentence about birth centres. We have added 2 sentences on integration but it is something we really do not have any data on – especially homebirth services.
ii. I’m not quite sure what the final sentence of paragraph one refers to – what are these differences? If this sentence is to remain I think more explanation is required.	We have added another sentence about the variability.
iii. The background section is quite long. The summary of evidence on planned place of birth and outcomes, in Australia and elsewhere, is a bit jumbled and could probably be shortened. I wonder if it would be clearer to restructure this and present evidence on maternal outcomes, which is fairly consistent, separately from that on perinatal outcomes, where there is more variation and uncertainty/evidence of adverse	We have tried to shorten this section but given we need to outline maternal and perinatal outcomes by 3 different places of birth it is a challenge. I hope we have done OK.

outcome, particularly for women planning a first birth at home.	
iv. The statement that “place of birth... [is] controversial in Australia” needs supporting evidence / a citation.	We have cited the RANZCOG statement which questions the safety of homebirth.
v. The aim of this study is clearly outlined at the end of the background. I would also like to see more specific objectives or research questions here, relating to the particular outcomes examined in this study.	We have included the specific objectives.
Methods	
i. Under “Study design” the authors say that “homebirth and birth centre options are mostly restricted to women who meet low-risk criteria”. Later on the same page they refer to eliminating women with “complicating conditions” from the dataset and on the next page there is a definition of “low-risk pregnancy” with more information in Box 1. Box 1 contains a list of medical conditions and pregnancy complications, plus “any other relevant pregnancy complications”. It would be helpful to have more clarity and consistency of terminology in relation to the creation of their ‘low-risk’ sample. How was the list of medical conditions/complications arrived at? Box 1 refers to the exclusion of unplanned births at home (i.e. BBAs) – how were these identified?	We have added a paragraph under definitions and have also sought to use consistent terms throughout – essentially uncomplicated rather than low risk. BBAs are identified in the datasets and could be removed.
ii. The data sources used for this study are in the main well described. I was not clear what the “immediate postpartum period” (line 256 page 9) meant.	We have added “during the birth admission” because as soon as the woman is discharged, the readmission is a new episode.
iii. While some of the relevant information is contained in the “Definitions” section, it would be clearer if all the outcomes examined in this study were clearly listed and described in a separate section. The combined perinatal mortality data, for example, is not listed on page 11 and it’s generally not clear if this is a complete list of outcomes considered or an indicative selection. From the way the results section is written it appears as if normal labour and birth is the main	We have separated out into a separate Box and ensured that all outcomes are included.

<p>outcome, but this isn't described elsewhere so it's not clear.</p>	
<p>iv. The normal labour and birth definition as described in this section and elsewhere does not exclude caesarean section, which I assume is an error.</p>	<p>Yes – thank you. Now added</p>
<p>v. The sentence “We also stratified combined perinatal mortality data by parity” on line 312, page 11 relates to analysis, not definitions/outcomes. This section also refers to “other specific definitions” in tables. All relevant definitions/categorisation/outcomes should be described in the methods section, not just in footnotes to tables, e.g. the sentence in the footnote to Table 3 which explains that variables on mode of birth and intervention are all as defined by each state or territory should be in the methods section.</p>	<p>Thank you. We have included these in the Methods.</p>
<p>vi. A flow chart would be helpful, if possible, to illustrate the data obtained from different sources, and the derivation of the analysis sample, indicating numbers of women excluded with risk factors etc.</p>	<p>Since we submitted this paper our methodology paper has been published. This does not have a flow chart but has more detail on the sample:</p> <p>Cheah SL, Scarf V, Rossiter C, Thornton C, Homer CSE. Creating the first national linked dataset on perinatal and maternal outcomes in Australia: Methods and challenges. Journal of Biomedical Informatics Volume 93, May 2019.</p> <p>The inclusion and exclusion process was reported in Fig. 4 of the Methodology Paper. Some datasets supplied are more clean than the others so a flow chart is more complex than we thought would be useful</p>
<p>vii. The section on data analysis would benefit from more structure, clarity and detail and should simply describe all analyses that were carried out.</p>	<p>We have provided a standard linked data analysis section and would prefer not to alter this.</p>
<p>viii. The sentence on lines 349-50 about “sphericities and specificities of the data” will be impenetrable to most people. I assume this is a reference to the fact that there are likely to be ‘repeated measures’ of some sort in the dataset, i.e. women who appeared more than once, but that analyses did not take account of this. This needs to be explained more clearly, with rationale (not just “for simplicity”), and any</p>	<p>We have simplified this as the other reviewer also found it impenetrable – as did the authors on a second read.</p>

