



STUDY PROTOCOL

REVISED

# Women's views and experiences of augmentation of labour with synthetic oxytocin infusion. A protocol for a qualitative evidence synthesis. [version 2; peer review: 2 approved]

Previously titled: 'Women's views and experiences of augmentation of labour with synthetic oxytocin infusion: a protocol for a qualitative evidence synthesis'

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## Abstract

**Background:** Augmentation of labour (AOL) is the most common intervention to treat labour dystocia. Previous research reported extensive disparities in AOL rates across countries and institutions. Despite its widespread use, women's views on and experiences of intrapartum augmentation with infused synthetic oxytocin are limited.

**Methods:** A qualitative evidence synthesis on women's views and experiences of AOL with synthetic oxytocin after spontaneous onset of labour will be conducted. Qualitative studies and studies employing a mixed methods design, where qualitative data can be extracted separately, will be included, as will surveys with open-ended questions that provide qualitative data. A systematic search will be performed of the databases: MEDLINE, CINAHL, EMBASE, PsycINFO, Maternity and Infant Care and Web of Science Core Collection from the date of inception. The methodological quality of included studies will be assessed using the Evidence for Policy and Practice Information and Co-ordinating Centre's appraisal tool. A three-stage approach, coding of data from primary studies, development of descriptive themes and generation of analytical themes, will be used to synthesise findings. Confidence in findings will be established by the Grading of Recommendations Assessment, Development and Evaluation-Confidence in the Evidence from Reviews of Qualitative research.

**Discussion:** This qualitative evidence synthesis may provide valuable information on women's experiences of AOL and contribute to a

## Open Peer Review

Approval Status

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1. **Claire Feeley** , King's College London, London, UK

2. **Linda Biesty** , National University of Ireland Galway, Galway, Ireland

Any reports and responses or comments on the article can be found at the end of the article.

review of clinical practice guidelines for maternity care providers.

**PROSPERO registration:** CRD42021285252 (14/11/2021)

### Keywords

Birth experience, Oxytocin, Pregnancy, Labor, Obstetric, Qualitative systematic review, acceleration of labour

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**REVISED Amendments from Version 1**

After the reviewers' feedback, the main modification in this version has been the addition of a reflexivity statement where the authors' backgrounds are discussed.

Other minor modifications that have been made are listed below:

1. One reference on the impact of negative childbirth experiences on women's mental health has been included (Ertan *et al.*, 2021) (Introduction)
2. The databases searched to source grey literature have been added (EThOS, DART-Europe, and the WHO International Clinical Trials Registry Platform) (Search strategy and study selection).
3. We have clarified that the data from the included studies will be extracted from both the findings and discussion sections (Data extraction and synthesis section).

Ertan D., Hingray C., Burlacu E., Sterlé A. & El-Hage W. (2021) Post-traumatic stress disorder following childbirth. *BMC Psychiatry* 21(1), 155. DOI:10.1186/s12888-021-03158-6.

**Any further responses from the reviewers can be found at the end of the article**

## Introduction

Augmentation of labour (AOL), the process of stimulating the uterus to increase the frequency, duration, and intensity of contractions after spontaneous onset of labour (World Health Organization (WHO), 2014), has been identified as one of the most common obstetric interventions (Miller *et al.*, 2016; Seijmonsbergen-Schermers *et al.*, 2020). Typically performed using a synthetic oxytocin infusion following artificial rupture of membranes, it is indicated in the management of labour dystocia, one of the main underlying reasons for performing caesarean sections (Boyle *et al.*, 2013; Riddell *et al.*, 2017). The proportion of women who have their labour augmented ranges from 22% to 71% in nulliparous women, and from 7% to 38% in multiparous women in high income countries, even after adjusting by population characteristics (Seijmonsbergen-Schermers *et al.*, 2020). Wide variation is also seen across maternity services within the same country, suggesting a potential misuse in clinical practice (Helbig *et al.*, 2019; Seijmonsbergen-Schermers *et al.*, 2018).

