Comparative Effectiveness Research Review Disposition of Comments Report

Research Review Title: *Strategies To Reduce Cesarean Birth in Low-Risk Women*

Draft review available for public comment from January 4, 2012 to February 8, 2012.

Research Review Citation: Hartmann KE, Andrews JC, Jerome RN, Lewis RM, Likis FE, McKoy JN, Surawicz TS, Walker SH.. Strategies To Reduce Cesarean Birth in Low-Risk Women. Comparative Effectiveness Review No. 80. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2007-10065-I.) AHRQ Publication No. 12(13)-EHC128-EF. Rockville, MD: Agency for Healthcare Research and Quality. October 2012. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Comments to Research Review

The Effective Health Care (EHC) Program encourages the public to participate in the development of its research projects. Each comparative effectiveness research review is posted to the EHC Program Web site in draft form for public comment for a 4-week period. Comments can be submitted via the EHC Program Web site, mail or email. At the conclusion of the public comment period, authors use the commentators' submissions and comments to revise the draft comparative effectiveness research review.

Comments on draft reviews and the authors' responses to the comments are posted for public viewing on the EHC Program Web site approximately 3 months after the final research review is published. Comments are not edited for spelling, grammar, or other content errors. Each comment is listed with the name and affiliation of the commentator, if this information is provided. Commentators are not required to provide their names or affiliations in order to submit suggestions or comments.

The tables below include the responses by the authors of the review to each comment that was submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.

Source: http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1290
Published Online: October 22, 2012

Reviewer	Section	Comment	Response
Peer Reviewer #1	Executive Summary	Both the Executive Summary and the Introduction to the text do an excellent job of explaining the background and need for the review.	Thank you for your comments.
Peer Reviewer #2	Executive Summary	The introduction is focused completely on the problem in the US and is nicely articulated. However, since the article reviews include many international studies a few comments about the problem internationally might be appropriate.	
Peer Reviewer #2	Executive Summary	Page ES-2; Line 35 The study questions are clear and the population definition also is clear about excluding VBACs.	Thank you for your comments.
Peer Reviewer #2	Executive Summary	Page ES-2; Line 35 The study background section seems to dismiss the VBAC issue by acknowledging previous systematic reviews. (ES-2, 35)	This report is focused on low-risk women. The definition of low-risk women for this report excludes women with a previous cesarean.
Peer Reviewer #4	Executive Summary	The Intro provides essential background material. The goals, scope, and key questions are stated clearly.	Thank you for your comments.
TEP #1	Executive Summary	Page ES-1; Line 50 the authors posit that code teams are required because of the rising cesarean section rate. Those teams have been in pace and were needed long before the section rate reached its current high rate. Hemorrhage has been the first or second leading cause of maternal death since well before this generation's more liberal recourse to surgery.	ES-1: Clarified to specify increased use of "code teams"
TEP #2	Executive Summary	The executive summary is generally well written and appropriate. However, in the executive summary and other summaries throughout, there is lack of attention to the appropriateness of some interventions. For example, it seems misleading to discucss the hyaluronidase intervention in summaries without any mention of its inappropriateness in the US context. This is only discussed in the detailed synthesis. In my view this should be brought to light earlier.	We did not exclude interventions from review based on current use patterns in the US (for instance fetal scalp pH sampling or amnioinfusion) believing it would be useful to highlight any interventions that have been found to meaningfully reduce use of cesarean. With regard to the specific concern about hyaluronidase, we note that the vehicles in the formulation used for hyaluronidase are not used in pregnancy in the US. This does not preclude potential interest, as noted in future research, of use of similar active components for further study and the data from the one trial is promising. We did add a phrase to this sentence in the executive summary (ES-9), noting that "This study was small (n=168), the vehicle used for the hyaluronidase injections is not allowed in the US, and no other studies...."
TEP #3	Executive Summary	Page ES-8; Line 27-34 the OR for use of a partogram is in the opposite direction from the other two strategy ORs; please check/clarify so directionality is consistent	The OR for this study has been verified and is correct.
Peer Reviewer #8	Executive Summary	The introduction is appropriate.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #8	Executive Summary	Page ES-9; Line 43-44 the phrasing is also inverted: (See explanation above) Where it reads, “Knowledge of intrapartum fetal oxygen saturation did not have a significant effect on the overall use of cesarean, however three of the four studies investigating use of fetal pulse oximetry, to measure oxygen levels and blood pH, reported a significant reduction in cesarean performed for fetal distress. Reduction in cesarean for fetal distress ranged from 5.7 to 24.6 percent,” it should read, “Three of the four studies investigating use of fetal pulse oximetry , to measure oxygen levels and blood pH, reported a significant reduction in cesarean performed for fetal distress. Reduction in cesarean for fetal distress ranged from 5.7 to 24.6 percent, however, knowledge of intrapartum fetal oxygen saturation did not have a significant effect on the overall use of cesarean.”	ES-11 Fetal Assessments: We have reversed the order of the information in the related key point as suggested.
TEP #3	Executive Summary	Page ES-10; Line 12 the conclusion sentence about amnioinfusion seems to contradict itself and should be rephrased	ES-11 Amnioinfusion: We have revised the text to clarify.
TEP #3	Executive Summary	Page ES-11; table, please clarify what the heading "Directness" means for readers who will only read the summary. including reference numbers here would be helpful.	ES-7: We have added additional references to the Methods section to explain the components of Strength of Evidence.
Peer Reviewer #10	Executive Summary	The introduction frames the issue well and contains adequate detail.	Thank you for your comments.
TEP #4	Executive Summary	Good.	Thank you for your comments.
Peer Reviewer #13	Executive Summary	Page ES-2; Line 6 Most research, including that of Wennberg (cited) points to a stronger effect of provider preferences than patient preferences on use of surgical interventions. Perhaps this could be reworded as “provider preferences, and to a lesser extent patient preferences…”. In addition, maternity-specific citations would be helpful. Baicker, K., Buckles, K. S., & Chandra, A. (2006). Geographic variation in the appropriate use of cesarean delivery. Health Affairs (Project Hope), 25(5), w355-67. doi:10.1377/hlthaff.25.w355 Luthy, D. A., Malmgren, J. A., Zingheim, R. W., & Leininger, C. J. (2003). Physician contribution to a cesarean delivery risk model. American Journal of Obstetrics and Gynecology, 188(6), 1579-1585.	ES-1-2: Revised.

Reviewer	Section	Comment	Response
Peer Reviewer #13	Executive Summary	Page ES-8; Line 6 Please add the number of studies (and total number of participants) for midwifery discussion.	Due to limited space, the discussion of individual study characteristics is limited in the Executive Summary. More detailed information about all studies is included in the full report.
Peer Reviewer #13	Executive Summary	Page ES-8; Line 24-60 It is confusing that individual studies showing benefit of different strategies are grouped together rather than with other studies of the same strategies. For example, partogram study showing benefit is discussed in line 28-29 but discussion of other partogram studies resumes at line 40.	For the Executive Summary all strategies are reported related to their use during pregnancy or during labor. All of the partogram studies are characterized as use during labor. More detailed information about all studies is included in the full report. In addition, Table B contains the number of studies and participants in the far left column under the strategy description.
Peer Reviewer #13	Executive Summary	Page ES-12; Table 2 For doula support, change "low strength of evidence" to "low strength of evidence for benefit" to be consistent with phrasing used for various strategies having low strength of evidence for no benefit. This same change should be made to Table 34 on p. 102.	Added to Table B.
Peer Reviewer #15	Executive Summary	Well written report which unfortunately has limited clinical or policy implications due to the poor quality of the research and lack of research demonstrating effective approaches.	Thank you for your comments.
Peer Reviewer #16	Executive Summary	Well-organized discussion of the context of this topic with useful general references regarding the magnitude of this public health concern. The abridged background in the executive summary is adequate and the expanded introduction in the main document outlines context and evidence for concerns raised with high cesarean rate. The remained of the introduction carefully and appropriately outlines the CER document.	Thank you for your comments.
Peer Reviewer #16	Executive Summary	Page ES-3; Line 56 Use KQ abbreviation several sections above where it is written out…move reference up to initial use of abbreviation	ES-3: Spelled out at first use.
Peer Reviewer #16	Executive Summary	Page ES-3; Table 1 identify that PICOTS is a framework used by AHRQ Effective Health Care Program as a summary of study characteristics identified. Authors list out the components which is helpful, but those unfamiliar with the Effective Health Care Program may not understand where this acronym comes from. This also refers to the same table and discussion in the entire report later p. 38	Added note to Table A and Table 1 in the full report.
Peer Reviewer #16	Executive Summary	Page ES-4; Line 9 Did authors intend for KQ3 to be head-to-head comparisons of strategies both during pregnancy and labor? I recognize no studies were actually included in this KQ category.	Yes, we sought head-to-head comparisons of strategies both during pregnancy and labor.

Reviewer	Section	Comment	Response
Peer Reviewer #16	Executive Summary	Page ES-5; Line 11 input from stakeholders – 2nd sentence very lengthy and hard to follow, had to read multiple times.	ES-6, Input from stakeholders: Revised for clarity.
Peer Reviewer #16	Executive Summary	Page ES-8; Line 36 second paragraph under KQ2 first sentence is awkward and hard to follow	ES-9 (2nd paragraph in KQ2 section): Revised for clarity.
Peer Reviewer #16	Executive Summary	Page ES-10; Line 54 last sentence change to "these data"	ES-12: Revised.
Peer Reviewer #16	Executive Summary	Page ES-11 Line 5 missing period in first sentence after intervention. "for instance, "	ES-12: Revised intervention to strategy and added comma after For instance.
Peer Reviewer #16	Executive Summary	Page ES-11; Line 9 Use consistent terminology for KQ4. Earlier in document refer repeatedly to "adverse effects" – change here to adverse effects instead of "harms"	Revised and have replaced harms with adverse effects throughout the report.
Peer Reviewer #16	Executive Summary	Page ES-11; Line 17 "such as for the use of in utero monitoring in labor and risk of infection" elimination of comma after "labor"	ES-12: Revised to delete the comma.
Peer Reviewer #16	Executive Summary	Page ES-12; Line 8 Use consistent format for shaded subheadings… KQ1. Change to KQ2. (instead of KQ2:)	ES-13-15: Revised Table B.
Peer Reviewer #16	Executive Summary	Page ES-13; Line 9 shaded subheading at top of page should be KQ2. Effectiveness of strategies during labor to reduce cesarean birth (not during pregnancy). This appears to be continuation of 84 studies included for KQ2 from table on page 22.	ES-13-15: Revised Table B.
Peer Reviewer #16	Executive Summary	Page ES-13; Line 38 Second shaded subheading should read KQ4. Adverse effects of strategies to reduce cesarean birth. This allows consistent formatting.	ES-13-15: Revised Table B..
Peer Reviewer #16	Executive Summary	Page ES-13; Table ES-2 listed number of strategies for KQ2 is 85 and KQ4 is 17. These numbers are slightly different than those listed in ES Figure 2 which lists 84 and 15 respectively. Need to overtly state why numbers are slightly different. It is likely several studies qualified for multiple categories.	ES-13-15: Revised Table B. There are 17 references for KQ4. One paper is in both in the Measurement of Labor Progress and the Systems level intervention (Hamilton E, Platt R, Gauthier R, et al. The effect of computer-assisted evaluation of labor on cesarean rates. J Healthc Qual. 2004 Jan-Feb;26(1):37-44)
Peer Reviewer #16	Executive Summary	Page ES-13; Line 55 "For all of the studies included in this review, the comparators…"	ES-16 (Applicability): Revised.
Peer Reviewer #16	Executive Summary	Page ES-13; Line 50-52"low-risk" – use of hyphen needs to be consistent throughout paper (some places hyphen is used and others it is not – need to choose one or other for consistency in formatting)	Revised to use the hyphen throughout the Executive Summary and report.

