PEER REVIEW HISTORY

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ARTICLE DETAILS

| TITLE (PROVISIONAL) | The Safer Baby Bundle: Study protocol for the economic evaluation of a quality improvement initiative to reduce stillbirths |
|---------------------|------------------------------------------------------------------------------------------------------------------|
| AUTHORS             | Callander, Emily; Andrews, Christine; Sketcher-Baker, Kirstine; Nicholl, Michael; Farrell, Tanya; Karger, Shae; Flenady, Vicki |

VERSION 1 – REVIEW

| REVIEWER             | Hanson, Claudia  |
|----------------------|------------------|
|                      | Karolinska Institute, Dept Public Global Health |
| REVIEW RETURNED      | 29-Dec-2021      |

GENERAL COMMENTS

Thank you providing me with the opportunity to review the Safer Baby Bundle – the economic evaluation.
My comments relate to the key trial write-up as relevant to the economic evaluation, not the economic evaluation methods per se as I am not an economist. However, is view that you plan a cost-effectiveness analysis, an appropriate description is warranted, and this is not sufficiently provided. I feel the authors would profit from reviewing CONSORT main trial checklists – not that I think they need to follow for the economic evaluation, but to help to check that all is sufficiently clearly described as relevant for the economic effect evaluation.

Abstract and title
I am missing the study design in the title. Also, there is no design described in the abstract?
Sure there are many stillborn babies, still, the number is quite low in HICs, thus the first sentence gives a wrong impression of the burden this protocol aims to address
I am missing the implementation setting, inclusion/exclusion criteria?

What is the origin of the population-based data set? There must be references / an official title?

Main write-up
The introduction is fine, but I wonder, is there no introduction needed to economic methods?
In the method section I expect more information on how the main trial is evaluated. There is only one sentence “.. impact evaluation exploring the effect on late gestational age” .. which is misleading as the verb exploring is typically indicating qualitative research? Please add here substantially on how the impact evaluation is done, the data sources, etc. As you aim to include an effectiveness evaluation, you will need to explain how the “effect” is assessed. Please also add early on the design: a before-after without control? Or with control – all not clearly outlined, sorry – I am trying too much to find pieces.
I am missing a hint who is implementing. Probably via ANC? Midwives/doctors ?? in the hospital? How can you reach women
early? You indicate that you want to costs salary, so the “who” is important. Is there any official description of the PDC? It is strange that this is not referenced. I am also missing clear timeframes throughout in the text, which data, when, which source, covering which inputs? Again, I finally found in the graph, but this needs to be upfront, also explaining what is intervention / control. In view that you also want to include outcomes selected 5 years post-partum, there will be very limited numbers as the intervention will need to reach these children? I have not checked if the main protocol has a sample size calculation, but I expect reference to the sample size. In the limitation section I miss a reference to the sample size and the quality of the data sources. I hope this will help you revise.

REVIEWER
Jackson, Louise
University of Birmingham, Health Economics Unit

REVIEW RETURNED
10-Feb-2022

GENERAL COMMENTS

General comments
This manuscript presents a protocol for the economic evaluation of the Safer Baby Bundle quality improvement initiative in Australia. The authors propose to use healthcare administrative records and will forecast likely longer term health outcomes to five years post-partum. This paper addresses an important and under-researched issue, namely the cost-effectiveness of interventions to reduce stillbirth. Such research could provide valuable information for those involved in providing healthcare in Australia and internationally. I enjoyed reading the paper and the proposed use of real-world data is a strength of the study.

The paper raises some interesting points, and the planned evaluation seems comprehensive. Some suggestions for each section of the paper are outlined below.

Introduction
The authors set out some of the background to their research and explain why it is important to understand the cost-effectiveness of interventions to reduce stillbirth. A little more background information would be helpful to give a fuller overview of previous economic evaluations of interventions to reduce stillbirth (and related areas).

Methods
The authors have set out the methods used in the study. Some detail is given on the costing approach and the data to be analysed. However, more justification is needed on the five-year time horizon for longer-term health outcomes (rather than a lifetime approach), drawing on the existing evidence base. The authors mention that they will be guided by the ISPOR RCT-CEA guidance. As the authors point out the study is not conducted alongside a trial, so some explanation is needed on why this guidance is relevant. The authors plan to adopt a health funder perspective for the study. Further justification is needed around this, given the broader societal impacts associated with stillbirth. The authors propose to use one way sensitivity analyses – further explanation is needed around this to demonstrate that all potential aspects of uncertainty will be explored.
**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1
Dr. Claudia Hanson, Karolinska Institute Comments to the Author:

Thank you providing me with the opportunity to review the Safer Baby Bundle – the economic evaluation.

My comments relate to the key trial write-up as relevant to the economic evaluation, not the economic evaluation methods per se as I am not an economist. However, is view that you plan a cost-effectiveness analysis, an appropriate description is warranted, and this is not sufficiently provided. I feel the authors would profit from reviewing CONSORT main trial checklists – not that I think they need to follow for the economic evaluation, but to help to check that all is sufficiently clearly described as relevant for the economic effect evaluation.

Abstract and title
I am missing the study design in the title. Also, there is no design described in the abstract?

Author response: The study design is an ‘economic evaluation’ which is currently noted in the Title. We have edited the abstract to explicitly state the study design, as requested.

Sure there are many stillborn babies, still, the number is quite low in HICs, thus the first sentence gives a wrong impression of the burden this protocol aims to address I am missing the implementation setting, inclusion/exclusion criteria?

Author response: This first sentence of the Abstract has been edited to reflect the HIC setting, as requested. The implementation setting is specified in the first sentence of the Methods section in the Abstract. The intervention is being applied at the state-level, with sites opting to participate or not, and no individual woman recruitment, this is now clarified in the Abstract.