While the main indication for AOL is for the management of labour dystocia (Bugg *et al.*, 2013), the lack of consensus on the diagnostic criteria for labour dystocia has brought into question the robustness of its diagnosis (Karaçam *et al.*, 2014; Neal *et al.*, 2015a; Neal *et al.*, 2015b; Oladapo *et al.*, 2018). In addition, there does not appear to be agreement on the regimens and doses of oxytocin that should be used (Daly *et al.*, 2020). Two systematic reviews on AOL have demonstrated its effectiveness in accelerating labour progression, with a reduction of two hours in mean labour duration (Bugg *et al.*, 2013; Kenyon *et al.*, 2013). However, data regarding women's experiences of AOL in both reviews was limited and recent studies have shown that AOL has been associated with

negative childbirth experiences (Johansson & Finnbogadóttir, 2019; Nahae *et al.*, 2020; Nystedt & Hildingsson, 2018).

Childbirth is a transcendental life experience that can lead to either positive feelings of empowerment and fulfilment or negative feelings of disappointment and fear, and can influence women's decision towards having another baby or a desire for a caesarean section in future pregnancies (Fuglenes *et al.*, 2011; Khajehei & Doherty, 2018; Larkin *et al.*, 2012; Nystedt & Hildingsson, 2014; Suwanrath *et al.*, 2021). Moreover, women with negative childbirth experiences are more vulnerable for developing serious mental health issues, including posttraumatic stress disorder (Ertan *et al.*, 2021). The WHO recommendations on intrapartum care for a positive childbirth experience state that most women pursue a physiological birth and want to be involved in decision-making when medical interventions are needed (WHO, 2018).

Women's experiences and perspectives of AOL are not well understood. While there is a plethora of quantitative research on AOL, there are very few qualitative studies about women's experiences. This qualitative evidence synthesis (QES) aims to integrate the findings from studies reporting on women's views and experiences of AOL with synthetic oxytocin after spontaneous onset of labour in order to deepen understanding and contribute to future reviews of clinical practice guidelines for maternity care providers.

## Protocol

### Inclusion criteria

We use the SPIDER (sample, phenomenon of interest, design, evaluation, and research type) tool (Cooke *et al.*, 2012) to identify the key concepts for inclusion criteria in the QES.

**-Sample:** women of any age, parity, and cultural background who, after spontaneous onset of labour, underwent AOL with synthetic oxytocin.

**-Phenomenon of Interest:** women's views and experiences of AOL with synthetic oxytocin. Alternative terminology referring to AOL such as augmentation, acceleration or stimulation of labour has been considered to ensure a wide retrieval of data (Table 1).

**-Design:** qualitative studies of any design including phenomenology, grounded theory, ethnography, action research and feminist research. Mixed methods design studies where qualitative data can be extracted separately will also be considered for inclusion, as well as survey designs with open-ended questions that provide qualitative data.

**-Evaluation:** inductive themes representative of women's views and experiences of AOL with synthetic oxytocin.

**-Research type:** published qualitative studies, in English or Spanish language.

### Search strategy and study selection

An initial scoping search of MEDLINE and CINAHL was undertaken to identify potentially relevant studies and search terms. Search terms were developed using the SPIDER acronym

and adapted for each database (Table 1). The databases to be searched are MEDLINE, CINAHL, EMBASE, PsycINFO, Maternity and Infant Care and Web of Science Core Collection. We will expand our search by additionally searching the grey literature in thesis repositories (EThOS and DART-Europe) and the WHO International Clinical Trials Registry Platform. The reference lists of the studies identified for inclusion will also be reviewed.

No time restrictions will be applied, and studies published in English or Spanish will be included. Following a search of each database, all citations retrieved will be uploaded into EndNote (version EN20) and duplicates removed. The remaining records will be uploaded to Covidence software for eligibility screening. Titles and abstracts will be screened by two independent reviewers (SAP and DOM) against the inclusion criteria. Full texts of potentially relevant studies will be reviewed. Reasons for exclusion of full text of papers that do not meet the inclusion criteria will be recorded and reported in the full report. Any disagreements that arise between the reviewers at each stage of the screening process will be resolved through discussion, or with an additional review author (DD) until consensus is achieved. The results of the search and the study inclusion process will be reported in full in the final QES and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram (Page et al., 2021).

**Assessment of methodological quality**

Appraising methodological quality of the studies included in a QES can strengthen its comprehension and applicability. There are many appraisal tools available and researchers might decide which to use according to their objectives, expertise, time and resources (Majid & Vanstone, 2018).