Reviewer	Section	Comment	Response
Peer Reviewer #16	Executive Summary	Page ES-15; Line 10 reference 12 missing “accessed on”	ES-18 (References): Revised.
Karen Peddicord, PhD, RN for AWHONN	Executive Summary	Page ES-10; Further outline the examples of successful system-level interventions. The interventions presented may fall into the rubric of quality improvement within individual facilities, and therefore may not provide evidence of interventions that universally reduce cesarean birth. However, providing more detailed examples would be extremely useful in helping like-facilities desiring to replicate the positive results reported in the systematic review. Further, AHRQ should encourage health care systems to continue these pursuits.	We have added additional information related to systems strategies to the text in the Executive Summary, Results (Page 65 “Observational Data”), and Discussion (Page 75 “Systems-level Strategies”.
Karen Peddicord, PhD, RN for AWHONN	Executive Summary	Page ES-14; Based on the conclusion, AHRQ should consider urging the scientific community to continue research in this area of health care delivery.	Thank you for your comments.
EC	Executive Summary	Page ES-2; Line 32 in the fourth paragraph, second sentence, an “a” needs to be inserted between “exception is” and “study of”.	ES-2 (Background): Corrected.
EC	Executive Summary	Page ES-11; Line 15 under the KQ4 heading, third sentence, “and” needs to be replaced with “are” before “anesthesia-related side effects”.	The sentence is correct as currently written. Maternal fever, nausea, and vomiting are not a list of anesthesia-related events.
EC	Executive Summary	Page ES-11-13; There should be a consistency in using either a period or a colon after the KQ1, KQ2, KQ3 in the titles of the categories listed in ES Table 2 and Table 34.	ES-4, ES-13-15 and Page 78-80: Corrected.
EC	Executive Summary	Page ES-13; Line 9 There is a discrepancy between the labeling of Table 2 in the ES, and Table 34 in the report. The third gray bar is titled “KQ1. Effectiveness of strategies during pregnancy to reduce cesarean birth”, whereas it should be labeled, “KQ2: Effectiveness of strategies during pregnancy to reduce cesarean birth”.	ES-13-15: Corrected.
EC	Executive Summary	Page ES-13; Line 38 The fourth gray bar in both tables is missing “Q4:” before the title.	ES-13-15: Corrected.
Peer Reviewer #1	Introduction	Both the Executive Summary and the Introduction to the text do an excellent job of explaining the background and need for the review.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #2	Introduction	The introduction is focused completely on the problem in the US and is nicely articulated. However, since the article reviews include many international studies a few comments about the problem internationally might be appropriate.	The review was intended to be applicable to US settings and international studies were included from developed countries with similar care parameters. Unfortunately fully contextualizing global trends in cesarean use is beyond our scope and might distract from the focus we hope to establish in the introduction. However, on the note of inclusion of international studies, we have added text in the discussion about the fact that generalizability of international studies, even from developed countries, may limit applicability to US populations.
Peer Reviewer #4	Introduction	The Intro provides essential background material. The goals, scope, and key questions are stated clearly.	Thank you for your comments.
TEP #1	Introduction	Page 1; Line 50 the authors posit that code teams are required because of the rising cesarean section rate. Those teams have been in pace and were needed long before the section rate reached its current high rate. Hemorrhage has been the first or second leading cause of maternal death since well before this generation's more liberal recourse to surgery.	Page 1: Clarified to specify increase use of "code teams"
TEP #1	Introduction	Page 3; Provided a good overview. The key questions are laid out. The distinction between questions one and three are not obvious on first read. It might be easier to understand if question three was a sub-question of question one or followed immediately from question one, since the contrast between what is being asked in the two questions might then be more readily apparent.	Thank you for your comments. Our intention was not for Key Question 3 to be a subquestion of Key Question 1. Key Question 3 focuses on any head-to-head comparisons of two or more novel strategies used during pregnancy or during labor. Comparisons to usual or standard care were the majority of the literature.
TEP #1	Introduction	The commentary on factors driving the change in cesarean section rates was a bit parsimonious, but I assume the target audience is well versed in these issues. Those who are not might need a bit more detail on several of issues that are mentioned but in only a cursory fashion (e.g., changing profile of parturients [adiposity, fetal size], defensive medicine).	The level of detail is appropriate for the intended audience--providers who service pregnant women.
Peer Reviewer #8	Introduction	The introduction is appropriate.	Thank you for your comments.
TEP #3	Introduction	Page 34; Line 3 well done; just a typo on AWHONN	Page 4: Revised.
Peer Reviewer #10	Introduction	The introduction frames the issue well and contains adequate detail.	Thank you for your comments.
TEP #4	Introduction	Good.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #13	Introduction	Page 1; Line 39-42 Most research, including that of Wennberg (cited) points to a stronger effect of provider preferences than patient preferences on use of surgical interventions. Perhaps this could be reworded as "provider preferences, and to a lesser extent patient preferences…". In addition, maternity-specific citations would be helpful.	Page 2: Revised.
Peer Reviewer #13	Introduction	Page 1; Line 39-42 In addition, maternity-specific citations would be helpful. Baicker, K., Buckles, K. S., & Chandra, A. (2006). Geographic variation in the appropriate use of cesarean delivery. Health Affairs (Project Hope), 25(5), w355-67. doi:10.1377/hlthaff.25.w355 Luthy, D. A., Malmgren, J. A., Zingheim, R. W., & Leininger, C. J. (2003). Physician contribution to a cesarean delivery risk model. American Journal of Obstetrics and Gynecology, 188(6), 1579-1585.	Page 1: Additional references added.
Peer Reviewer #13	Introduction	Page 34; Consider adding childbirth education organizations/professionals as other potential users of this report.	Page 4: Revised.
TEP #5	Introduction	OK, but seems short. The introduction should make sure that it links in other relevant AHRQ reports (e.g. VBAC, elective induction of labor, diabetes in pregnancy). It should also speak to the downstream effects of CS, including limited availability of VBAC, implications for future pregnancies,	Page 3 (Goals of this Comparative Effectiveness Review): We have now referred to the other recent AHRQ reports relevant to this CER in the introduction.
Peer Reviewer #15	Introduction	Well written report which unfortunately has limited clinical or policy implications due to the poor quality of the research and lack of research demonstrating effective approaches.	Thank you for your comments, we concur the state of the literature is disappointing.
Peer Reviewer #16	Introduction	Well-organized discussion of the context of this topic with useful general references regarding the magnitude of this public health concern. The abridged background in the executive summary is adequate and the expanded introduction in the main document outlines context and evidence for concerns raised with high cesarean rate. The remained of the introduction carefully and appropriately outlines the CER document.	Thank you for your comments.
Peer Reviewer #16	Introduction	Page 31; Line 24 "has the potential to"	Page 1: Revised.
Peer Reviewer #16	Introduction	Page 31; Line 28 change to "associated"	Page 1: Revised.

Reviewer	Section	Comment	Response
Peer Reviewer #16	Introduction	Page 31; Line 44 missing period. “less ambitious over time. The Healthy…”	Page 1: Revised.
Peer Reviewer #16	Introduction	Page 32; Line 47 "low-risk"	Revised to use the hyphen throughout the report.
Peer Reviewer #16	Introduction	Page 32; Line 21 "low-risk"	Revised to use the hyphen throughout the report.
Karen Peddicord, PhD, RN for AWHONN	Introduction	Page 4; Line 3 Change AWHONN’s name to read, “Association of Women's Health, Obstetric and Neonatal Nurses.”	Page 4: Revised.
Karen Peddicord, PhD, RN for AWHONN	Introduction	Page 21; The report identifies one study related to the second stage of labor. AWHONN suggests that AHRQ look more broadly at the literature on the second stage of labor with a special focus on spontaneous pushing versus traditional, directed pushing.	The inclusion and exclusion criteria for this report were uniform for all interventions because we undertook to look at all trials that examine use of an intervention to reduce the use of cesarean. We are not aware of any RCTs designed to assess a second stage labor intervention to reduce cesarean. Agree that this is a topic that could be the focus of a specific review on management of second stage in which outcomes could be more varied that the singular outcome for this review which is the effectiveness of the intervention for reducing cesarean.
Peer Reviewer #18	Introduction	Page 4; Line 4 Change "Nurse" to "Nurses"	Page 4: Revised.
Peer Reviewer #1	Methods	The methodology is impeccable. I did not see the exact years that the study encompassed (unless I missed it). Studies from what years were searched for and when was the review completed? There have been some recent publications along these lines, and there will also be some studies presented at the Society for Maternal Fetal Medicine meeting in Feburary 2012. For example, I recently reviewed a paper from Taiwan on financial incentives to lower the cesarean rate for a Health Management journal (sorry I did not keep the review) which did not show much effect.	Thank you for alerting us to upcoming publications. In order to prepare the report for publication, we needed to have an ending search date for inclusion of February 2012. In a growing field there will always be new studies published, and it is difficult but necessary to stop the search at some reasonable point if publication of the review is to be possible. Nonetheless, we look forward to reading new studies, and anticipate that an update of the review may be possible in the future.
Peer Reviewer #2	Methods	Of some concern is the length of publication dates included in the study. Clinical practices change quickly; however, it is possible that some older strategies are worthy of consideration. Again, would have been helpful to have more content on VBACs and more complete rationale for their exclusion.	ES-6 and Page 10: We have added detail specifying that the literature search is from 1968-present. 1968 was the earliest year available at the time of the search.