<p>limitations of this approach considered in the discussion.</p>	
<p>ix. The analyses using chi-squared test and ANOVA appear to relate to comparison of demographic characteristics across planned birth settings (and presumably chi squared test may have been used for initial exploration of outcomes), but the sentences describing these initial analyses are separated by several other sentences. Were the continuous variables categorised in the multivariable modelling (using the same categories as presented in Table 1) or included as linear variables?</p>	<p>It is written underneath Table 1 that chi-square tests were performed on categorical data and GLM was for continuous data that involved comparison between means.</p>
<p>x. It is sufficient in the methods section to explain that associations between planned place of birth and outcomes were adjusted for those clinical/demographic factors which were available across all linked datasets (listing those factors that were included in the multivariable logistic regression). Would it have been possible to carry out any sensitivity analyses, using data from one or more states which have more data on demographic factors, to explore the effect of this further adjustment?</p>	<p>A stepwise binary logistic regression with sensitivity classification was performed. We feel that adding this to the tables will make them even more complex and we would prefer not to do this unless required by the Editor.</p>
<p>xi. What was the rationale for stratifying by parity only for the normal labour and birth outcome and the combined perinatal mortality outcome? Was this pre-specified? Were any formal tests of interaction carried out?</p>	<p>We categorized the cohorts by parity (primiparus vs multiparous) as described earlier. This was pre-specified. No formal tests of interaction were undertaken.</p>
<p>xii. The approach to missing data seems broadly appropriate, although there is a curiously worded footnote to Table 3 which I don't understand - "No imputation was implemented to avoid data contamination. However, noises from data was unavoidably retained". Again, new information should not appear only in table footnotes. I am also puzzled by the statement that "wherever necessary" missing data was reported. It would be helpful to know how much missing data there was in relation to outcomes and whether those women who were excluded from analyses for this reason are likely to have been different in any way. In Table 3 the outcome "Mode of birth not stated" is also included, but this is not referred to anywhere. Is there a difference between 'missing' and 'not stated' in Table 1?</p>	<p>We have deleted this information as it is confusing and already included elsewhere. We have also referred to the Methods paper.</p>

<p>xiii. The final sentence of the data analysis section explains that cells with less than five women will not be reported in the paper, but in Table 5 there are three cells where there are less than five women, e.g. four nulliparous women who planned birth at home and had a stillbirth or early neonatal death. If this sentence is correct, which I assume it is since this is standard practice, I would not expect to see absolute numbers of deaths or incidence (since absolute numbers can be calculated from incidence) reported in Table 5 for these outcomes.</p>	<p>We apologise for this oversight. We have replaced those outputs by “na” for sizes < 5 in Table 5.</p>
<p>Results</p>	
<p>i. The sentence at the top of page 14 (lines 369-71) states that women planning to give birth in hospital labour wards were more likely to be Australian born – this is not what the data in Table 1 show.</p>	<p>Sorry – we meant non-Australian born</p>
<p>ii. Table 2 appears in the middle of Table 3</p>	<p>We have fixed this we hope.</p>
<p>iii. Tables 2-5 would be easier to read if the number of events and number of births were in separate columns and the Totals for each outcome were at the bottom of each cell rather than at the top.</p>	<p>We have redone the tables with the number of events and number of births in separate columns. We have left the totals at the top. We can alter this if requested.</p>
<p>iv. Another level of subheading separating maternal and perinatal outcomes would be helpful so that it is clear that postpartum complications relate to the mother.</p>	<p>We have added ‘maternal’ postpartum to the table</p>
<p>v. In relation to the perinatal outcomes, it would be better to more clearly highlight that the absolute risks and relative increase in the odds were higher in the planned home birth group, although not statistically significant, and that overall numbers were small, rather than simply stating that there were no significant differences. Although there is considerable uncertainty, because of the small number of events, the direction of effect is the same for all mortality outcomes in the planned home birth group, irrespective of parity and I would like to see the</p>	<p>We have included a clearer statement to address this.</p>