What is the origin of the population-based data set? There must be references / an official title?

Author response: Per abstract convention, no references to the administrative data sources have been in included in the abstract. The dataset is fully described in the full-text.

Main write-up
The introduction is fine, but I wonder, is there no introduction needed to economic methods? In the method section I expect more information on how the main trial is evaluated. There is only one sentence “.. impact evaluation exploring the effect on late gestational age” .. which is misleading as the verb exploring is typically indicating qualitative research?

Author response: This sentence has been edited for clarity. The methods for the overall evaluation of the Safe Baby Bundle has been published previously in a separate publication, and this manuscript focuses solely on the economic evaluation. The economic evaluation is being conducted independently of the overall evaluation, and thus there is no need to detail the overall evaluation. This is now noted, please see page 6.
Please add here substantially on how the impact evaluation is done, the data sources, etc. As you aim to include an effectiveness evaluation, you will need to explain how the “effect” is assessed. Please also add early on the design: a before-after without control? Or with control – all not clearly outlined, sorry – I am trying too much to find pieces.

I am missing a hint who is implementing. Probably via ANC? Midwives/doctors ?? in the hospital? How can you reach women early? You indicate that you want to costs salary, so the “who” is important.

Author response: Additional details of the intervention has been added, please see page 5.

Is there any official description of the PDC? It is strange that this is not referenced.

Author response: The PDC is an online electronic medical record data system, which is described on page 7-8.

I am also missing clear timeframes throughout the text, which data, when, which source, covering which inputs? Again, I finally found in the graph, but this needs to be upfront, also explaining what is intervention / control. In view that you also want to include outcomes selected 5 years post-partum, there will be very limited numbers as the intervention will need to reach these children?

Author response: All data from 1st of January 2016 and 31st December 2023 is being collected. The post-implementation phase stretches from January 2022 to December 2023, as noted on page 6; the pre-implementation phase is described on page 7. The text headings have been edited to make the implementation and pre-implementation stages easier to identify.

I have not checked if the main protocol has a sample size calculation, but I expect reference to the sample size. In the limitation section I miss a reference to the sample size and the quality of the data sources I hope this will help yo revise

Author response: There is no sample, this is a whole of population analysis, this is now clarified on page 6.

Reviewer: 2
Dr. Louise Jackson, University of Birmingham Comments to the Author:
General comments
This manuscript presents a protocol for the economic evaluation of the Safer Baby Bundle quality improvement initiative in Australia. The authors propose to use healthcare administrative records and will forecast likely longer term health outcomes to five years post-partum. This paper addresses an important and under-researched issue, namely the cost-effectiveness of interventions to reduce stillbirth. Such research could provide valuable information for those involved in providing healthcare in Australia and internationally. I enjoyed reading the paper and the proposed use of real-world data is a strength of the study.

The paper raises some interesting points, and the planned evaluation seems comprehensive. Some suggestions for each section of the paper are outlined below.

Introduction
The authors set out some of the background to their research and explain why it is important to understand the cost-effectiveness of interventions to reduce stillbirth. A little more background
information would be helpful to give a fuller overview of previous economic evaluations of interventions to reduce stillbirth (and related areas).

Author response: Details of previous economic evaluations conducted in this area have been added to the Introduction section, please see page 5.

Methods
The authors have set out the methods used in the study. Some detail is given on the costing approach and the data to be analysed. However, more justification is needed on the five-year time horizon for longer-term health outcomes (rather than a lifetime approach), drawing on the existing evidence base.

Author response: There is limited guidance on time horizons for use in maternal economic evaluations. As noted, the five-year horizon was considered to give balance to the uncertainty that would be introduced with a lifetime horizon from birth, which will be influenced by many factors beyond the SBB. However, in response to this comment, we have included a lifetime horizon scenario as a sensitivity analysis see page 6.

The authors mention that they will be guided by the ISPOR RCT-CEA guidance. As the authors point out the study is not conducted alongside a trial, so some explanation is needed on why this guidance is relevant.

Author response: This has been addressed please see page 6.

The authors plan to adopt a health funder perspective for the study. Further justification is needed around this, given the broader societal impacts associated with stillbirth.

Author response: The choice of health funder perspective is to align with the preferred study design of Australian funding decision-makers, as the ultimate end-audience for this analysis. This is now noted on page 6. This is also a within-study analysis, with no modelled input utilised, and so broader societal costs are not available. This is now clarified on page 6.

The authors propose to use one way sensitivity analyses – further explanation is needed around this to demonstrate that all potential aspects of uncertainty will be explored.

Author response: The selection of variables to be included in the one-way sensitivity analysis will be exploratory, and depend upon the influence on results - as such they are unable to be pre-specified.

General points
More information is needed on the existing economic evidence relating to stillbirth and how this study will add to the literature. This would also help in terms of justifying the planned approach to evaluation. Careful proofreading is needed in places to ensure all ideas are expressed as clearly as possible.

Author response: Further edits for clarity have been made throughout.

Reviewer: 1
Competing interests of Reviewer: I declare no competing interests

Reviewer: 2
Competing interests of Reviewer: None - I work in a similar area but I am not currently working on any studies relating to stillbirth
| REVIEWER            | Hanson, Claudia                  |
|---------------------|----------------------------------|
|                     | Karolinska Institute, Dept Public Global Health |
| REVIEW RETURNED     | 21-Jun-2022                      |
| **GENERAL COMMENTS** | Thank you very much, reads much clearer now |

| REVIEWER            | Jackson, Louise                  |
|---------------------|----------------------------------|
|                     | University of Birmingham, Health Economics Unit |
| REVIEW RETURNED     | 28-Jun-2022                      |
| **GENERAL COMMENTS** | I am happy that the authors have satisfactorily addressed my comments. |