Reviewer	Section	Comment	Response
Peer Reviewer #3	Methods	Criteria for inclusion and exclusion are appropriate. Agree with definitions used. Sound statistical methodology utilized.	Thank you for your comments.
Peer Reviewer #4	Methods	I found the inclusiveness of appropriate studies to be impressive. It is a sad state of the research on this important topic that there were relatively few studies meeting criteria to be included. The inclusion of non-RCT studies for examination of systems level interventions was appropriate and informative.	Thank you for your comments.
Peer Reviewer #5	Methods	seems appropriate and complete	Thank you for your comments.
TEP #1	Methods	Figure 1 Although discussed elsewhere, some key factors are not listed in the boxes in figure 1 (analytic framework). For example the first box doesn't specify that these are women with a vertex fetus, and health systems factors include the medico-legal environment.	Page 8: Have modified the analytic framework to include vertex presentation. The medical/legal environment was previously included in the "Health System Factors" box.
TEP #1	Methods	While the categorization of potential bias is appropriate, it might have been possible to change a paper's category from unclear risk to low risk if the study's authors had been contacted. Was there any attempt to speak with authors of studies that were otherwise strong but which were unclear in one particular domain of bias (e.g., reviewers couldn't determine if there was detection bias)?	It is true that unclear reporting makes the assessment of risk of bias particularly difficult; however, if authors meet current standards for reporting, including CONSORT, this should not be the case. To be systematic in our approach, we would have needed to contact all authors whose papers would have been potentially been judged differently with additional information, and this was beyond the scope of the review. It is incumbent upon authors of studies to publish clear and transparent methods.
TEP #1	Methods	Since very little of the literature reviewed was graded as having a strength that was "high" it might have been useful to be more explicit in saying why studies had "moderate" strength. All flaws are not equal and it might have been helpful to have a better sense of what the particular failings of a paper were as readers try to gauge where to go from here.	Individual studies were not graded as high, moderate, or low. However, the high, moderate, or low designation refers to the overall state of the literature for a given key question. Limitations of the literature are discussed in the Discussion and Future Research sections of the report. Assessment of the Risk of Bias for individual studies is provided in Appendix D.
TEP #2	Methods	Inclusion/exclusion criteria are justifiable and the search strategies are clearly outlined. While the outcome measure are appropriate, it might be helpful to discuss in a little bit more detail/more explicitly why the outcomes NICU admission and NICU days are the relevant intermediate neonatal outcomes (between apgar score and mortality).	The use of NICU admissions and NICU days reflect acuity of health conditions in the neonate prior to discharge. Because they are a direct measure of health conditions they are an appropriate intermediate outcome.
Peer Reviewer #8	Methods	The inclusion and exclusion criteria are justifiable and make any comparisons across studies possible. The search strategies are explicitly stated and logical. The definitions for outcome measures are appropriate. I'll let the statisticians comment on the statistical methods.	Thank you for your comments.

Reviewer	Section	Comment	Response
TEP #3	Methods	inclusion/exclusion criteria were described --it appears that "term" was never explicitly defined for purposes of selecting studies --definitions, search methods, and analytic methods seem appropriate. --in hindsight, limitation to RCTs is perhaps too restrictive, but understandable. Again, suggest that more flexibility in the interpretation of results could have given clinicians and other stakeholders more to go on.	Standard EPC methodology for comparative effectiveness reviews is to look first to RCTs, then include other study designs if determined to be particularly necessary, especially for issues such as identifying harms of interventions. It should be noted that this review was a comparative effectiveness review of interventions, and it is widely accepted that well conducted RCTs confer the lowest risk of bias and are able to be used to assess causal relationships, whereas observational studies have inherent biases and most often cannot be used to assess cause and effect. The report was focused on low-risk women. As such, women giving birth prematurely are by definition not low-risk; therefore, we used term pregnancy, in addition to other characteristics including vertex presentation, as a surrogate for a low-risk pregnancy.
Peer Reviewer #13	Methods	Limiting the included studies to those with an implicit or explicit intent of evaluating effect on cesarean rates makes this a much more manageable review. However, good quality systematic reviews exist for several of the interventions and these SRs include many more studies, as well as sub-set and sensitivity analyses that offer a more nuanced picture. The reviewers could have indicated that a Cochrane review that implicitly or explicitly sought to determine effectiveness of interventions aimed at reducing cesareans would also be acceptable evidence, and then limit further review to subsequent RCTs. As it is likely not feasible to change the methods so fundamentally at this time, the researchers could be more consistent about summarizing findings from relevant Cochrane SRs. Relevant Cochrane reviews are currently referenced inconsistently. For example, Cochrane results are discussed in the Amniotomy and Active Management sections but not in the Psychosocial Support/Doula section. The most recent Cochrane review of continuous labor support found a significant reduction in cesarean in the main analysis and several subgroup analyses.	We are not aware of other reviews that sought explicitly to review RCTs specifically aimed at decreasing cesarean use among low-risk women. This is a crucial consideration for getting a firm grasp on the applicability of the studies to the narrower question of what can we be doing in the care of low-risk women, with uncomplicated pregnancies at term who are hoping for a vaginal birth to optimize their chance of achieving a vaginal birth and not having a cesarean. We have added references to other Cochrane reviews including active management of labor, labor support, including doulas, and VBAC; however, we have also noted the ways in which those reviews depart from the ideal studies and low-risk populations to which this review was restricted.
Peer Reviewer #13	Methods	There seems to be inconsistent inclusion of studies done in developing countries. Several doula trials conducted in Sub-Saharan Africa were excluded on the basis that they “do not reflect contemporary U.S. practice” while amnioinfusion trials, for instance, from the same region were included.	The trials of two approaches to amnioinfusion are a valid comparison regardless of the context. Conversely, the doula studies compared doula support to standard of care, which in Sub-Saharan Africa is substantially different from that in the United States. Thus the comparison would not have been valid.

Reviewer	Section	Comment	Response
Peer Reviewer #13	Methods	The methods section in the Structured Abstract lists results of search rather than summarizing review methods.	Page X: The structured abstract has been revised to clarify methods and results.
TEP #5	Methods	No. The inclusion criteria that were discussed by the TEP are not reflected in this report. The report limited to studies that had a stated AIM of reducing cesarean birth. This eliminates much important literature. I would strongly suggest that the report be rewritten with the more inclusive methodology that was suggested by the TEP.	The inclusion and exclusion criteria used for this review were reviewed and discussed with the technical expert panel. The need to limit the review to those studies that sought to reduce cesarean allowed the team to focus on studies aimed at reducing cesarean rather than those studies that report cesareans as a routine outcome in obstetric literature, which our very experienced library scientists estimate as a minimum of 37,000+ papers.
TEP #5	Methods	I am not seeing anywhere in ref #28 the background on using a scoring algorithm for Strength of Evidence rating. There is a large body of literature which suggests that these sypes of scoring systems create spurious precision and should be avoided. If a scoring system is used then the authors of this report should at least detail it and discuss why it is valid.	ES-7 and Page 12: The reviewer seems to be referring to studies of quality rating approaches for assessing individual studies. The strength of evidence approach is a way of assessing our confidence in the identified effect and is detailed in Owens et al. (Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--agency for healthcare research and quality and the effective health-care program. J Clin Epidemiol. 2010 May;63(5):513-23. PMID: 19595577). We have added this reference to the report.
Peer Reviewer #15	Methods	Well defined search strategies and inclusion/exclusion criteria	Thank you for your comments.
Peer Reviewer #16	Methods	The inclusion and exclusion criteria are justifiable and appropriate for the types of studies that are published on this topic. I felt it particularly important that the authors clearly excluded studies that did not have reduction of cesarean as primary stated goal of the study. This helped to provide consistently to this CER and the evidence the authors chose to include. I felt they also adequately justified their limitation to using only studies published in English. The authors seemed to appropriately anticipate questions and critiques and preemptively address these in the document.	Thank you for your comments.
Peer Reviewer #16	Methods	The search strategies are transparently included. It is helpful to have also included a narrative of the careful process used for searching including following up review of the reference list of additional articles by hand, but also to include an attachment outlining the exact keywords.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #16	Methods	The outcome measures of interest for this CER are clearly stated. The authors did an outstanding job of limiting these outcome measures across a wide range of studies with variably reported outcome measures. The narrow definition of included outcome measures (method of delivery - effect on cesarean rate, maternal and neonatal morbidity and mortality) helped to clearly analyze the primary objective of this CER without clouding additional related issues.	Thank you for your comments.
Peer Reviewer #16	Methods	The included exhaustive evidence tables are also helpful documentation of the process used to review the outcome measures.	Thank you for your comments.
Peer Reviewer #16	Methods	The statistical methods used are appropriate and the data included highlight a balanced look at the included studies while not overwhelming the reader with extraneous data outside the stated outcome measures.	Thank you for your comments.
Peer Reviewer #16	Methods	The authors also appropriately addressed the issue of not using meta-analysis based on the included studies for this topic.	Thank you for your comments.
Peer Reviewer #16	Methods	Page 37; Table 1 identify that PICOTS is a framework used by AHRQ Effective Health Care Program as a summary of study characteristics identified. Authors list out the components which is helpful, but those unfamiliar with the Effective Health Care Program may not understand where this acronym comes from. This also refers to the same table and discussion in the entire report later p. 38	Added note to Table A and Table 1
Peer Reviewer #16	Methods	Page 37; Line 57 no time limits were set for review of articles, but abstract notes articles cited range from 1968-2011. May be useful to include this again here.	Have added clarification. The search was from the earliest available literature, which was 1968.
Peer Reviewer #16	Methods	Page 40; Line 51 change to “calculated”	Revised.
Karen Peddicord, PhD, RN for AWHONN	Methods	Page 21; Line 50-onward The report identifies one study related to the second stage of labor. AWHONN suggests that AHRQ look more broadly at the literature on the second stage of labor with a special focus on spontaneous pushing versus traditional, directed pushing.	The review did include strategies used during labor, including during second stage of labor. The particular focus of this review was not a comparison of spontaneous pushing versus traditional, directed pushing, as noted. The reviewer may want to know that any individual or organization is welcome to nominate topics through the EHC website.

Reviewer	Section	Comment	Response
Peer Reviewer #18	Methods	Inclusion criteria: OK Search strategies: OK Definitions: OK No meta-analysis was performed, rather a descriptive review based on the assessment of the quality of each study. While the Cochrane Risk of Bias tool is certainly a reasonable choice, the issue of blinding in behavioral clinical studies is by nature frequently not feasible. The authors of the report should have considered revising the tool or reconceptualizing bias in these circumstances, or at lead acknowledged this limitation of bias assessment when evaluating the effects of psychosocial/behavioral interventions.	This is an important point, and we have clarified in the methods that no points were subtracted for not blinding for those studies in which it would not have been feasible to blind (e.g. doula studies). Thus, the Cochrane RoB tool was modified as suggested by the reviewer.
Peer Reviewer #1	Results	All of the characteristics and details are appropriate.	Thank you for your comments.
Peer Reviewer #1	Results	Although there is a section on management of labor, I did not see much about interventions for the second stage of labor or the actual vaginal delivery (which is the time that many decisions are made to proceed to cesarean). In other words, were studies evaluated that attempted to increase vaginal breech, forceps or vacuum deliveries rather than resort to cesarean? A study was published somewhere last year showing that a veteran obstetrician skilled at forceps could train the residents safely and increased the rate of forceps deliveries which previously would have been cesareans. Some cesareans now seem to be done because the provider is either reluctant or no longer has the skill to perform anything but a spontaneous delivery.	All identified trials or systems interventions that stated an aim of reducing cesarean were systematically sought and included as identified. We did not find the type of RCTs you describe; however, we have added this as a key area for future research in agreement with your comment about the importance of not losing these skills and understanding what they can contribute to reduction of cesarean.
Peer Reviewer #1	Results	Page 21; My impression was that there were more studies showing that induction of labor in primigravidas with an unripe cervix increased the cesarean rate	There is a large body of literature related to induction that was excluded from this review because the target population is low-risk women at term, with an uncomplicated pregnancy, and vertex presentation. Since inductions are largely undertaken for specific indications that are not considered low risk (PIH, pre-eclampsia, growth restriction, macrosomia, poorly controlled diabetes, etc), women who required induction were not considered low risk. Elective induction of labor was also considered a separate topic.