results presented in a way which more clearly expresses this.	
vi. As referred to above, I am concerned that the small numbers in some cells in Table 5 mean that some women are potentially identifiable, e.g. four women planned birth at home and had a stillbirth, one woman planned birth in a birth centre and had a baby who died in the first 28 days of life. In my view, to comply with ethics approvals, these numbers and event rates should be suppressed and odds ratios presented alone	We have removed the cell sizes <5 and replaced with 'na'
vii. In Table 5 for early neonatal death there are two asterisks in the table which are not explained in the footnotes	It's * = Excluded VIC. We have corrected that into one *.
Discussion and conclusions	
<p>The discussion of findings relating to perinatal mortality appropriately expresses some of the uncertainty around these findings, particularly in relation to planned home birth. The Birthplace study results are not quite represented accurately here (lines 439-40). The primary outcome for Birthplace was a composite of perinatal mortality and selected early neonatal morbidities, not just perinatal mortality as is reported in this paper.</p> <p>I would also like to see some brief consideration of the context for planned home births in Australia, for example, the very low numbers of women planning birth at home, the extent of publicly funded maternity services for home birth, and the integration, or lack of it between, home birth services and hospital-based maternity care, particularly important to ensure seamless transfer.</p>	<p>We have corrected this.</p> <p>We have added a para to explain the low numbers and the context as you suggest.</p>
ii. Although there is a thoughtful discussion of the potential limitations of this study, I would like to see more explicit consideration of the possible impact of selection bias on the results of the study. It is also likely that there is some residual confounding – women planning birth in birth centres, and particularly home birth given the very small numbers, are likely to be different	We have added a para to address these issues – thank you.

from those planning hospital birth in a number of ways, for example in their attitudes to intervention and approach to birth, which are not measurable and which are likely to impact on the findings in relation to interventions and outcomes.	
iii. The authors also refer to the difficulties they experienced identifying transfers. However, their consideration of this aspect of the study is relatively brief and limited to an explanation that they were unable to report transfer rates. Given that they were not able to accurately identify transfers during labour, how confident are they that they were able to correctly identify intended place of birth? Is there a possibility that some planned birth centre/home births were erroneously classified as planned hospital births? This needs considering and explaining.	We have quite a long section in the limitations on this already. We have added a sentence for clarity.
STROBE	
In the STROBE checklist the section on participants is not strictly speaking appropriately completed. A flow diagram illustrating the derivation of the study sample would be helpful. The study size question has not been completed.	We refer to the Methods paper.

VERSION 2 – REVIEW

REVIEWER	Marit L. Bovbjerg Epidemiology Program Oregon State University Corvallis, OR USA
REVIEW RETURNED	02-Aug-2019

GENERAL COMMENTS	<p>This revision of a birthplace in Australia retrospective cohort study will be a valuable contribution to the literature. It is much improved from the initial version, though as the version given to reviewers this round did not include a cover letter addressing previous reviewer comments, the process on my end took longer than expected (and the reviewing website contains no space for confidential comments to editors, which is why I'm writing this here. Hopefully they will read!) Minimal revisions are suggested below.</p> <p>Introduction</p> <ul style="list-style-type: none"> • Lines 169-170—I still want to know what “uncomplicated pregnancies” means—‘without obstetric or medical risk factors’ is not sufficiently clear. Are women with elevated BMI included? What about those over age 35? What about women with a history of depression? etc. (ETA: I see that it's explained in great detail in
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	<p>the methods. Maybe refer the reader down there in the intro? like, “without obstetric or medical RFs, see below”)</p> <ul style="list-style-type: none"> • line 174—the parenthetical statement needs a citation • lines 191-192—an evaluation of the outcomes of publicly funded models...for home birth? <p>Methods</p> <ul style="list-style-type: none"> • I think the last sentence of the paragraph, on lines 284-285, can be deleted. There will be so few maternal deaths in a sample of this size that nothing can be done with them, statistically. Also maternal death was not an outcome from the Aims. <p>Results</p> <ul style="list-style-type: none"> • Thanks for leading with the proportion of normal births, rather than the proportion of adverse events! it’s good to challenge the dominant narrative
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REVIEWER	Dr Rachel Rowe National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, United Kingdom
REVIEW RETURNED	26-Jul-2019