In this review, we have chosen the Evidence for Policy and Practice Information (EPPI) and Co-ordinating Centre’s appraisal tool. This tool assesses the quality of the methods and the study reporting across 12 criteria (Table 2). It was designed specifically for synthesising qualitative data (Thomas et al., 2003) and has been successfully used in previous QES on maternal health (Panda et al., 2018; Smith et al., 2021).

Two reviewers will independently quality assess the primary studies (SAP and DOM). The results of the critical appraisal will be reported in narrative and tabular form. All studies, regardless of the results of their methodological quality, will undergo data extraction and synthesis (where possible), as even poorly conducted qualitative studies may provide important data to our QES.

**Data extraction and synthesis**

Data will be extracted using a purposively designed data extraction form (Alòs-Pereñíguez et al., 2021). The data extracted will include specific details about the setting, study period, aim, design, description of the population, methods of data collection and analysis, and findings regarding women’s views and experiences of AOL with synthetic oxytocin. Regarding the findings, data from both, the results and discussion sections will be included. When synthesising the data from the studies included, we will use the thematic synthesis approach developed by Thomas & Harden (2008). This method enables description of recurring themes in the primary studies, as well as creating new concepts and hypotheses. Following the authors’ guidance, the synthesis will be performed in three sequential stages that may overlap to some degree: 1) line by line coding of data from primary studies, 2) development of descriptive themes and 3) generating analytical themes. Coding will be conducted independently by SAP and one other review

**Table 1. Search terms.**

<b>Sample</b>	women* OR woman* OR mother* OR parturit* OR matern* OR pregnan* OR nullipar* OR multipar* OR postnatal* OR perinatal* OR post-natal* OR peri-natal* OR childbirth* OR birth* OR postpartum*
<b>Phenomenon of Interest</b>	(augment* OR accelerat* OR stimulat* OR speed*) N4 (labor* OR labour* OR birth* OR parturit* OR childbirth* OR "child birth*") OR oxtoc* OR oxytoc* OR ocytoc* OR ocitoc* OR pitocin OR syntocinon OR "oxytocin-induce*" OR "oxytocin prepar*"
<b>Design or Evaluation</b>	<p>("qualitativ*" OR "qualitative stud*" OR "qualitative analysis" OR "qualitative method*" OR "focus group*" OR interview* OR "triangulat*" OR "narrative*" OR "naturalistic inquir*" OR "feminist research*" OR "grounded theor*" OR "hermeneutic*" OR "phenomenol*" OR "ethnograph*" OR "ethnonurs*" OR "ethnological research" OR "ethnomethodolog*" OR "purposive sampl*" OR "theoretical sampl*" OR "thematic analysis" OR "content analysis" OR "discourse analysis" OR "action research" OR "participatory research" OR "constant comparative method" OR "mixed model" OR "mixed method*" OR "mixed design*" OR "multiple method*" OR multimethod* OR "open-ended question*" OR "open-ended survey*" OR "open-ended interview*")</p> <p>OR</p> <p>(experien* OR view* OR percept* OR perceiv* OR attitud* OR believ* OR belief* OR perspective* OR opinion* OR express* OR thought* OR think* OR feel* OR reaction* OR emotion* OR comprehen* OR understand* OR stance* OR "personal valu*" OR awar* OR approach* OR "self report*" OR self-report* OR emote*)</p>
<b>Research type</b>	Published studies in English OR Spanish language

author (DOM and DD). Subsequently, similarities and differences will be identified, and codes will be grouped into descriptive categories and, through their further interpretation, reflection and discussion within the review team analytical themes will be generated.

### Assessing confidence in the findings

The level of confidence in the review findings will be established using Grading of Recommendations Assessment, Development and Evaluation-Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) (Booth *et al.*, 2018; Colvin *et al.*, 2018; Glenton *et al.*, 2018; Lewin *et al.*, 2018a; Lewin *et al.*, 2018b; Munthe-Kaas *et al.*, 2018; Noyes *et al.*, 2018). GRADE-CERQual assesses, individually, every distinct review finding according to its four components: the methodological limitations, coherence,

extant or adequacy of contributing data, and relevancy to the review question. Then, an overall assessment of confidence in each finding is categorised as high, moderate, low, or very low confidence (Table 3). Findings will be deemed to be of 'high confidence' at the outset and will be downgraded accordingly if there are concerns regarding any of the GRADE-CERQual components. Following the GRADE-CERQual recommendations, this process will be performed independently by two reviewers (SAP and DOM), facilitating opportunities for reflection and discussion within the review team (Lewin *et al.*, 2018a).