Reviewer	Section	Comment	Response
Peer Reviewer #1	Results	Page 40-46; The section on fetal monitoring was a little confusing to me (pp 40-46). It appeared that the authors were attempting to determine whether any monitoring technique would lower the cesarean rate. However, almost all studies have shown that electronic FHR monitoring actually increases the cesarean rate. Did they review the studies comparing intermittent auscultation with continuous electronic fetal monitoring? It was also my impression that there were more older studies showing that fetal scalp blood sampling does lower the cesarean rate. If so, this would be worth pursuing since the technique has been largely abandoned in the U.S.	We included only those studies that met the inclusion criteria described in methods. Namely the authors had to have a stated or implied aim to reduce cesarean births (determined by one or more of the following criteria): *The introduction of the paper includes a literature review of rationale, indicating interest in improving or reducing cesarean risk/rate or in influencing route of birth (vaginal, assisted, cesarean) as an outcome that would be influenced by the intervention strategy under study. *The stated primary or secondary aims indicate intention to examine influence of the intervention strategy on cesarean risk/rate or route of birth. *The analytic models indicate the authors conducted data analysis of the effect of the intervention strategy as it relates to cesarean risk/rate or route of birth. *The results feature data about the relationship of the intervention strategy to cesarean risk/rate or route of birth as reporting of a primary or secondary aim. *The tables in the results section feature data about the relationship of the strategy to cesarean risk/rate or route of birth as reporting of a primary or secondary aim. *The discussion interprets the strategy as potentially having value for modifying cesarean risk/rates or influencing route of birth or the authors express dismay that they did not find it had value for modifying cesarean risk/rates or influencing route of birth. The majority of these studies rested on the hypothesis that care teams would be less inclined to intervene with cesarean if they had higher quality information about fetal well-being. We did not retrieve other studies about fetal scalp sampling that had the aim of reducing cesarean. Agreeing with the hypothesis that knowledge of fetal status might forestall intervention we did include this as a future research item because our take on the literature is the same that trials and observational studies designed with other aims have found decreased cesarean use when fetal scalp sampling is used. We did not find RCTS of intermittent versus continuous monitoring that were designed to reduce cesarean.
Peer Reviewer #2	Results	Detail is presented clearly and organized well. The tables are helpful.	Thank you for your comments.
Peer Reviewer #3	Results	Really like the schematic framework.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #4	Results	It was somewhat difficult to wade through each section, but the tables and especially the Key Points sections keep the reader anchored well. Overall summary tables are very informative. The charts in the appendix that provided details for each study are excellent although probably most useful as a reference for studies of particular interest to the reader.	Thank you for your comments.
Peer Reviewer #4	Results	I was somewhat disappointed in the lack of highlight of the issue of nulliparous women. Clearly the greatest impact on the total cesarean delivery rate is made on the basis of primary cesarean delivery rate. Although that begs the usefulness of the totality of literature reviewed, I would have like to see an explicit statement for each study as to whether or not nulliparity was an inclusion criterion. Most but not all of the individual study summaries did mention parity somewhere in the paragraph. I wonder if this could be included in the charts?	The detail related to parity (if reported) is included in each evidence table found in Appendix C. When reported this data is reported in the discussion of each study in the detailed synthesis. Of note we did exclude studies that were focused on VBAC so this literature does reflect risk of first cesarean among low-risk women whether nulliparous or parous.
Peer Reviewer #5	Results	My main focus was the system level interventions. Clearly this is a difficult analysis due to the wide variety of components of the studies. I would like to see the audit and feedback data put a bit more into context with liturature outside of OB for audit and feedback. It is the most common component of the "sucessful" studies but also common in non successful studies. Is it possible to have a table of studies where it was a "major" part of the intervention compared to a "minor" In otherwords, get a better sense of how audit and feedback influences. This may not be possible within the scope of the report	We do identify audit and feedback studies in Table 30 and note in the discussion that audit and feedback was the most common component of interventions that achieved reductions in cesarean. We have amplified this in the Systems-level section of the Summary and Discussion (Page 75) by adding: …five percent or more. “Of the eight studies in which the primary intervention was audit and feedback of cesarean data (not embedded in a larger quality improvement program), five achieved a reduction of use of cesarean ranging from 7.2 to 2.5 percent. This is compatible with systematic reviews in obstetrics and general use{Jamtvedt, G) of audit and feedback suggesting it is effective for changing provider behavior.{Kongnyuy} [new paragraph for “The next most…”
TEP #1	Results	Since just over 1% of initially reviewed publications made the final cut, I think a bit more detail than “the most common reasons for exclusion were irrelevance to the topic and ineligible study design” would be helpful.	This review was focused on RCTs of strategies that sought to affect the number of cesareans compared to standard care or another strategy. In order to comprehensively identify systems-level studies, we did not restrict our search strategy to RCTs; therefore, a large number of studies were excluded because they were not RCTs. We have added in the text the proportion of papers excluded because they were neither RCT nor systems interventions.

Reviewer	Section	Comment	Response
TEP #1	Results	In all table and text the % change in cesarean section is always given as an absolute change (i.e., a change from 5% to 4% would be a 1% change, not a 20% change.) Given the dramatic differences in some baseline rates, it might be useful to also consider looking at change as a percent drop such that 20% to 18% would be a 10% change rather than a 2% change.	We have a methods preference for absolute change since it best answers the question "How much did the intervention decrease the proportion of birth occurring by cesarean?" However, we have provided the absolute risk of cesarean in each arm for the RCTs and the baseline and post-intervention risk in the systems level studies so the relative proportions are readily calculated if desired.
TEP #1	Results	I may have missed it, but I didn't see mention of the IHI induction bundle, which limits inductions to 39 or more weeks (unless there is a medical indication), which has been widely used, and which I believe has been demonstrated to lower the section rate in some health care systems.	Our intended population for the review is low-risk women intending a spontaneous vaginal birth. Except in the instance of elective induction, which is a topic of burgeoning importance, induction is undertaken for indications that move a patient out of the low-risk pool. We excluded methods of induction of labor overall from this review. On another note we are not aware of RCTs of the IHI induction bundle.
TEP #1	Results	Similarly I didn't see the work by Rouse showing the success of augmentations once the time to continue Pitocin before going to the operating room was changed to four hours from two.	The Rouse study was reviewed and excluded because it is not an RCT and is not a pre-post system level intervention.
TEP #1	Results	As a general comment, it is hard to know, when all that is stated is that a study is of "fair quality" (for example "nurse support"), whether the study is just a technical step away from being resurrected as a good study, or is far from ever providing useful data. In other words, at times it would be nice to go beyond the broad definitions and to hone down on the problem. There were not 6,000 reviewed articles, there were only 90+. Thus getting a sense of what were the precise flaws of some of the larger works might allow readers to get a sense of whether following the same path, but perhaps avoiding a pitfall of the original researchers, would be a potentially productive avenue to pursue.	Assessment of the Risk of Bias for individual studies is provided in Appendix D with details of the individual components scored to produce the final overall classification. A more detailed overview of the flaws of this literature will be included in the future research needs report which is a separate publication currently in development.
TEP #1	Results	Page 26; Sometimes the sheer volume of the data presented makes it possible to miss something that may be of relatively greater import than the numerous other works against which it abuts. For example, on page 26 a Cochrane review of seven studies had significant findings once a single study, with numerous post randomization exclusions, was removed. Given the low frequency with which anything was found that seemed to make a difference, perhaps the authors could spend more time on findings like this and explain whether they felt the exclusion was appropriate, and if so how much heed should be paid to that review.	We have added text to clarify the reasons for excluding that study in the Cochrane analysis and how their review differs from this report.

Reviewer	Section	Comment	Response
TEP #1	Results	Table 27 In the last column of some tables (e.g., Table 27) the % change is note, and directly below that is the term “same,” indicating no significant difference in the intervention group. That term (“same”) may frame the results in an odd light; “same” doesn’t sound like “underpowered.” It may lead the reader to conflate absence of evidence with evidence of absence.	Our rationale for not simply reporting absolute difference and adding the "lower, same, higher" designation was to emphasize that though the point estimate may suggest benefit, the data should not be interpreted as evidence of effectiveness. Since the total "n" per arm is also listed, a reader with sophistication to wonder if this is a power problem is likely able to assess whether this is a power problem or definitive evidence of lack of benefit. We do define "same" as not statistically different across the intervention and comparison arms in each table and believe it probably works better in the tables where there are a range of findings.
TEP #2	Results	Detailed syntheses are generally extremely well written and clear. It would be useful to discuss more thoroughly the impact of the very low cesarean birth rates in many of the studies. With rates much lower than the current US rates of concern, how are we to interpret a lack of effect? For example, in the Hodnett et al study on nurse labor support, the cesarean bith rate in both groups was in the 12% range. This is much lower than the rates in common in current practice, and lower than any national intervention target. Is there a floor in US practice below which we would not expect to see a difference in cesarean birth rates?	Differences in baseline rate were part of the rational for choosing to present the rates in the usual care and intervention arms of trials and for presenting the baseline and post-intervention cesarean data from systems interventions. While there is no a priori reason to believe that strategies that work in settings that have low cesarean use could not work in settings with higher use, we concur that it is harder to dismiss the potential for benefit of a strategy that did not provide statistically meaningful reductions in a low use setting. This motivated the analysis in the systems intervention section of time effects and base rate effects, neither of which contributed substantially to predicting the success of interventions. Your question is intriguing and we have carried it forward into the Future Research Needs project which will produce a separate document for AHRQ with reflections on future research methods and priorities.
TEP #2	Results	It would be helpful to state explicitly that amnioninfusion is not used for meconium in the US after the Fraser trial demonstrated no benefit r/t MAS. The mechanism for improvement in neonatal outcome in under-resourced environments may be different.	Page 54: Have deleted the comment about meconium. Agree it confuses the issue about use of amnioinfusion for reducing cesarean.
TEP #2	Results	Page 71; Line 15-20 Scalp sampling is virtually unavailable in the US today. (p. 71 lines 15-20). The section on fetal surveillance in general could benefit from more precise language. For example, rather that "periodic increases" being described as normal, it might be better to state that accelerations (increases in the fetal hear rate meeting specific criteria) indicate the fetus is well oxygenated at the time they are observed. Similarly, it seems to broad to say that "variable decelerations in general are harmless."	Page 45: Good suggestion, we have made that edit and noted that variable decelerations are common and may accompany each contraction. They are not specifically indicative of distress and are interpreted in the larger context of monitoring patterns

Reviewer	Section	Comment	Response
TEP #2	Results	Page 77; Line 31 Rather a statement to the effect that under certain conditions variable decelerations may be associated with a risk for fetal acidemia sufficient to warrant intervention would be more appropriate.	Page 51: Have reworded to indicate variable decelerations are common and may accompany each contraction. While not specifically indicative of distress they may indicate in the larger context that there is risk for fetal acidemia and intervention can be warranted.
TEP #2	Results	Page 84; Line 20-29 The absolute hemorrhage rates in the accupunture and sham accupuncture groups were remarkably high, despite lack of statistical significance. (10 and 7 vs. 0-3.3; lines 20-29, page 84; most studies estimate the population rate to be close to 3%). This study was likely underpowered to detect a difference in harm.	Correct, for this reason we do not imply statistical significance or note that it is a risk of acupuncture. However these are the data provided and they are of interest as they generate questions about whether there could be risk that needs to be further explored.
Peer Reviewer #8	Results	The amount of detail in the results section is appropriate. The characteristics of the studies are sufficiently described and key messages conveyed. Tables and figures appear exhaustive and I am unaware of other studies that should have been included. Nor do I think any studies should have been excluded.	Thank you for your comments.
Peer Reviewer #8	Results	Page 41 Re fetal scalp sampling (Page 41 of the manuscript) “often is used in conjunction with EFM,” is not true anymore. This statement should be qualified, as fetal scalp sampling is rarely, if ever, used in current practice.	Page 45: Have edited to" sometimes used in conjunction with EFM, with a trend towards less use over time in the US." While major academic sites have abandoned fetal scalp sampling it is not clear that less well resourced sites in the US have. We with grey hair may be keeping the lost art alive.
Peer Reviewer #8	Results	Page 41 re fetal pulse oximetry – (Page 41 of the manuscript) ”It is another way to continuously monitor the fetus during labor.” This statement should be qualified, too, as there is an implication that fetal pulse oximetry is used in practice when, in fact, it was never actually adopted in the U.S. outside of clinical trials.	Page 45: Thank you for reminding us to be more precise. Have edited to say "is another way that has been developed to continuously monitor the fetus during labor. It has been used for research purposes in the US and is not in general use."