GENERAL COMMENTS	<p>Thank you for sending me this revised paper to review. The authors’ changes have, in the main, resulted in an improved paper. I do have some further comments, which now need to be addressed before publication.</p> <p>My detailed comments are as follows:</p> <ol style="list-style-type: none"> 1. Abstract: <ol style="list-style-type: none"> i. The authors have added a statement to the conclusion to highlight the small numbers overall in the home birth group. I am still concerned however, that without some explicit qualification in the conclusions, the statement in the results section that there were no statistically significant differences in perinatal death between the three settings is likely to be misinterpreted. Based on these results I don’t think it is possible to rule out an increased perinatal mortality rate in the planned home birth group. I would therefore like to see an explicit statement in the conclusions to the effect that the small numbers of planned home births and the small number of events means that there is considerable uncertainty in relation to perinatal mortality outcomes in this group. 2. Background: <ol style="list-style-type: none"> i. This section has been in the main improved by the authors’ additions. I did ask for more detail on specific objectives, but on reflection there is now more detail here than is appropriate. I had inferred from the previous version that the study had a primary outcome, normal labour and birth, and a number of secondary outcomes, but I assume from the revisions made that this was not the case. I suggest removing the text which has been added and replacing it with a sentence along the lines of: “Outcomes investigated included normal labour and birth, mode of birth, interventions during labour, postpartum maternal complications and perinatal mortality and morbidity.” 3. Methods: <ol style="list-style-type: none"> i. Again, in the main, my comments have been appropriately addressed and the reference to the separate methodological paper on data linkage is helpful. ii. Separating and listing the outcomes in Box 2 is helpful, but the mixture of ‘type of outcome’, list, description and definition here does not help with clarity. Some of my original concerns therefore
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	<p>remain in relation to clarity around description of outcomes. For example “perineal status” is not an outcome – the outcomes relating to perineal status appear to be “intact perineum” and “3rd or 4th degree perineal trauma”, which appears later in Box 2, listed under Postpartum complications. The use of the word “includes” should be avoided, since this could imply that there were some other outcomes not listed here. For clarity it would be better simply to list the outcomes, separated out by maternal and perinatal e.g.</p> <p>Maternal outcomes: Normal labour and birth (defined as...) Normal vaginal birth (defined as...) Forceps birth Vacuum extraction Intrapartum Caesarean section Mode of birth not stated Episiotomy Oxytocin augmentation Epidural or spinal analgesia Etc</p> <p>Perinatal outcomes: Perinatal mortality (defined as...) Intrapartum stillbirth Early neonatal death Etc</p> <p>It is not necessary in this box to explain that perinatal mortality was presented stratified by parity as this doesn't relate to the outcome, this is about analysis. The sentence at line 314 should state that Box 2 “lists and defines” all maternal and perinatal outcomes used.</p> <p>iii. I still have some issues with the section on data analysis. I may not have been clear enough in my previous comments.</p> <p>Specifically:</p> <p>i. The sentence about “sphericities and specificities of the data” has been removed and replaced with “For simplicity, percentages were computed for the incidence of events at each birth setting”. I'm still not sure what this means – what does “for simplicity” mean here? In fact, for some outcomes n/1000 rather than percentages have been presented. Since the authors have not responded to my original comment about ‘repeated measures’ of some sort in the dataset, i.e. women who appeared more than once, I assume that this does not apply, but it would be good to have reassurance on this.</p> <p>ii. I think my original comment about analyses using ANOVA may have been unclear. I simply meant that because the sentence about ANOVA appears at the end of the paragraph, after the description of the multivariable analysis, it's a bit confusing (it appears out of order). I suggest that the sentence is moved earlier in the paragraph. For example: “Categorical variables were initially compared using chi-square tests. For continuous data such as maternal age and gestation week, we used general linear mode.... Odds ratios comparing each outcome by planned place of birth were calculated using logistic regression, adjusted for ...”.</p> <p>iii. I don't think the sentence at lines 353-356 is necessary in this section – it is a limitation, not part of the methods.</p> <p>iv. In one of my original comments I asked whether the authors had carried out any sensitivity analyses, using data from states with more data about demographic factors, to explore the effect of the further adjustment that would be possible using these data. I'm not sure if I understand the authors' response correctly, but I think it indicates that they may have carried out some sensitivity analysis along these lines. I appreciate that they do not want to</p>
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	<p>complicate their tables and the message of their paper. However, if such analyses were carried out they should be described in the methods section and the results reported, even if this simply comprises a brief paragraph in the results section with a link to further tables in a supplementary file.</p> <p>4. Results:</p> <p>i. I missed this on first review, but I'm not clear why "3rd / 4th degree perineal trauma" is in Table 3 (Mode of birth and intervention rates). Should it be in Table 4 instead? Also, I appreciate that "intact perineum" isn't a postpartum complication so may not fit in Table 4, but it doesn't really fit in Table 3 either as it's not mode of birth or an intervention. Perhaps it could be moved to Table 4 and this could be renamed "Maternal postpartum outcomes...".</p> <p>ii. In response to my original comment about the reporting of results about perinatal outcomes, the authors have stated that they "have included a clearer statement to address this". Where is this statement? They have not made any change that I can see to the section on perinatal outcomes.</p> <p>iii. The authors have appropriately suppressed numbers in cells with less than 5 events in Table 5. However, it is often possible to work out what the missing numbers are so this is insufficient, e.g. for the combined mortality variable in the home birth group you can simply subtract the number in the multiparous group from the overall figure. These all need to be checked carefully to make sure that no small numbers can be inferred from other data and further removals made as appropriate. The incidence and unadjusted ORs have been appropriately removed, but the adjusted ORs should be reinstated since they are informative and it is not possible to work backwards from these to calculate the small numbers.</p> <p>5. Discussion & conclusions</p> <p>i. I think the sentence about the Birthplace findings (lines 444-7) still needs some minor rewording as it doesn't quite make sense currently. I suggest "However, it is similar to the findings of the Birthplace in England study, which found a statistically significant higher odds of a composite outcome combining perinatal mortality and selected early neonatal morbidities among primiparous women planning home birth".</p> <p>ii. The additional text considering residual confounding is welcome, but I don't think the first sentence in that paragraph (lines 511-2) makes sense as it confuses selection bias and confounding. My original comment may have been unclear, but selection bias is a separate issue.</p> <p>6. General</p> <p>i. There are a few instances where "low-risk" has not been replaced with "uncomplicated", e.g. in the abstract at lines 71 and 85, at line 471 etc.</p> <p>ii. Depending on whether sensitivity analyses were carried out (see my comment above) the STROBE checklist may need changing to reflect that.</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

