Author’s response to reviews

Title: Reducing unnecessary caesarean sections: scoping review of financial and regulatory interventions

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Author’s response to reviews:

Reviewer #1:

Reviewer comment:
This scoping review tackles an important subject—the safety and effectiveness of financial, regulatory, and legislative interventions to reduce CS rates—providing relevant and timely information for policies and research related to lowering CS rates. Overall, the introduction/rationale and methods are sound. However, the sheer volume of details of interventions included and their results necessitates careful consideration of how to best organize and present the data and conclusions for readability and comprehension.

Authors' responses
A more integrated synthesis of results across studies and intervention categories now provided, rather than a listing of individual studies and effects of interventions. Repetition of information presented in tables now avoided in the main text as appropriate. Discussion section also revised to ensure focused interpretation of findings. Overall, length of review (main text) now reduced from 4843 to 3777 words.

Reviewer comment:
Abstract: if possible within word limits, provide additional details regarding number of studies identified in the search review, review/data extraction process, study population (low risk women), specify that line 54-56 was based on 2 studies.
Authors responses
Number of articles and full-texts assessed now specified:

Page 2, Paragraph 3.
“We identified 9057 articles and assessed 65 full-texts.”

Below text (in capital letters) added to make clear the number of studies contributing to the findings in lines 54-56.

Page 2, Paragraph 10.
“Studied regulatory and legislative interventions (comprising legislatively imposed practice guidelines for physicians in ONE STUDY and multi-faceted strategy which included policies to control CS on maternal request IN ANOTHER STUDY) were found to reduce CS rates.”

We are however not able to include any other additional details due to limitations in word account (currently 347 words against maximum permitted 350 words).

Reviewer comment:
Background:

1. Page 5, line 8-10: this statement (that the majority of CS are medically unnecessary) requires more support/context/justification.

Authors' responses
The referred statement is based on interpretation of the available data (now cited) indicating steady increases in CS, but with no accompanying reduction in maternal or perinatal outcomes, as would be expected. Except for Eastern and Southern Africa (6.2%), and West and Central Africa (4.1%), the latest available CS rates (range: 18.1% in South Asia to 44.3% in Latin America and the Caribbean) exceed rates considered ideal (10 to 15%) [4].

Below publications now cited to further justify the statement that available evidence suggests majority of CS are medically unnecessary.

Page 5, Paragraph 1.

WHO statement on caesarean section rates. Geneva: World Health Organization; 2015 (Ref no. 6)

Reviewer comment:

2. Provide citations for paragraph page 5, lines 31-37

Authors' responses
Page 5, Paragraph 2.

Below publications now cited to support the statement: “The steady increase in CS in the last decades coupled with the limited success of tested interventions to stop and reverse this trend have raised concerns among governments and health care professionals”

WHO statement on caesarean section rates. Geneva: World Health Organization; 2015 (Ref no. 6)


Below text deleted (as mainly based on informal correspondence between WHO and member countries).

“Governments have prioritized this issue for research and maternal health programmes, and an increasing number of countries have requested technical assistance from specialized agencies like WHO and UNICEF for evidence-based intervention strategies to address rising CS rates.”

Reviewer comment:

Methods:

1. Since the review protocol was not pre-registered, it would be helpful to know which aspects were specified a priori or determined post hoc (if applicable)

Authors' comments
All the methods utilized were specified a priori; there were no post-hoc modification of pre-specified methods based on studies identified.

Reviewer comment:

2. Clarify whether review and data extraction all done independently and in duplicate.

Authors' responses
Study selection, data extraction and risk of bias assessment were done independently and in duplicate. This is now clarified – below text (in capital letters) added:
Two reviewers (NO, CY) extracted and entered data (e.g., on study settings, participants, interventions, outcome measures) INDEPENDENTLY AND IN DUPLICATE into pilot-tested data extraction forms.

Risk of bias in each study was assessed INDEPENDENTLY AND IN DUPLICATE by two reviewers (NO, CY) and reported as one element of Grading of Recommendations Assessment, Development and Evaluation (GRADE) [20].

Reviewer comment:

3. Were attempts made to contact study authors for missing information (applicable for Tsai 2006 [Table 3]; Keeler 1996 [page 10, lines 37-38])?

Authors' responses
We contacted the Authors of the referred studies during the conduct of a previous broader related Cochrane review [15], but no response was received. We did not contact the authors again in this review.


Reviewer comment:
Results/Tables/Figures:
The Results section and Tables contain an overwhelming volume of information and in the current form are difficult to follow and glean an overall impression of results. Consideration of the following would improve readability:

Authors response
Below changes made to reduce the length of review and improve readability.