Reviewer	Section	Comment	Response
Peer Reviewer #8	Results	Page 42; The phrasing is inverted here. Where it reads, "Knowledge of intrapartum fetal oxygen saturation did not have a significant effect on the overall use of cesarean; however three of the four studies looking at the use of fetal pulse oximetry demonstrated a significant reduction in cesarean performed for fetal distress ranging from 5.7 to 24.6 percent," it should read, "Three of the four studies looking at the use of fetal pulse oximetry demonstrated a significant reduction in cesarean performed for fetal distress; however, knowledge of intrapartum fetal oxygen saturation did not have a significant effect on the overall use of cesarean." The rate of dystocia went up as the rate of fetal distress went down. These studies suggested that there are fetal physiological changes with dystocia that traditional electronic fetal monitoring detects (ie heart rate decelerations) that fetal pulse oximetry does not. In these studies, subjects with traditional electronic fetal monitoring got a cesarean with an indication of fetal distress. Those who had fetal pulse oximetry got a cesarean with an indication of dystocia. The important point from these studies is that the overall rate of cesarean did not change whether subjects had fetal pulse oximetry or not.	Page 46 & 74: Good call. We have reversed the order of the information in the related key point as suggested. We have also added a future research question that aims to standardize operational definitions of indications and to investigate whether changes in trends in cesarean for dystocia are real or indication switching.
TEP #3	Results	amount of detail does make for dense reading in K1-K2; then seems to have fallen off and been a bit too little detail in the KQ4 section.	Harms in this literature are inconsistently sought and poorly documented. A number of the interventions have no readily measured or suspected harms (midwifery care, doula support). We did intentionally minimize both the chapter and the discussion of implications since little useful information that rises to the level of evidence is available. There were no statistically meaningful assessments of risk of harms from these techniques in the included papers. We have expanded the chapter to reflect on what information is provided with the caveat that they are often known complications of the intervention and not specifically linked to the use of the intervention for the purpose of reducing cesarean.

Reviewer	Section	Comment	Response
TEP #3	Results	for the systems level studies, how was inclusion of studies with vbac candidates handled in analysis or conclusions?	We excluded trials and system level interventions in which VBAC approaches were the only component. However within systems intervention this was among the more common elements and excluding VBAC approaches completely would have severely reduced the scope. We did want to make clear, as you note, that VBAC policies are an included element. It is noted in the text among the components of intervention. We have added an additional note about this consideration/limitation on page 61 in the first paragraph of "Observation Data" : "Eight studies explicitly included policies about management of vaginal birth after cesarean among other components of a system intervention. Other studies that provide limited detail and describe only implementation of uniform policies or review of all cesareans may also have included this element. Since it was a common element, these studies are included. It is important to note that this departs from the overall structure of this review since it means that women who are not at low risk for cesarean are included. This situation would be expected whenever a full health care system implements a policy for all births. However it is a limitation since it means, in the related studies, that some of the change in cesarean use may have been accomplished (or failed) because of the VBAC elements."
TEP #3	Results	Formatting on the tables of maternal and neonatal outcomes needs careful copy-editing for consistency in presentation.	Formatting throughout the document has been reviewed and made consistent.
TEP #3	Results	Page 14; Line 31 Table 2, p. 44 the data entered for the Kennell study are not clear	For this study there were three groups of participants. The control group was 204 women who did not participate in the strategies using either a doula or the observer. The 10% and 5% change in cesarean represented in the third column is the 18% cesareans in the control group compared to the 8% of cesareans in the doula group and the 13% of cesareans in the observer group, respectively (18-8 and 18-13). We have added text to the table to explain values given in the table.
TEP #3	Results	Page 25; Line 25-57 the OR for use of a partogram is in the opposite direction from the other two strategy ORs; please check/clarify so directionality is consistent	The OR for this study has been verified and is correct.

Reviewer	Section	Comment	Response
TEP #3	Results	Page 69; Line 22-30 data on the Oloffson study in table 16 doesn't match the discussion	The authors reported results for cesarean and instrumental vaginal deliveries combined with odds ratio and CI as reported in the text. The authors did not report on cesarean births separately– but gave data in a table- so that we calculated the percent of women who had cesareans. The text is correct in stating that the statistical results were not reported. The quality rating of good has been revised to poor.
TEP #3	Results	Page 77; Line 47-48 typo	Page 65: Corrected.
TEP #3	Results	Page 86; Line 4 addsup to 29 studies when otherwise referring to 27 studies.	There are 31 total studies, which is summarized in the first sentence of prior paragraph. Revised the section noted by reviewer for greater clarity. This section (Page 60) now states: "Four studies provide outcomes from randomized trials: three conducted outside the United States and one within a consortium of US and Canadian hospitals. Of the 27 pre-post assessment studies, 16 were conducted...."
Peer Reviewer #10	Results	Detail is appropriate. I'm unaware of additional studies that should have been included or any that were ought to have been excluded.	Thank you for your comments.
TEP #4	Results	Many times it seemed more redundant than it needed. Too much of the studies was described under the subheading, then two paragraphs down went into the narative as well.	The template for CERS calls for Key Points at the beginning of each substantive section. This does create some redundancy but has the advantage of allowing the reader to skim key points and decide which sections to "drill down on" and read with greater attention to detail.
Peer Reviewer #13	Results	Although maternal satisfaction, mother-infant bonding, and breastfeeding were listed as final outcomes, they are not included in outcomes tables and are not mentioned in the text with the exception of maternal satisfaction addressed briefly in the Discussion section. Several studies do report on these outcomes, and these data would be valuable to women and clinicians seeking to choose from among different strategies.	Information related to maternal satisfaction is included in the discussion of each study in the detailed synthesis related to each strategy when available. Reporting of this information was disappointingly rare and not uniform in studies. Review of the evidence tables that documented these outcomes reveals that very, very few studies included them. It could not be included in tables for this reason. We included in the figure as a key outcome to emphasize it should be measured and this report helps show that it is not. The topic is also addressed in future research needs in the list of "Methodologic Issues" (Page 81-82).

Reviewer	Section	Comment	Response
Peer Reviewer #13	Results	Many other studies reporting c-section rates that were included in the Cochrane review of midwife-led care are neither included nor excluded from this review, and thus do not appear to have been evaluated for inclusion. Note that unlike Harvey 1996 which compared midwifery care with physician care, the following studies compare midwifery care with midwifery care – the intervention is different schemes of organizing care (e.g. midwife-led vs physician-led or shared caseload). Biro MA, Waldenstrom U, Pannifex JH. Team midwifery care in a tertiary level obstetric service: a randomized controlled trial. Birth 2000;27(3):168–73. Flint C, Poulengeris P, Grant A M. The “Know your midwife “scheme - a randomised trial of continuity of care by a team of midwives. Midwifery 1989;5:11–6. MacVicar J, Dobbie G, Owen-Johnstone L, Jagger C, Hopkins M, Kennedy J. Simulated home delivery in hospital: a randomised con- trolled trial. British Journal of Obstetrics and Gynaecology 1993;100: 316–23. North Staffordshire Changing Childbirth Research Team. A randomised study of midwifery caseload care and traditional ’shared- care’. Midwifery 2000;16:295–302. Rowley MJ, Hensley MJ, Brinsmead MW, Wlodarczyk JH. Continuity of care by a midwife team vs routine care during pregnancy and birth: a randomised trial. Medical Journal of Australia 1995;163: 289–93. Cheyne H, Mcginley M, Turnbull D, Holmes A, Shields N, Greer I, et al.Midwife managed care: results of a randomised controlled trial of 1299 women. Prenatal and Neonatal Medicine 1996;1(Suppl 1): 129.	We aimed to identify publications in which the explicit aim was to assess impact on cesarean use. Many of these papers are directed at other outcomes as the primary aims and happen to report on cesarean. We have added discussion of the Cochrane review and findings in the Results to acknowledge the difference in methods and findings. We have been stricter than many reviews of specific interventions because we sought to identify the entire literature in which authors asserted they had designed a study specifically to reduce cesarean. Cesarean as an outcome in the birth literature is ubiquitous so we did face an unpleasant challenge of restricting to those studies that aimed to reduce cesarean in low-risk women. Of note reproductive health topics seem especially at risk of "make do" syntheses that combine studies done with different intentions. This can be useful as the review you note is; however, the approach undermines ability to detect the frank lack of data on the direct question of concern: what interventions reduce cesarean in low-risk women? Few reviews of management of hypertension would include papers that set out to change cholesterol and happened to report on hypertension. We believe this is because that literature is a feast while in the instance of this report, we may face a famine. We do list an RCT of midwifery versus conventional care in the US as an important trial to be a priority for future research (Page 82).
Peer Reviewer #13	Results	The bullet lists of "Methodologic Issues" and "Gaps in Areas of Research" do not seem to be clearly delineated. Several recommendations in the former seem to belong in the latter and vice versa. The Gaps in Areas of Research should directly address the need for more and better research on maternal satisfaction, mother-infant attachment, and breastfeeding.	Thank you for your comments. We have revised to more clearly separate items that are specific research concepts from more cross-cutting methodologic concerns (Pages 81-82). The lists retain a methodologic priority suggesting expansion of maternal outcomes and development of more robust measures of maternal coping, maternal-infant bonding, and satisfaction that address this issue.

Reviewer	Section	Comment	Response
Peer Reviewer #13	Results	For the size of the report and the complexity of the subject matter, the review was well organized. The report is unlikely to be usable to guide policy and/or practice decisions due to limitations in the research and limitations in the scope of this report (namely, exclusion of non-RCT studies and of RCTs that identify strategies to reduce cesareans but were not designed with that specific aim.)	We appreciate the clear description of the dilemma. As the strength of evidence table reveals, little rises to the level of being advisable to act on the data. While observational studies are informative in understanding constraints like effect modification and confounding factors, policy must typically rest on strong evidence of effectiveness from trials. Since nearly 100% of the obstetric outcome literature includes cesarean as an outcome, we faced and exquisite challenge in trying to wrap our hands around the intended literature. With very experienced library scientists we were not able to craft a more consolidated approach to find the needles in a haystack smaller than 37,000+ papers at the narrowest when we included a broader array of trials that reported on cesarean as an outcome. Nonetheless, we believe in an ideal world that the study population defined is the correct target - well-conducted trials designed to assess effectiveness of an intervention for reducing cesarean in low-risk women.
Peer Reviewer #13	Results	Page 48; Table 3 Clarify what “community-based model care” means (line 45) – perhaps just call it “continuity of care model”	This is the terminology used in the study.
Peer Reviewer #13	Results	Page 49; Line 51 consider clarifying that birth centers in Waldenstrom 1997 were hospital-based as opposed to freestanding. Consider as well clarifying that the standard care group was also cared for by midwives (this would dampen observed differences in mode of birth as both groups were exposed to midwifery care – it was the organization and site of care that differed).	Page 22: We have added text to clarify.