This revision of a birthplace in Australia retrospective cohort study will be a valuable contribution to the literature. It is much improved from the initial version, though as the version given to reviewers this round did not include a cover letter addressing previous reviewer comments, the process on my end took longer than expected (and the reviewing website contains no space for confidential comments to editors, which is why I'm writing this here. Hopefully they will read!) Minimal revisions are suggested below.

The detailed response to reviewer document was provided on the online system.

Introduction

• **Lines 169-170—I still want to know what “uncomplicated pregnancies” means—‘without obstetric or medical risk factors’ is not sufficiently clear. Are women with elevated BMI included? What about those over age 35? What about women with a history of depression? etc. (ETA: I see that it’s explained in great detail in the methods. Maybe refer the reader down there in the intro? like, “without obstetric or medical RFs, see below”)**

We have added these words in brackets – to be honest it looks a bit odd to refer to the Methods in the opening paragraph but to provide a long definition with all the exclusions and exclusions here is also not feeling right.

• **line 174—the parenthetical statement needs a citation**

For the most part, this used the Australian College of Midwives Guidelines for Consultation and Referral as a basis for the description of uncomplicated pregnancies so we have cited this.

• **lines 191-192—an evaluation of the outcomes of publicly funded models...for home birth?**

Yes – thank you. We have added this.

Methods

• **I think the last sentence of the paragraph, on lines 284-285, can be deleted. There will be so few maternal deaths in a sample of this size that nothing can be done with them, statistically. Also maternal death was not an outcome from the Aims.**

Apologies, we are unable to find the sentence and mention of maternal death which you are referring to. We have word searched for maternal deaths with no results.

Results

• **Thanks for leading with the proportion of normal births, rather than the proportion of adverse events! it’s good to challenge the dominant narrative**

Thank you

Reviewer: 2

1. Abstract:

i. **The authors have added a statement to the conclusion to highlight the small numbers overall in the home birth group. I am still concerned however, that without some explicit qualification**

in the conclusions, the statement in the results section that there were no statistically significant differences in perinatal death between the three settings is likely to be misinterpreted. Based on these results I don't think it is possible to rule out an increased perinatal mortality rate in the planned home birth group. I would therefore like to see an explicit statement in the conclusions to the effect that the small numbers of planned home births and the small number of events means that there is considerable uncertainty in relation to perinatal mortality outcomes in this group.

We feel that we have been quite cautious about our findings but we have made changes to the final sentence in response to this comment.