Results
• An integrated synthesis of results across studies and interventions now made. Repetition of information presented in Tables now avoided.

Tables
• Data now reorganized by intervention categories as done in the Results section (similar groups of interventions grouped together for ease of comparison of effects)
• Table 1 now deleted (details about Robson classification can be found in below cited publication)

Reviewer comment:

1. Results
   a. Page 10, line 13: the section "c) other interventions" is missing a summarizing sentence (similar to the sentence above for "b) regulatory and legislative interventions", page 10 line 2-3)

Authors' response
Below summarising text now added for “Other interventions”

Page 9, Paragraph 12.
“Two studies, retrospective cohort study (USA) [36] and interrupted time series study (Brazil) [37], assessed the following interventions”

Reviewer comment:

b. Effects of interventions (page 10, line 20-page 13, line 51)

i. It would be helpful to provide more synthesis of evidence across studies for each type of intervention (similar to as presented in abstract, which was more initiative/easy to follow) as opposed to a long list of the effects of each intervention separately

Authors' responses
An integrated synthesis of results across studies and interventions, drawing out patterns in effects and similarities or differences, now provided (see Pages 10 to 14).

Reviewer comment:

ii. Limit repetition in text of all information in tables (which can be referred to for details)

Authors' responses
Repetition of detailed information presented in Tables now avoided in main text (see Pages 10 to 14).

Reviewer comments:

2. Figure 1: specify the number of articles from each source (were any articles identified in review of references of included studies?), number of duplicates between databases, breakdown of exclusions for full text review

Authors' response
Figure 1 now updated with the following information added:
Number of records identified from each of the sources searched
- Main databases (n=9891)
- Trial registries (n=683)
- Reference lists (n=12)

Number of duplicates removed (n=1529)

Number of full texts excluded, due to ineligible
- Study designs (n=30)
- Interventions (n=17)
- Outcomes (n=2)

Reviewer comment:

3. Table 2: For some of the interventions listed on page 25 (copayment, insurance, quality of care) and page 26 (all), it is unclear how the interventions would help to reduce CS.

Authors' responses

Potential pathways for the effect of interventions on CS now specified (below text in capital letters added in the referred table).

Equalizing reimbursement fees for vaginal and caesarean deliveries: EQUALISING FEES INTENDED TO REDUCE INCENTIVES / MOTIVATIONS FOR HEALTHCARE PROVIDERS TO PERFORM CS.

Higher reimbursement fees for vaginal than caesarean deliveries: HIGHER FEES FOR VAGINAL DELIVERIES INTENDED TO MOTIVATE HEALTHCARE PROVIDERS TO SWITCH FROM CAESAREAN TO VAGINAL DELIVERIES.

Copayment: Direct patient payments for part of the cost of health services. COPAYMENT WHEN CS IS NOT MEDICALLY INDICATED IS INTENDED TO DISINCENTIVIZE WOMEN FROM CHOOSING MEDICALLY UNNECESSARY CS, BY INCREASING THE COST OF CS TO PATIENTS.

Liability of health care organisations: Interventions that limit liability of health care organisations, for example malpractice lawsuits (LEGAL COVER MAY REDUCE CS CONDUCTED FOR FEAR OF MEDICAL LAWSUITS).

Insurance: Regulation of the provision of insurance, for example insurance coverage of maternal health services (MAY INFLUENCE WOMEN’S REQUESTS FOR NON-MEDICALLY INDICATED CS, PARTICULARLY IF THEY DO NOT BEAR THE FULL COST THROUGH INSURANCE).
Professional competence: Interventions for assuring professional competence (FOR EXAMPLE, ACCREDITATION REQUIREMENTS INTENDED TO IMPROVE COMPLIANCE WITH EVIDENCE-BASED OBSTETRIC PRACTICE MAY REDUCE NON-MEDICALLY INDICATED CS).

Professional liability: Regulation of liability for health professionals (FOR EXAMPLE, PROVISION OF LEGAL COVER MAY REDUCE CS CONDUCTED FOR FEAR OF MEDICAL LAWSUITS).

Reviewer comment:

4. Tables 3-5: lengthy and challenging to follow. The following should be considered to improve readability:

Authors' responses
Tables 3-5 now reorganized to improve readability (specific changes outlined below).