Reviewer	Section	Comment	Response
Peer Reviewer #13	Results	Page 49-50 Antenatal Care Strategies section: I strongly believe that Harvey 1996 (reference 2266 in Excluded Studies) should have been included. This is an RCT of nurse-midwifery care conducted in Canada. The reason for exclusion was cited as: “Does not state that intent was to improve/reduce cesarean rates” however per the guidelines stated in Study Design on p. 38, this study should have been included as: - it includes a robust discussion of the potential for the strategy (nurse-midwifery care) to reduce cesarean rates in the Introduction section of the paper. - “intervention rates” were a secondary variable, with cesarean rates the first outcome measure reported in the relevant table and text. - the researchers measured and reported the impact of the intervention on cesarean rates - the discussion section of the paper interprets the intervention as having potential to reduce cesarean rates. Thus, this study meets all of the stated criteria for inclusion based on having a “stated or implied aim” of reducing cesareans.	We required that included studies state as an aim the intention to reduce cesarean. The Harvey paper is tricky since unlike many of the studies in which we had to assess implied aims using the criteria list, it is more explicit than many others and states: "The two primary hypotheses were that the rate of episiotomy and the rate of epidural anesthesia would be less for women who received nurse-midwifery care than for those who received physician care." This trial, which is described as a pilot study, included 193 women and was explicitly powered for differences in episiotomy rate. While the paper in essence did disqualify itself on the basis of other stated aims, we concur it should not be penalized because the authors were more clear than others about specific aims and methods. We have included the results of the trial in the revision.
Peer Reviewer #13	Results	Page 50-51; Table 4 and 5 Citations are given inconsistently for the numbers in the table. In some cases, it seems they are combined and the table is reporting a range. It is clear from the study descriptions and the wildly different baseline cesarean rates that populations across studies are not similar. Thus, expected rates of adverse outcomes rates may not be comparable across studies and ranges are not meaningful. Some tables (e.g. table 18) provide citations for every cell of the table, which helps interpret differences. Still, a table may not be the optimal way to convey this information.	Page 23-24: References for all papers are in the left column. We have checked that data sources can be identified. When there was a range of it was stated, and the references for those studies are included in the outcomes columns. Full evidence tables are also available within the report. We agree that the mismatch across studies of control rates and intervention rates makes the comparisons less than optimal. The data about harms are sparse and we have attempted not to overplay them, noting in text that there is overall insufficient attention to the issue of harms.
Peer Reviewer #13	Results	Page 71; Line 3 external EFM does not reliably measure the strength of uterine contractions.	Page 45: Thank you - revised to say "another belt is placed on the abdomen to measure the frequency and duration of contractions." [omitting strength]
Peer Reviewer #13	Results	Page 94; Some of the interventions studied, including continuity of caregiver and continuous labor support, have no “harms that are plausibly caused by the strategy.” This should be stated explicitly in this section.	Page 68: The following text has been added… "Many of the studies included in this review, such as those related to psychosocial support have no known adverse effects."
Peer Reviewer #13	Results	Page 101; Line 54 references a “table that follows” but there is no table present.	Page 66: Revised text to refer to Table 32.

Reviewer	Section	Comment	Response
TEP #5	Results	Detail appropriate. Particularly appreciate that each results section starts with a Review/Summary. There were many studies not included that should have been. For example, there is great controversy about whether limitations on induction of labor can reduce CS. It would have been a great service to look at that literature, whether or not it aimed at reducing CS. Similarly, the Cochrane review on active management of labor included 16 RCTs. Only one RCT was examined in this report.	Our inclusion criteria were stricter than many reviews of specific interventions because we sought to identify the entire literature in which authors asserted they had designed a study specifically to reduce cesarean. Cesarean as an outcome of trials in labor and delivery is ubiquitous so we did, as noted above, face an unpleasant challenge of restricting to those studies that aimed to reduce cesarean in low-risk women, as opposed to reducing time in labor, risk of infection, etc. while also reporting cesarean rate. Women's health topics seem especially at risk of "make do" syntheses that combine studies done with different intentions. This can be useful as the reviews you note are; however, it undermines ability to detect the frank lack of data on the direct question of concern: what interventions reduce cesarean in low-risk women? Women requiring induction typically are not among the "low risk" though elective use may be changing this. Few reviews of management of hypertension would include papers that set out to change cholesterol and happened to report on hypertension. We believe this is because that literature is a feast while in the instance of this report, we face a famine. Well designed research of sufficient power to detect the ultimate outcome - use of cesarean - is very much needed.
Peer Reviewer #15	Results	Detail level and tables are appropriate. Important studies have been included	Thank you for your comments.
Peer Reviewer #16	Results	The results section was well-organized with an initial discussion of the article selection process, followed by careful descriptions of the evidence for each KQ and subsection with several of the KQ (namely KQ2).	Thank you for your comments.
Peer Reviewer #16	Results	Organization under each KQ with overview of literature, key points, and a detailed data synthesis is a helpful approach for the reader. In nearly each case, the detailed synthesis clearly documented careful review of the study (as evidenced by the evidence tables included later), but distilled the necessary findings for the reader so that he/she can remain focused on the outcome measures of interest in this CER. This was done well throughout the careful review for each KQ.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #16	Results	The characteristics of the studies are accurately described in both the body of the text and the accompanying figures and tables. The figures and tables are easy to follow and appropriately descriptive. Please see my attached document for specific formatting suggestions and for recommended correction of several typographical errors.	Thank you for your comments.
Peer Reviewer #16	Results	I could not find any studies that should have been included based on the explicit criteria used. Conversely, I did not feel they should have excluded any of the studies used.	Thank you for your comments.
Peer Reviewer #16	Results	Page 35; Line 38 missing period at end of last bullet point	Added.
Peer Reviewer #16	Results	Page 44-47; Table 2 footnote for table needs to be on p. 48	Page 16-20: Have added footnote to each page of Table 2.
Peer Reviewer #16	Results	Page 50; Line 6 consistently use hyphens “intention-to-treat” as this is used in page before (need to be consistent with hyphen use or not)	Revised to use the hyphen throughout the report.
Peer Reviewer #16	Results	Page 50; Table 4 document definition of NR in footnote of table (obvious to those familiar w/lit reviews, but other items are clearly defined for wide audience. This would be easy to add for clarity.)	Have added "NR=not reported" to all appropriate tables.
Peer Reviewer #16	Results	Page 50; Line 34 citation for statement in first sentence under exercise training subheading	Page 23: Added 2 citations: Hall DC, Kaufmann DA. Effects of aerobic and strength conditioning on pregnancy outcomes. Am J Obstet Gynecol. 1987 Nov;157(5):1199-203. Bungum TJ, Peaslee DL, Jackson AW, et al. Exercise during pregnancy and type of delivery in nulliparae. J Obstet Gynecol Neonatal Nurs. 2000 May-Jun;29(3):258-64.
Peer Reviewer #16	Results	Page 50; Line 49 "low-risk"	Revised to use the hyphen throughout the report.
Peer Reviewer #16	Results	Page 53; Line 36 how is “active management” defined here. This is defined on p. 57 and 58 as each study defined it – maybe just reference longer discussion explaining this is located here.	Page 26: Added "as defined by the authors".
Peer Reviewer #16	Results	Page 55; Line 28 How is “active labor” defined in this study (cervical dilatation 4cm or more robust definition? Included later in detailed synthesis discussion.) It would be helpful to include definition or reference to later more expanded discussion based upon how it is defined in each study).	Page 27: Added "defined as presence of regular, painful contractions and cervical dilation greater than 3 cm".

Reviewer	Section	Comment	Response
Peer Reviewer #16	Results	Page 59; footnote for table needs moved to p. 58	Revised.
Peer Reviewer #16	Results	Page 72; Line 15 recommend change to “use of fetal ST-segment analysis”	Page 45: Revised.
Peer Reviewer #16	Results	Page 86; consider word use of “interventions v. strategies” based on TEP recommendations as noted early in document. Interventions is used pages 86-88, but associated table uses “strategies”	Where appropriate “intervention” has been replaced with “strategy” throughout the report.
Peer Reviewer #16	Results	Page 87; Line 43 recommend change to “outcomes of systems-level…”	Revised to use the hyphen throughout the report.
Peer Reviewer #16	Results	Page 88-89; Title for table 30 “systems-level”	Revised to use the hyphen throughout the report.
Peer Reviewer #16	Results	Page 88-89; Missing period on footnote b and footnote c needs moved from p 89 to 88	Have revised footnotes so that they only point to actual notes used in the table.
Peer Reviewer #16	Results	Page 90; Line 33 formatting needs changed line 33	Corrected.
Peer Reviewer #16	Results	Page 93; great addition to highlight US evidence that may be most applicable to stated audience	Thank you for your comments.
Peer Reviewer #16	Results	Page 95; consistent use of “harms” v. “adverse effects”	Have revised throughout the report.
Peer Reviewer #16	Results	Page 103; double period in footnote at bottom of table	Revised.
Peer Reviewer #16	Results	Page 109; Line 12 missing “accessed on”	Corrected.
Peer Reviewer #16	Results	Table 34 please refer to the feedback on shaded headings from same table in summary – formatting issue, include KQ4 in last shaded heading to be consistent.	Page 78-80: Corrected.
Peer Reviewer #18	Results	In general, the results section is clear. There is a major organizational issue apparent in the discussion of results by key question. This issue is the arrangementof the entries in the supporting tables versus the presentation in the text.	When possible the tables representing change in cesarean are represented immediately following the text. Because of the various strategies related to Key Question 2 (and a desire to reduce the number of small tables in the report) the maternal and neonatal outcomes for these strategies were combined in Tables 10 and 11.