2. Background:

i. This section has been in the main improved by the authors' additions. I did ask for more detail on specific objectives, but on reflection there is now more detail here than is appropriate. I had inferred from the previous version that the study had a primary outcome, normal labour and birth, and a number of secondary outcomes, but I assume from the revisions made that this was not the case. I suggest removing the text which has been added and replacing it with a sentence along the lines of: "Outcomes investigated included normal labour and birth, mode of birth, interventions during labour, postpartum maternal complications and perinatal mortality and morbidity."

It is difficult to know which added text the reviewer would now like removed but we assume it is the dot points of specific objectives. We have replaced this list with the suggested text as now requested.

3. Methods:

i. Again, in the main, my comments have been appropriately addressed and the reference to the separate methodological paper on data linkage is helpful.

ii. Separating and listing the outcomes in Box 2 is helpful, but the mixture of 'type of outcome', list, description and definition here does not help with clarity. Some of my original concerns therefore remain in relation to clarity around description of outcomes. For example "perineal status" is not an outcome – the outcomes relating to perineal status appear to be "intact perineum" and "3rd or 4th degree perineal trauma", which appears later in Box 2, listed under Postpartum complications. The use of the word "includes" should be avoided, since this could imply that there were some other outcomes not listed here. For clarity it would be better simply to list the outcomes, separated out by maternal and perinatal e.g.

Maternal outcomes:

Normal labour and birth (defined as...)

Normal vaginal birth (defined as...)

Forceps birth

Vacuum extraction

Intrapartum Caesarean section

Mode of birth not stated

Episiotomy

Oxytocin augmentation

Epidural or spinal analgesia

Etc

Perinatal outcomes:

Perinatal mortality (defined as...)

Intrapartum stillbirth

Early neonatal death

Etc

It is not necessary in this box to explain that perinatal mortality was presented stratified by

parity as this doesn't relate to the outcome, this is about analysis. The sentence at line 314 should state that Box 2 "lists and defines" all maternal and perinatal outcomes used.

We have made these changes – We decided not to present them as a long list but have categorised them accordingly and removed 'included'.

iii. I still have some issues with the section on data analysis. I may not have been clear enough in my previous comments. Specifically:

i. The sentence about "sphericities and specificities of the data" has been removed and replaced with "For simplicity, percentages were computed for the incidence of events at each birth setting". I'm still not sure what this means – what does "for simplicity" mean here? In fact, for some outcomes n/1000 rather than percentages have been presented. Since the authors have not responded to my original comment about 'repeated measures' of some sort in the dataset, i.e. women who appeared more than once, I assume that this does not apply, but it would be good to have reassurance on this.

We have altered the sentence to include the proportion per 1000 as well. We basically applied the frequency count and obtained the odds ratios. Repeated measures are not applicable in the data analysis.

ii. I think my original comment about analyses using ANOVA may have been unclear. I simply meant that because the sentence about ANOVA appears at the end of the paragraph, after the description of the multivariable analysis, it's a bit confusing (it appears out of order). I suggest that the sentence is moved earlier in the paragraph. For example: "Categorical variables were initially compared using chi-square tests. For continuous data such as maternal age and gestation week, we used general linear mode.... Odds ratios comparing each outcome by planned place of birth were calculated using logistic regression, adjusted for ..."

We have made this change as requested.

iii. I don't think the sentence at lines 353-356 is necessary in this section – it is a limitation, not part of the methods.

We have moved this as suggested.

iv. In one of my original comments I asked whether the authors had carried out any sensitivity analyses, using data from states with more data about demographic factors, to explore the effect of the further adjustment that would be possible using these data. I'm not sure if I understand the authors' response correctly, but I think it indicates that they may have carried out some sensitivity analysis along these lines. I appreciate that they do not want to complicate their tables and the message of their paper. However, if such analyses were carried out they should be described in the methods section and the results reported, even if this simply comprises a brief paragraph in the results section with a link to further tables in a supplementary file.

We did not undertake a sensitivity analysis that is easy to interpret given the differences across the data sets and so we would prefer not to provide this as an additional file.

4. Results:

i. I missed this on first review, but I'm not clear why "3rd / 4th degree perineal trauma" is in Table 3 (Mode of birth and intervention rates). Should it be in Table 4 instead? Also, I

appreciate that “intact perineum” isn’t a postpartum complication so may not fit in Table 4, but it doesn’t really fit in Table 3 either as it’s not mode of birth or an intervention. Perhaps it could be moved to Table 4 and this could be renamed “Maternal postpartum outcomes...”.