Reviewer comment:

a. Organize the studies by intervention type (similar to headings used in Table 2 and as written in accompanying text in Results, pages 10-13) so that similar interventions can be compared more easily

Authors' responses
Studies in Tables 3-5 now categorized by intervention types as follows:

a) Financial strategies
   Payment methods for health workers
   • Equalising physician reimbursement fees for vaginal and caesarean delivery

   Payment methods for health organisations
   • Diagnosis-related group (DRG) payment systems
   • Global budget payment (GBP) systems
   • Case-based payment system
   • Cap-based payment system

Other financial interventions
• Financial incentive and free vaginal delivery policy

b) Regulatory and legislative interventions
   Legislatively imposed practice guidelines
   Multifaceted institutional and policy interventions

c) Other interventions
   “Hard stop” policy limiting elective inductions and caesarean births
   Multifaceted quality improvement initiative (“Appropriate Birth”)
Reviewer comment:
b. Table 3+4: since interventions are fully detailed in Table 4, simplify Table 3 by removing the “Interventions” column (particularly if row headings are used as in Table 2 to organize studies by type, this would provide sufficient information on the interventions for Table 3)

Authors' responses
We agree and have deleted Interventions column in Table 3.

Reviewer comment:
c. Table 5: create a figure for quality assessment or reorganize into a single column, include a column to capture solely whether CS rates increased, decreased, or did not change following intervention (with the details provided in a separate column)

Authors' response
Below changes made improve readability:

- Study design column deleted as this information is already presented in Table 3.
- List of outcomes assessed moved to Table 3.
- New column (‘Effects on CS’) summarising direction of effects of interventions created.

Reviewer comment:
Discussion: As in the results, careful consideration of how to best organize and present this information is needed to improve readability and pull the paper together. Specifically, aspects of the different subsections by heading are scattered across other sections and a general interpretation of the results is lacking. Suggestions for revision:

Authors' response
Discussion section now reorganized for logical flow of identified evidence and focused interpretation of findings provided (see specific revisions made, Pages 14 to 18).

Reviewer comment:

1. Summary of main results:
a. Limit to one concise paragraph

Authors' responses
Summary of results now limited to a single paragraph.

Pages 14-15.
“This scoping review identified diverse financial and legislative strategies intended to reduce CS rates, mostly from high income countries. Most of the studies assessed reimbursement strategies
for health providers and organisations. Only two studies assessed regulatory and legislative strategies. Effects of the interventions were inconsistent across settings (for example, a global payment policy comprising a single facility or professional services payment regardless of delivery mode resulted in a decrease in CS in USA [28], but no effect was found in Taiwan [32]. For some interventions, effects were contradictory given hypothesised mechanisms of action (e.g. increased CS rates following cap-based payment system in USA [22]). Overall, our confidence in these findings is low given limitations in available evidence. It is plausible that confounding due to observational designs impacted on the observed effects (for example, it was unclear in most of the studies whether the intervention occurred independent of other changes over time).”

Reviewer comment:
b. Page 14, lines 5-9: could be moved to limitations

Authors' responses
Below aspects moved to “Limitations of the evidence’ section.

Page 16, Paragraph 2.
“None of the studies was done in a low-income country. Limited data was available on maternal and neonatal outcomes and health care resource utilisation, including impact on medical costs. This represents a significant gap in knowledge about the studied interventions.”

Reviewer comment:
c. Page 14, lines 13-41: After discussing by intervention type in the abstract and Results, presenting the overall results here by their effects is inconsistent. It also obscures the finding that some intervention types performed better than other. For instance, no differences were found for GBP systems, but were found in both studies of regulatory/legislative interventions. These details could be moved to a separate section (or incorporated into a later section, potentially “Key lessons learned”) and better placed in the context of the literature/available evidence regarding which types of interventions may work best, or in comparison to clinical and non-clinical interventions.

Authors' responses
Referred text now amended as follows.

Page 15
“Effects of the interventions were inconsistent across settings (for example, a global payment policy comprising a single facility or professional services payment regardless of delivery mode resulted in a decrease in CS in USA [28], but no effect was found in Taiwan [32]. For some interventions, effects were contradictory given hypothesised mechanisms of action (e.g. increased CS rates following cap-based payment system in USA [22]). Overall, our confidence in these findings is low given limitations in available evidence. It is plausible that confounding due to observational designs impacted on the observed effects (for example, it was unclear in most of the studies whether the intervention occurred independent of other changes over time).”
Reviewer comment:

2. **Certainty of evidence (page 14, lines 46-57)-Details of this section referring to in Table 5 can be reported in the Results and overall low quality more briefly mentioned in summary of results/limitations/conclusion**

Authors' responses
Aspects of certainty of evidence now moved to ‘Summary of main results’ section, rephrased as follows.

Page 15, Paragraph 2.
“Overall, our confidence in these findings is low given limitations in the available evidence. It is plausible that confounding due to observational designs impacted on the observed effects (for example, it was unclear in most of the studies whether the intervention occurred independent of other changes over time).”