Reviewer	Section	Comment	Response
Peer Reviewer #18	Results	Page 20-22; Table 4 The 4th entry in the table is "hyaluronidase injection" yet the section on "hyaluronidase injection into the cervix" is the final subsection appearing on page 22.	Page 70: Added "into the cervix"
Peer Reviewer #18	Results	Table 4 and 5 The entries in Table 4 and Table 5 should match the organization of the text for the benefit of the reader. Also, although an "Acronyms and Abbreviations" list is provided on page 85, I am a firm believer that tables must stand alone. Therefore, entries such as "NR" for "not reported" should be notated at the end of each table. Again, this is an issue of reader friendliness of the report and each set of table throughout the results should be reviewed for their match to the presentation of the sections of the text.	Good point; have added "NR=not reported" to all appropriate tables.
Peer Reviewer #18	Results	Page 23 For Key Question 2, the Key Points on page 23 doe not match the organization of the text that follows. The first key point is about early labor assessment strategies including 2 strategies: use of partograms and active management. However, the text headings under "Detailed Synthesis" begin with "Early Labor Assessment" that is about bullets three and 4. This again relates to a careful logical progression of ideas, terms used, and scientific consistency within the report to allow the reader to easily follow the text without a lot of mental gymnastics. Perhaps it is the key points that require more careful, logical editing so that they are consistent with the organization of the text that follows. Because this is the most complex section of the report , attention to these organizational elements will greatly improve the readability of the report.	Page 26: Thank you for your comments. The Key Points have been reordered to more closely follow the text of the Detailed Synthesis.
EC	Results	Page 20; Line 7 under Exercise Training heading, there is an extra period at the end of the second sentence.	Page 23: Corrected.
EC	Results	Page 60; under the Randomized Clinical Trials heading, there is an extra space at the beginning of the title of the first bullet point.	Page 64: Corrected.
Peer Reviewer #1	Discussion & Conclusion	The limitations of the studies in the literature are and the type of research needed are clearly stated.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #2	Discussion & Conclusion	The area of systems research is particularly difficult as is outlined in this review. There are multiple systems issues that will effect the culture of the institution and potentially influence the clinical practices. A whole review could be done just of those issues...or perhaps new research that would compare hospitals with comparable descriptors. It would be helpful for the strength/applicability/future research sections to be organized by prenatal/intrapartum/systems/ and then an other...e.g. medical education needs, types of institutions (academic/community)...etc.	We agree that the topic of systems intervention is large and thorny. Secular trends and differences in care routine across countries and even across hospitals within the same city make it a particular challenge. We are developing a separate manuscript to enlarge on some of the challenges from a program evaluation and statistical methods vantage point. In effect this extension is part of the separate report that will be produced as a future research needs document for AHRQ and that involves stakeholder input in prioritizing questions.
Peer Reviewer #3	Discussion & Conclusion	Think this report will catalyze research in this area. Gave me some ideas.	Thank you for your comments.
Peer Reviewer #4	Discussion & Conclusion	The results are clearly summarized. I found the Future Research section particularly insightful. This should be very informative for those conducting research in this area.	Thank you for your comments.
TEP #1	Discussion & Conclusion	In a manuscript that tries to summarize such a large and diverse literature there is a unique burden on the discussion section to provide a synthesis that can transform a “data dump” into a road map. In that regard I would gauge this discussion as a partial success. As a summary it hits high marks. However as a reader I sense a pulling back from any attempt to “editorialize” or “to choose favorites” among the interventions. That may be the appropriate attitude for the authors but it can leave the reader adrift. A study that is strong other than a failure to detail blinding procedures may be dismissed with the same label as one with much more substantive flaws. Similarly a good quality study, showing a large difference between groups, but failing to reach significance because of sample size inadequacies should at least be considered “intriguing” and described as such rather than merely being dismissed as one more inadequate work.	We are vigilant about the need to balance between a useful summary and crossing into guidance or recommendations. To some degree the strength of evidence summaries are meant to integrate across all the available literature to give an overall impression of where the most promising/informative evidence lies. We hope we have identified areas such as doula support as promising and specific trials such as those of beta-blockers as intriguing. The majority of this literature consists of single studies which do not constitute an evidence-base. We have added information in a new “Limitations of the Literature” section in the discussion that provides a better overview of the common inadequacies. Across all the studies, failure to mask intervention groups was the most common limitation with biases in design and analysis like failure to conduct intention to treat analyses the next most common, and poor documentation of randomization methods and failure to indicate that allocation sequence was concealed as the next most common. These particular types of flaws make findings very challenging to interpret. We hope additional commentary throughout the revised version will mitigate the perception that we are dismissing studies as inadequate work rather than insufficient evidence with which to guide care.

Reviewer	Section	Comment	Response
TEP #1	Discussion & Conclusion	The discussion of methodologic issues was quite helpful. However, when they suggest consideration of innovative means of masking patients, they might have been a bit more forthcoming in making their own suggestions or giving examples. Also, when they suggest replication of individual but promising studies, they could have make a major contribution by listing those they think have made that grade. It is a long and detailed document with which they have lived for some time. For the reviewer to pick those out as they meander through 100 pages may be difficult.	We have added some ideas related to masking and specific examples of interventions that were innovative and showed promise. We are also pleased to report that Strategies to Reduce Cesarean Birth was chosen as an AHRQ Future Research Needs Projects which means a more detailed document, complemented by stakeholder input as well as the research team's will be produced to explore what has appeared most promising and among them which research the group recommends prioritizing.
TEP #2	Discussion & Conclusion	Summary for KQ1 should reiterate the issues around the safety of the substances in the hyaluronidase injection. The issue of lack of power to detect harm should be highlighted and discussed in more detail. It is a short step from "no statistically significant difference" to "this intervention is safe." In my view we should be careful to differentiate between the two concepts and highlight the fact that much larger trails are needed to detect serious adverse effects. Although I agree that the gaps identified are indeed gaps, it is not always clear how they follow from the report. For example, the note of staffing phenomena as a gap. This is no doubt correct, it seems to come "out of the blue." It would be hepful to make clearer links between the review and the gap statements.	Page 81: We have added notes on the lack of approval of the vehicle in the US so that it is noted in each location that the study is discussed. We agree completely on these observations about power (and on the history in OB/GYN of considering similar underpowered outcomes evidence of equal risk). We have more fully discussed lack of power to detect harms in a new section of the discussion called "Limitations of the Literature" that precedes the "Future Research Needs". Gaps were developed over the course of the review in part by noting areas in which we hoped to identify literature and did not. Staffing patterns is one of these, we anticipated that we would see some trials or at least systems interventions that attempted to modify staffing or change of shift routines to decrease cesareans. Items on our list expected that were not found are included in gaps. Added a sentence to that effect in the future research section.
Peer Reviewer #8	Discussion & Conclusion	Overal the implications of the major findings are clearly stated and the limitations adequately described.	Thank you for your comments.
Peer Reviewer #8	Discussion & Conclusion	Page 70; The entire paragraph beginning with the sentence, “Caution must be used in interpretation of this literature,” should be rewritten to make the paragraph more comprehensible. The second sentence is unclear. Even substituting “drawn” for “draw” does not completely solve the problem. The last sentence is also unclear.	Page 75: Good call. It has been revised: Caution must be used in interpreting this literature. Both trials and observational studies have limitations in ensuring the intervention is the cause of change, or lack of change, in cesarean use. To be a site in a randomized trial, at minimum, the leadership of units involved was invested in the importance of research on reducing cesarean and willing to participate in a study about how best to accomplish that goal. In the included randomized studies, trial assignment could not possibly be masked at all levels - sites would have been able to infer their status.

Reviewer	Section	Comment	Response
Peer Reviewer #8	Discussion & Conclusion	Page 71; The authors or editors should consider removing the metaphor, “closing the window” and the description of healthcare systems as “jaded.”	Page 76: Have removed "jaded" but retained the overall comment as there is quite active discussion in professional forums about whether there is a felt need to change trends that is accompanied by a "so what" or "not a problem" attitude. The observation is also necessary to set up the following analysis of time trends as an explanation.
TEP #3	Discussion & Conclusion	Page 102; Line 16-17 what do the authors suggest to overcome the challenge of bias? Comment on whether a study without risk of bias can be designed and if not, what the implications are for clinical practice or future reviews. --see general comments for thoughts on conclusions --the future research section does identify new directions.	We have addressed how to reduce biases and associated issues in the Discussion and Future Research sections of the report.
Peer Reviewer #10	Discussion & Conclusion	The future research section is particularly noteworthy in light of the fact that no interventions were found to be uniformly effective in reducing Cesareans. The future research section explains the methodologic problems and gaps in research well. Given that women and labor have not changed biologically, there must be behavioral and systems level factors at play that can be defined and studied if we are smart enough.	Thank you for affirming the content is helpful. We concur systems factors must be at work.
TEP #4	Discussion & Conclusion	Implication is that we have no perfect studies out there. But if there are plenty of studies over the years, and nothing has come of it to find one cause, that does mean it is multifactorial I suspect a bigger deal about that should be made in the body of the study description. The idea of torte reform was totally set aside until the very end, pg 107.	Our team would summarize that there is not plenty of research and that the dearth of applicable studies is concerning. Overall the literature is skimpy for either accepting or setting aside interventions. It seems certain many factors are in play, but the specific note of a multifactorial contribution to rising rates doesn't seem to address a particular desired edit. We sought and would have included pre-post comparisons of outcomes of tort reform as systems intervention but did not identify such papers linking reform of litigation law to rates. For that reason it appears late in the speculative discussion of analyses that need to be done.

Reviewer	Section	Comment	Response
TEP #5	Discussion & Conclusion	The summary and discussion section is short and needs to be fleshed out with much more discussion about the limitations and strengths of the literature. This will be particularly useful and important if AHRQ can ask the EPC to go back and include literature that was excluded and which the TEP suggested be included.	A number of recent AHRQ products address other aspects of the challenge of changing cesarean use. These include the reports on Cesarean on Maternal Request, the VBAC report, induction of labor, and future research needs projects that are underway. This report was explicitly positioned to determine what data was available from RCTS to provide evidence about approaches to reducing use of cesarean among low-risk women at term, without prior cesarean, with uncomplicated pregnancies. We are not certain what topics or specific studies are referred to by the reference to "which the TEP suggested". They may have been areas of interest like management of breech births or induction of labor that were assessed to be outside the scope of this review.
TEP #5	Discussion & Conclusion	The future research and gaps sections are cursory, at best. Both the methodologic issues section and the gaps section should detail for specific interventions discussed in the report what needs to be done in the future and why. The issues and gaps identified are high level and need to be much more specific to guide future research meaningfully.	Future research needs are in the process of being much more fully developed in a process that includes multiple stakeholders, care providers, patient advocates, and funders. That process and its findings for prioritization of future research to reduce cesarean use will result in a separate document. We have however improved the organization of this portion of the report to more clearly and consistently describe the gaps and where they lie within the causal framework.
Peer Reviewer #15	Discussion & Conclusion	Implications and limitations clearly stated. The parameters for future research are clearly stated and well delineated and the report should be useful for assessing the most appropriate future research.	Thank you for your comments.
Peer Reviewer #16	Discussion & Conclusion	The authors made it clear that the evidence is not sufficient at this point to demonstrate a clear method to reduce the cesarean rate in the specified low-risk population within the US. They do however, clearly document useful future study suggestions that if adequately investigated would have implications for clinical practice and population-level assessments. They appropriately included background literature, including reference to accepted public health parameters (ex. HP goals from 2000-2020) relevant to the topics addressed here.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #18	Discussion & Conclusion	I am fascinated by the inclusion of bullet 4 of "Methodological Issues" on page 76. What about long-term effects of being born by cesarean? Why is the assumption ther that more "normal, physiologic" births my result in "future neurodevelopment impairments"? There is a bias inherent in this bullet that is not supported by the data or scope of the review. If this bullet is included, then a similar one on the long-term effects on women's health of 1/3 (or more) of the population of women who have had children having a "surgical abdomen" with all of its long-term effects into later stages of life should be added.	The item was included on the basis of a European study that included follow-up and did find excess neurodevelopmental delay among those in the trial who had vaginal births. Agree about inherent bias to basing directionality on a single follow-up study and have revised that item and added the item about long-term consequences of cesarean beyond influence on future childbearing.
Peer Reviewer #18	Discussion & Conclusion	Page 76; 53 "Midwives" is correct spelling.	Page 83: Corrected.
TEP #5	References	Also, some references are not fully or suggiciently detailed. For example, reference 28 just says the EHC program and doesn't send me to a specific publication or place on that website. Please don't make your readers work that hard, it takes away from the message and the work.	Page 88: The URL for the Methods Guide has been added to the citation.
Peer Reviewer #1	Clarity & Usability	The report is well organized. Unfortunately, high quality studies are rather meager, and the authors offer few practical suggestions to lower the cesarean rate at the present time. Do they have any specific recommendations based on their findings that the reader (physicians) can use?	Thank you for your comments.
Peer Reviewer #2	Clarity & Usability	I would like to see the conclusions developed in the full paper be part of the Executive Summary. The natural question is: what direction(s) would likely prove to be most productive in future studies. How important is the randomizing technique to ultimate data strength. Because of the implications of C/S for the future childbearing outcomes of women it is very important to look for effective ways to reverse the rise in primary C/S. It is of concern that very few studies have looked at the potential for prenatal care to influence delivery method. Also, the question should be raised about how much data still is needed for the evidence for doulas to be rated high. There are some trends expressed that could be used to encourage further studies. Ex: what data has been presented that likely would/should provide some direction to answering the questions. This report will be helpful to researchers; it's less clear that there is enough data to support policy decisions .	We agree it would be optimal to move more discussion into the executive summary; however, we are constrained by page limit and the template for the Executive Summary. We agree that the literature retrieved is in general insufficient to guide care, somewhat surprising in its limited content, and has the most potential to influence future research (as opposed to setting policy). An ongoing process to describe important future research priorities is building from this report using a panel of stakeholders to outline approaches to your questions. The recommendations from that future research needs process will also be available as a separate and more detailed document.