We would prefer to keep all the perineal outcomes in one table and intact perineum and episiotomy are not really maternal complications per se. So we have re-named Table 3 to include perineal outcomes and have moved the three perineal outcome rows to the end of the table.

ii. In response to my original comment about the reporting of results about perinatal outcomes, the authors have stated that they “have included a clearer statement to address this”. Where is this statement? They have not made any change that I can see to the section on perinatal outcomes.

Apologies for the lack of clarity in the last iteration of this paper. We have now re-worded as follows:

Although the planned homebirth group had higher odds ratios for intrapartum stillbirth and early neonatal death than the other planned places of birth, the differences were not statistically significant. Combined data on stillbirth during labour, early and late neonatal death indicate that women planning a home birth were no more likely to experience perinatal mortality than those planning a hospital birth (AOR 1.55; 99% CI 0.65-3.69), although the absolute number of deaths was very small (9/8182).

iii. The authors have appropriately suppressed numbers in cells with less than 5 events in Table 5. However, it is often possible to work out what the missing numbers are so this is insufficient, e.g. for the combined mortality variable in the home birth group you can simply subtract the number in the multiparous group from the overall figure. These all need to be checked carefully to make sure that no small numbers can be inferred from other data and further removals made as appropriate. The incidence and unadjusted ORs have been appropriately removed, but the adjusted ORs should be reinstated since they are informative and it is not possible to work backwards from these to calculate the small numbers.

We have reinstated the adjusted odds ratios and removed any raw numbers or rates which could be extrapolated from other cells.

5. Discussion & conclusions

i. I think the sentence about the Birthplace findings (lines 444-7) still needs some minor rewording as it doesn’t quite make sense currently. I suggest “However, it is similar to the findings of the Birthplace in England study, which found a statistically significant higher odds of a composite outcome combining perinatal mortality and selected early neonatal morbidities among primiparous women planning home birth”.

Changes made as requested.

ii. The additional text considering residual confounding is welcome, but I don’t think the first sentence in that paragraph (lines 511-2) makes sense as it confuses selection bias and confounding. My original comment may have been unclear, but selection bias is a separate issue.

We have re-worded the paragraph as follows:

It is possible, despite our best efforts to reduce selection bias, that there remains some residual unobservable differences in the groups. It is possible that women planning to give birth in a birth centre or at home are different from those planning a hospital birth in a number of ways, including their motivation, attitudes to intervention and approach to birth. These are not able to be measured but may impact on the findings in relation to interventions and outcomes.

6. General

i. There are a few instances where “low-risk” has not been replaced with “uncomplicated”, e.g. in the abstract at lines 71 and 85, at line 471 etc.

Thank you for pointing this out. The changes are now made.

ii. Depending on whether sensitivity analyses were carried out (see my comment above) the STROBE checklist may need changing to reflect that.

We have not altered this.

VERSION 3 – REVIEW

REVIEWER	Marit Bovbjerg Oregon State University, USA University College Cork, Ireland
REVIEW RETURNED	17-Sep-2019
GENERAL COMMENTS	The reviewer completed the checklist but made no further comments.
REVIEWER	Dr Rachel Rowe National Perinatal Epidemiology Unit, University of Oxford, United Kingdom
REVIEW RETURNED	03-Sep-2019
GENERAL COMMENTS	<p>Thank you, the authors have done a good job in addressing my comments. There are two points outstanding which need a response.</p> <p>1. Unfortunately the authors’ response to my comments about sensitivity analyses begs more questions than it answers. There are a number of ways in which the results of these sensitivity analyses might have been difficult to interpret, but without more information it is difficult to determine how much detail should be provided in the paper. Whatever is presented in terms of the results of these analyses however, in my view, for the sake of transparency, the fact that these analyses were carried out, with a brief description of the dataset(s) and methods used, should be presented in the paper. Then it would be perfectly reasonable to add a couple of sentences to the results section to explain that the results of these analyses were contradictory, or inconclusive, or difficult to interpret in other ways, and why. This would be meaningful and helpful information, which would improve and not detract from the strength of the paper. If the authors feel that it is not helpful to provide additional tables this would be acceptable,</p>