### Study status

A total of 9306 articles were retrieved and title and abstract screening is in progress. The review will be finished in February 2022.

**Table 2. Criteria for methodological quality assessment (Thomas *et al.*, 2003).**

<i>Quality of study reporting</i>	A - Aims and objectives clearly reported
	B - Adequately described the context of the research
	C - Adequately described the sample & sampling methods
	D - Adequately described the data collection methods
	E - Adequately described the data analysis methods
<i>There was good or some attempt to establish the:</i>	F - Reliability of the data collection tools
	G - Validity of the data collection tools
	H - Reliability of the data analysis
	I - Validity of the data analysis
<i>Quality of the methods</i>	J - Used the appropriate data collection methods to allow for expression of views
	K - Used the appropriate methods for ensuring the analysis was grounded in the views
	L - Actively involved the participants in the design and conduct of the study

**Table 3. GRADE-CERQual assessment (Lewin *et al.*, 2018b).**

Level of confidence	Definition
High	It is highly likely that the review finding is a reasonable representation of the phenomenon of interest
Moderate	It is likely that the review finding is a reasonable representation of the phenomenon of interest
Low	It is possible that the review finding is a reasonable representation of the phenomenon of interest
Very low	It is not clear whether the review finding is a reasonable representation of the phenomenon of interest

## Discussion

This QES will be the first to date to synthesise qualitative research on women's views and experiences of AOL with synthetic oxytocin after spontaneous onset of labour. Due to the frequency with which AOL is carried out in modern maternity care, it is vital that midwives, obstetricians, and policy makers have a clear understanding of how women experience this intervention. The findings of this review will provide a deeper insight into the current gaps in clinical practice. This evidence will potentially support the development of new strategies to improve women's care into the future.

We will disseminate the findings of this QES through publication in a peer-reviewed journal that predominantly publishes maternity care research and through academic conference presentations. Social media posts (e.g. Instagram and Twitter) will be also employed as part of the dissemination strategy.

## Reflexivity statement

In accordance with rigour in qualitative research, it is important that the authors discuss how their background or expertise may have influenced the interpretation of the findings (Barrett *et al.*, 2020). SAP is a PhD student with a clinical background in midwifery. She became interested in AOL while working in acute maternity settings, where she observed and performed this intervention. Augmentation of labour has become her PhD topic.

DOM, Lecturer in Midwifery, is a general nurse, midwife and clinical midwife teacher. DOM has experience in both quantitative and qualitative methodologies, including expertise in QES.

DD is an Associate Professor in Midwifery. Her areas of methodological research expertise include cohort studies, mixed methods studies, qualitative research, and randomised trials. DD has conducted previous research on the use of synthetic

oxytocin during labour. She led a multinational study that highlighted the variations in the regimens and dosages on synthetic oxytocin use.

Acknowledging that the findings of this QES will be the research teams' interpretation, several procedures will be put into practice to ensure trustworthiness, i.e two independent coders, keeping a research diary which will document thoughts and direction from the beginning of the process of undertaking the QES, and frequent discussions within the research team to agree evolution of descriptive themes to analytical themes. To add to the transparency of the analytic process, quotations from the primary studies to support the results will be provided.

## Data availability

### Underlying data

No data are associated with this article.

### Extended data

Open Science Framework: Women's views and experiences of augmentation of labour with synthetic oxytocin. A protocol for a qualitative evidence synthesis, <https://doi.org/10.17605/OSF.IO/2QYJC> (Alòs-Pereñíguez *et al.*, 2021).

This project contains the following extended data:

Appendix 1: Data.Extraction.Form.Excel.

### Reporting guidelines

Open Science Framework: PRISMA-P Checklist for 'Women's views and experiences of augmentation of labour with synthetic oxytocin infusion. A protocol for a qualitative evidence synthesis': <https://doi.org/10.17605/OSF.IO/2QYJC>.