Reviewer comment:

3. **Limitations: address potential for publication bias**

Authors' responses
Below text added to address potential publication bias.

“Lastly, although our searches were relatively comprehensive, it is possible that we did not identify some relevant studies, particularly as no grey literature sources were searched.”

Reviewer comment:

4. **Key lessons learned:**
a. **Page 16, lines 5-13 could be moved to Limitations**

Authors' responses
Referred text moved to ‘Limitations of the evidence’ section.

Page 16, Paragraph 5.
“The reliability of the effects of the interventions on CS rates depend on the quality (accuracy and completeness) of data available in the study sites. Coding errors limit reliability and validity of measurements [22]. In addition, coding practices in diagnosis-related payment systems may vary limiting comparisons across hospitals and sites. Thus, robust, standardized health information system for routine data collection are needed to support reliable monitoring of the impact of studied financial and regulatory interventions.”
Reviewer comment:
b. Page 16, lines 16-35 could be moved to Implications for future research

Authors' responses
Referred text now moved to ‘Implications for future research’ section.

Page 17, Paragraph 2.
“None of the 16 included studies utilised a randomised design. This suggests that there might be challenges to using randomised study designs for evaluating financial, legislative and regulatory interventions (e.g. randomisation of policy reforms may not be feasible in practice). Changes in payment systems or legislative policies are often implemented suddenly or nationwide, which prevents the use of randomised studies. In addition, identification of comparable control groups remains a challenge given inherent differences in contexts such as health systems, policy environments and population groups. Given these methodological challenges, balancing pragmatism and research rigour is encouraged in evaluating the effects of financial, regulatory and legislative interventions [39]. Similarly, new methods for assessing the quality of evidence optimised for studied and related policy interventions should be developed (existing systems such as GRADE may not be reliable given the highlighted methodological challenges in the conduct of primary studies). Well conducted controlled before and after designs and interrupted time series, with appropriate analysis to control for contextual factors and possible confounders, appear feasible alternatives to randomised designs.”

Reviewer #2

Reviewer comment:
This article provides a scoping review of studies that have assessed the effect of financial incentives and related regulatory and legislative factors on C-section rates. Overall, they find that the evidence is inconclusive because of inconsistent effects and low quality evidence. The authors highlight the need for more rigorous studies in order to attain more rigorous evidence.

Overall, the article was very well written. The authors provide a very thorough assessment of the studies that exist on this topic. I appreciate the amount of detail they have provided in tables to highlight the different components of the studies, what they have found, and how they rated the quality of evidence. This is an important topic, so it is crucial to have this type of review to be able to understand what we do and don't know about contributing factors related to financial and regulatory interventions and C-sections. I have limited comments, as I feel that the paper is very thorough in its review and there are very few things for improvement.

Authors' response
Thank you for the commendation.
Reviewer comment:

Suggestions for revisions:

1) Background: the authors refer to the high rates of C-sections but don’t actually present the figures. It would help to show some numbers in the Intro section.

Authors' responses

Data on the latest available global estimates of CS use now stated:

Page 5, Paragraph 1.
“Latest trends analysis shows that between 2000 and 2015, the global average CS rate increased by 9.0% (from 12.1% to 21.1%) [4]. Latin America and the Caribbean had the highest CS rates (44.3%), followed by North America (32.0%), Middle East and North Africa (29.6%), East Asia and Pacific (28.8%), Eastern Europe and Central Asia (27.3%), Western Europe (26.9%), South Asia (18.1%), Eastern and Southern Africa (6.2%) and West and Central Africa (4.1%) [4].”

Reviewer comment:

2) Within the Results section, it would be helpful for the authors to add 1-2 sentences per study reviewed to explain the limits of the study. This would be especially useful for studies where the effect is in the opposite direction than expected. In addition, this would also be the place to add what is “weak” about the analysis. The authors mention this in the Discussion under Certainty of Evidence, but when each study is discussed, it would help to know what contributed to the weak evidence or might have caused there to be no effect/effect in opposite direction than expected.

Authors' responses

The results section now reorganized to provide an integrated synthesis of findings across studies and interventions. We considered but opted not to add suggested 1-2 sentences for each study for the following reasons:

1. Study limitations have been taken into account in the GRADE certainty ratings, alongside other factors. It’s more reliable to base interpretation on the aggregate GRADE ratings (rather than individual limitations). For this reason, GRADE ratings are presented in the Results section, and should be taken into account when interpreting reported magnitude and direction of effects.

2. Individual study limitations are summarised in Table 4. We feel this is sufficient to avoid repetition in the main text (adding 1-2 sentences for each of the 16 studies as suggested would substantially increase the length of manuscript and impact on readability).