	<p>but they need to explain in the paper that they are not presenting detailed results and why this is. A couple of sentences added to the limitations section about the sensitivity analyses would also be helpful. Again this would just demonstrate that the research team have considered these important questions, done all that they could to investigate, given the data available, but were not able to draw any firm conclusions. I appreciate that this study has been extremely challenging to carry out and the publication has probably been a long time in preparation, and I don't want to prolong things more than is necessary, but it is important to be open and transparent about what analyses were carried out and their results, even if detailed tables are not presented.</p> <p>2. Thank you for making the changes to Table 5 to suppress small numbers and to reinstate the adjusted odds ratios. I may be wrong, but I think it is still possible to infer from the data in the table that there was one late neonatal death in a planned birth centre birth, so some further redaction may be necessary.</p> <p>3. For what it's worth I don't think the change to the sentence at lines 171-2 (in response to a comment from Reviewer 1) is a good one. I agree with the authors that it does not make sense to refer to the Methods section here. The sentence is an introductory one, setting the scene with policy context. It does not require a precise definition of 'uncomplicated pregnancies' as it's referring to a definition that is contained within a cited document (the ACM guidelines), it is not referring to the definition used in this study.</p>
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VERSION 3 – AUTHOR RESPONSE

Reviewer: 2

Reviewer Name: Dr Rachel Rowe

Institution and Country: National Perinatal Epidemiology Unit, University of Oxford, United Kingdom

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

Thank you, the authors have done a good job in addressing my comments. There are two points outstanding which need a response.

1. Unfortunately the authors' response to my comments about sensitivity analyses begs more questions than it answers. There are a number of ways in which the results of these sensitivity analyses might have been difficult to interpret, but without more information it is difficult to determine how much detail should be provided in the paper. Whatever is presented in terms of the results of these analyses however, in my view, for the sake of transparency, the fact that these analyses were carried out, with a brief description of the dataset(s) and methods used, should be presented in the paper. Then it would be perfectly reasonable to add a couple of sentences to the results section to explain that the results of these analyses were contradictory, or inconclusive, or difficult to interpret in other ways, and why. This would be meaningful and helpful information, which would improve and not detract from the strength of the paper. If the authors feel that it is not helpful to provide additional tables this would be acceptable, but they need to explain in the paper that they are not presenting detailed results and why this is.

A couple of sentences added to the limitations section about the sensitivity analyses would

also be helpful. Again this would just demonstrate that the research team have considered these important questions, done all that they could to investigate, given the data available, but were not able to draw any firm conclusions. I appreciate that this study has been extremely challenging to carry out and the publication has probably been a long time in preparation, and I don't want to prolong things more than is necessary, but it is important to be open and transparent about what analyses were carried out and their results, even if detailed tables are not presented.

We did attempt a sensitivity analysis on the accuracy of the data but we could only do it on very limited outcomes (ie parity). The findings were not helpful in explaining the data or the findings and so we have not included them. Given sensitivity analyses in population based studies like this are not commonly done, and it was probably more of a data exploration and checking process rather than findings per se, we have chosen not to include them.

2. Thank you for making the changes to Table 5 to suppress small numbers and to reinstate the adjusted odds ratios. I may be wrong, but I think it is still possible to infer from the data in the table that there was one late neonatal death in a planned birth centre birth, so some further redaction may be necessary

We have removed the AOR as requested.

3. For what it's worth I don't think the change to the sentence at lines 171-2 (in response to a comment from Reviewer 1) is a good one. I agree with the authors that it does not make sense to refer to the Methods section here. The sentence is an introductory one, setting the scene with policy context. It does not require a precise definition of 'uncomplicated pregnancies' as it's referring to a definition that is contained within a cited document (the ACM guidelines), it is not referring to the definition used in this study.

We have now removed the statement as suggested

VERSION 4 – REVIEW

REVIEWER	Dr Rachel Rowe National Perinatal Epidemiology Unit University of Oxford United Kingdom
REVIEW RETURNED	01-Oct-2019

GENERAL COMMENTS	<p>Thank you for responding to my remaining comments. With respect to the sensitivity analyses, I am satisfied that important sensitivity analyses, of the kind I was referring to, which might have explored the effect of greater adjustment for socio-demographic characteristics, were not in fact carried out. I am happy with no further changes being made to the paper in this regard.</p> <p>In Table 5 I was not suggesting that the AOR was removed. It is fine to keep the AOR for the late neonatal death birth centre group as it is not possible to infer 1 late neonatal death in the planned birth centre group from the AOR. However, by subtracting the 17 stillbirths and 14 early neonatal deaths from the total of 32 perinatal deaths in the birth centre group it is possible to infer that there was 1 late neonatal death in this group, so some further</p>
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	redaction of the number of events, incidence and unadjusted ORs may be required, depending on what the authors' consider to be required by their regulatory approvals. This can be done at the authors'/editor's discretion.
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