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/) (CC-BY 4.0).

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## Open Peer Review

Current Peer Review Status:  

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### Version 2

Reviewer Report 27 April 2022

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Linda Biesty 

School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland

No further comments to add. Wishing the team the best of luck with their QES. I am looking forward to reading the completed work.

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** My research areas of interest lie in all aspects of midwifery and maternity care. My methodological areas of expertise are qualitative research methodologies and methods including qualitative evidence synthesis.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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### Version 1

Reviewer Report 07 February 2022

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Linda Biesty 

School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland

This is an incredibly important study and I am delighted to read the protocol. Some minor points



of thought that the review team might consider:

- In the Introduction interesting information is provided in relation to the AOL ranges, variation across criteria, services etc. have the team considered how these variations may impact on their synthesis?
- In the assessment of methodological quality have the team considered how they will interpret Criteria R,G,H and I, given that the prompts of the criteria speak to reliability and validity?
- The extraction of the "findings" - the team should indicate if they will include findings from findings / results sections of included studies, from discussion section or both?
- I suggest that it is important that the team include a reflexive section in their protocol to highlight how their professional and research backgrounds will influence their engagement with all methods of this QES.

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** My research areas of interest lie in all aspects of midwifery and maternity care. My methodological areas of expertise are qualitative research methodologies and methods including qualitative evidence synthesis.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Author Response 31 Mar 2022

**Silvia Alòs Pereñíguez**, Trinity College Dublin, Dublin, Ireland

Thank you for considering our protocol and giving us some comments and suggestions that will add to the quality of this QES. We have addressed each comment in the table below and highlighted changes in the text of the manuscript.

- *In the Introduction interesting information is provided in relation to the AOL ranges, variation across criteria, services etc. have the team considered how these variations may impact on their synthesis?*

- **Response:** Our QES have included 25 studies providing qualitative data on women's views and experiences of AOL with synthetic oxytocin infusion from 14 different countries. Of these, some have high AOL rates, others not. This has emerged in our preliminary findings. For example, some women expected to be augmented during labour, while others did not anticipate an AOL and did not read/seek information about it. We feel that the large and varied dataset will ensure that variation rates of AOL will not negatively impact on our QES. Furthermore, assessing the quality of our review findings using CERQual and, in particular, the 'adequacy and relevance' components will further address any concern about variations in prevalence of AOL in different jurisdictions.
- *In the assessment of methodological quality have the team considered how they will interpret Criteria R,G,H and I, given that the prompts of the criteria speak to reliability and validity?*
- **Response:** Regarding the methodological quality appraisal, we agreed to use the different criteria as explained in the original article (Thomas *et al.* 2003). For example, regarding the "Reliability of the data collection tools" (F), we considered they met the criteria if the authors used a topic guide or they provided examples of the topics addressed during the interviews. For "Validity of the data collection tools" (G), any type of recording was considered sufficient. Regarding "Reliability of the data analysis" (H), we considered the criteria met if the more than one author participated in the data analysis and/or if the authors contacted an additional person with qualitative expertise to review the data analysis. We also considered the amount of data provided to support their findings. Regarding "Validity of the data analysis" (I), the criteria was met if the authors conducted negative cases analysis and/or member checking of the preliminary findings.
- *The extraction of the "findings" - the team should indicate if they will include findings from findings / results sections of included studies, from discussion section or both?*
- **Response:** We have included data from both results and discussion sections. Added: 'Regarding the findings, data from both, the results and discussion sections will be included'.
- *I suggest that it is important that the team include a reflexive section in their protocol to highlight how their professional and research backgrounds will influence their engagement with all methods of this QES.*
- **Response:** Added. Please, refer to section "Reflexivity statement".

**Competing Interests:** No competing interests were disclosed.

Reviewer Report 31 January 2022

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**Claire Feeley** 

King's College London, London, UK

Thank you for giving me the opportunity to review this timely and important qualitative systematic review regarding women's experiences of AOL. It is a very exciting piece of work and I look forward to reading the findings.

Some minor but important comments:

- **Introduction:**
  - Wouldn't agree 'traditionally' is the right term, maybe typically? Although in the US they are known for AOL with membranes intact...!
  - Need some further acknowledgement/discussion around the huge variation of rates of AOL, why this might be, what does the literature say? That you are focusing on spontaneous labor, this is very important to consider. Birth setting/planned place of birth and where labor is mostly experienced for example will influence the rates of synthesis. Perhaps a minor mention of non-pharma methods e.g. water immersion reduces transfer rates from homebirth/FMU, which haven't had much look in via research? A great opportunity to critique these statistics.
  - Negative experiences may also mean traumatic experiences/PTSD a point that asserts the importance of getting labor care right so would add this in. (It also influences women to opt out of maternity care altogether, a key point for maternity services to consider).
- **Search strategy:** What sort of grey literature, be specific.
- **Quality appraisal:** Not convinced this tool is appropriate for qualitative papers, much debate out there appraising quality in qualitative reviews but I personally agree it should be done. However, this tool reads as a quant tool- reliability/validity are positivist terms, you want to look for trustworthiness. Strongly suggest changing this.

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Midwifery practice, women's experiences of care, midwives supporting women outside of the guidelines, normal birth across the risk spectrum

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Author Response 31 Mar 2022

**Silvia Alòs Pereñíguez**, Trinity College Dublin, Dublin, Ireland

### Reviewer comment

#### Reply

- *Introduction: Wouldn't agree 'traditionally' is the right term, maybe typically? Although in the US they are known for AOL with membranes intact...!*
- **Response:** Yes, we agree. Typically might be more appropriate.
  
- *Need some further acknowledgement/discussion around the huge variation of rates of AOL, why this might be, what does the literature say? That you are focusing on spontaneous labor, this is very important to consider. Birth setting/planned place of birth and where labor is mostly experienced for example will influence the rates of synthesis. Perhaps a minor mention of non-pharma methods e.g. water immersion reduces transfer rates from homebirth/FMU, which haven't had much look in via research? A great opportunity to critique these statistics.*
- **Response:** Although we acknowledge the importance and the effectiveness of non-pharmacological methods for AOL, this QES will focus on AOL with synthetic oxytocin infusion. Our intention for the full report is to include a paragraph about other non-pharmacological methods that have demonstrated to be effective in managing prolonged labour (i.e, water immersion). Previous research suggested a potential overuse in clinical practice. Further discussion will be included in the QES. Added:
  - [...] suggesting a potential misuse in clinical practice.
  - As briefly discussed in the protocol, probably one of the main contributory causes to this disparity is that there is no clear diagnosis criteria for labour dystocia.
  - [...] the lack of consensus on the diagnostic criteria for labour dystocia has brought into question the robustness of its diagnosis.
  - Our preliminary findings also suggest the need to improve the indications for AOL. This will be also discussed in our QES.
  
- *Negative experiences may also mean traumatic experiences/PTSD a point that asserts the importance of getting labor care right so would add this in. (It also influences women to opt out of maternity care altogether, a key point for maternity services to consider).*
- **Response:** Yes, birth trauma is an important health problem that needs to be considered when talking about childbirth experiences. Added: 'Moreover, women

with negative childbirth experiences are more vulnerable to developing serious mental health issues, including posttraumatic stress disorder (Ertan et al. 2021)

- *Search strategy: What sort of grey literature, be specific.*
- **Response:** Added: 'We will expand our search by additionally searching the grey literature in thesis repositories (ETHOS and DART-Europe) and the WHO International Clinical Trials Registry Platform. The reference lists of studies identified for inclusion will also be reviewed'.
- *Quality appraisal: Not convinced this tool is appropriate for qualitative papers, much debate out there appraising quality in qualitative reviews but I personally agree it should be done. However, this tool reads as a quant tool- reliability/validity are positivist terms, you want to look for trustworthiness. Strongly suggest changing this.*
- **Response:** Although the terms reliability and validity may be considered as quantitative terms, Evidence for Policy and Practice Information (EPPI) and Co-ordinating Centre's appraisal tool was designed specifically for synthesising qualitative studies (Thomas et al. 2003). It assesses the studies through 12 criteria and has been successfully used in previous QES on maternal health (Panda et al. 2018, Smith et al. 2021a, Smith et al. 2021b)

**Competing Interests:** No competing interests were disclosed.

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