Reviewer	Section	Comment	Response
Peer Reviewer #3	Clarity & Usability	Clearly written and tightly organized.	Thank you for your comments.
Peer Reviewer #4	Clarity & Usability	Well organized, well written, informative.	Thank you for your comments.
Peer Reviewer #5	Clarity & Usability	Document is complete, need a "clinical" version that summarizes main points for people running obstetrics services who will not plow through the whole document	Thank you for your comments. The Executive Summary will serve as a more succinct version of the full report. Clinicians will be able to go to the full report if they desire more detail.
TEP #1	Clarity & Usability	The good news is that the bottom line message was clear. The bad news is that the message apparently is that we have a very long way to go. Since this is such a weighty tome, it might have been helpful if the authors were more liberal with the use of bolding or italics to focus the readers on the key points along the way. By this I don't just mean section headings, but individual points of note, or studies of particular interest. Otherwise give the wealth of data, no point seems to be more important than any other and it is possible for the reader to drift over key pieces of information.	You've received the correct message. We understand the challenges of voluminous reports. Standardized document templates prohibit use of other forms of drawing attention to key details. We hope the key points can help serve this function.
TEP #2	Clarity & Usability	The report is well organized, well written, and important. It would benefit further from attention to the usability in the US context of the interventions, and explicit discussion of power to detect harm.	Thank you for your comments.
Peer Reviewer #8	Clarity & Usability	My only comments about clarity are above. The report is well-organized and the conclusions are helpful for policy decisions, practice guidelines, and as a baseline for future research.	Thank you for your comments.
TEP #3	Clarity & Usability	The phrase "low strength of evidence for lack of benefit," which appears first in the executive summary but is not clarified in meaning until the main report, is a bit of a head scratcher. I'd recommend either rephrasing or including some explanation in the exec summary to assist readers who may only read the summary	ES-13: We have clarified this definition with the addition of the following text to the Strength of the Evidence section," At times there was low strength of evidence for lack of benefit. This means studies with some deficiencies did not demonstrate reduced use of cesarean, but future research could change that assessment."
TEP #4	Clarity & Usability	Report followed a pattern, which made it much easier to read. See above comment for repeating information. Conclusions however were basically to do more research. I did see that the authors gave specific requests for research, not just 'more research needs to be done".	Thank you for your comments.

Reviewer	Section	Comment	Response
TEP #5	Clarity & Usability	This report, as done, has very limited usability. I will not be able to use it to inform policy or products that our academy is doing because it is so very limited.	Understood. It does however reflect what is actually known from clinical trials and pre-post systems level interventions to decrease cesarean use among low-risk women. This suggests that the literature is insufficient to provide definitive guidance for this specific population about approaches that are proven to be effective. That said, as care providers we do need to make decisions and intermediate outcomes, such as time in labor and risk of infection, or additional topics such as VBAC, elective cesarean, and induction, covered in other AHRQ products that can provide additional data.
Peer Reviewer #15	Clarity & Usability	Excellent and clear structure but the results have few policy or practice implications due to the poor quality of the body of research and lack of detection of interventions with benefit to clinical practice. The report is most useful for assessing the value of future research strategies.	Thank you for your comments.
Peer Reviewer #16	Clarity & Usability	As discussed above, the report is structured and organized well such that the engaged reader may follow with ease. The conclusions from this particular review are limited from both policy and practice perspectives because a large amount of additional research is necessary for conclusive strategies to reduce cesarean rates of delivery in this defined population. This is a critical individual and public health issue that must be addressed on both practice and policy levels, but the available data as exhaustively reviewed in this document do not clearly provide definitive conclusions that will currently change clinical practice or inform policy to a large extent.	Thank you. We concur that the report frames the need for future research on reducing cesarean in low -risk women. The topic was selected for AHRQ Future Research Needs project. Results of that stakeholder driven process designed to highlight and prioritize research needs will also be available as a separate AHRQ report.
Peer Reviewer #18	Clarity & Usability	I have addressed these issues earlier.	Thank you for your comments.
Peer Reviewer #18	Clarity & Usability	Unfortunately, because the level of evidence is generally poor across strategies, the report is most useful to inform future research rather than policy and/or practice.	Thank you for your comments.

Reviewer	Section	Comment	Response
EC	Clarity & Usability	a. The comparators used in this report are referred to as the standard or usual care but a definition is not provided. Upon further investigation, it appears that standard care has multiple definitions across studies and is defined in different contexts depending on what specific intervention was being studied. The standard of care was not universal though it is treated as such across findings.	Correct, the research literature provides little detail about the background in which these studies took place. All we can know with certainty is that the use of cesarean was in the reported "usual" or "standard" care arm compared to the intervention group being studied. We did not allude to any expected standard package and take care to note international versus US setting differences as well as to emphasize that any reduction in use is site specific. Precisely this concern is why there is no aggregate meta-estimate for effects. The settings, populations, and usual care models are varied and in most instances incompletely described.
EC	Clarity & Usability	b. It was unclear what the efficacy of the standard of care was as a comparator. The effect of the strategy on reducing cesarean was communicated, but it was not clear what effect the standard of care had on reducing cesarean birth or what the rate of cesarean birth was when using the standard of care. Is standard of care being used as a true comparator or as an expression of a control?	We treated the usual or standard care group as the comparator and expressed changes that were intended to result from the intervention as the reduction in cesarean use for that setting. We agree that unlike in placebo controlled trials, the "comparator" is varied. This topic is also discussed in the comment above.
EC	Clarity & Usability	c. There is limited applicability of studies to current treatment contexts due to the fact that the new strategies that revealed a potential reduction in cesarean birth are not offered or attainable by the majority of pregnant women in the United States. Many of them require a clinical setting that is advanced enough to provide the strategy or a personal financial standing of the pregnant woman sufficient enough to afford the intervention. This limit should be addressed or acknowledged in the discussion section.	We have added a note in applicability about variable availability (Pages 80-81). Doula support was the only item that seems particularly related to the individual patient's ability to pay. For other interventions, the availability is likely determined by setting characteristics and by cross-cutting and varied payor rules such as whether acupuncture is covered. However of the approaches that have any level of promise with some strength of evidence, doulas seem to be the main ability to pay item. The concept is noted in applicability in the Discussion and Summary section.
Peer Reviewer #1	General Comments	The question is an important one, and the key questions are reasonable. However, the results will be somewhat disappointing for clinicians. The report will be most useful from a research standpoint and to point out the future studies that are necessary. The answers to the key questions do not offer anything very helpful or practical for physicians and fot actual patient care.	We concur that the state of the literature is disappointing.
Peer Reviewer #2	General Comments	There is wide-spread concern about the rising C/S rate of births in the US and internationally. These concerns rate both to the primary C/S rate and to the rate of VBACs. There was no attempt in this study to look at VBACs rated to outcomes, safety or guideline evidence that has led to the decrease in VBACs.	This report is focused on low-risk women, which was defined to exclude those with previous cesarean. We have provided the reference to another AHRQ review that addresses VBAC.

Reviewer	Section	Comment	Response
Peer Reviewer #3	General Comments	Important messages for practicing OBGs,midwives,and family physicians. Key questions are on target. I wish that the underlying evidence was stronger.	We concur that the state of the literature is disappointing.
Peer Reviewer #4	General Comments	The report addresses a critically important public health issue with appropriate key questions. I believe that all in the defined audience will benefit from reading this.	Thank you for your comments.
Peer Reviewer #5	General Comments	Content and review is of high quality and very relevant, The report itself seem a bit redundant, though this is partly how these reports are designed. I would suggest a "clinical" summary designed for directors of obstetric services that summarizes the report.	The Executive Summary will serve as a more succinct version of the full report.
TEP #1	General Comments	This is a thorough, clear review of the state of the literature in regard to interventions designed to modify the primary cesarean section rate. While the data appear encompassing and the language is crisp, the considerations of what the data mean is not up to that same standard. Thus one gets a clear sense that either the results were ambiguous or that the quality of the work was suboptimal, leaving almost all possible interventions as uniformly unproven. While that might be the case, the authors might have ended up with a sense of which interventions, though studied in underpowered projects, had results that were sufficiently “provocative” to warrant a closer, more methodologically sound look.	This interpretation is correct. Many of the individual findings and findings across studies of similar intervention provide ambiguous or conflicting results. Much of the literature is of poor or fair quality, lacking key requirements like masking of participants/providers/assessors and selecting conducting outcome analyses, in some cases not providing intention to treat analyses. There is not strong evidence available to support any of the strategies we evaluated which is disappointing since observational studies have at times suggested promise for many of the strategies investigated. This is crucial since it highlights the higher potential for premature adoption of strategies based on cohort and database analyses that have not been supported by subsequent trials. We do note beginning as early as the abstract where there are intriguing findings from individual studies, or from families of studies – like those of doula support – that warrant stronger studies to confirm what appear to be benefits but do not yet have strong evidence. Future research also flags some of these as promising areas for research.
TEP #2	General Comments	The report is clinically meaningful, and the target population is clearly defined. The audience is less clearly defined. The key questions are appropriate and clearly stated. However, the use of the abbreviation "KQ" appears for the first time in the report (executive summary) before the term and abbreviations are explained. This could be confusing to readers unfamiliar with the process.	ES-3, Page 3: We have spelled out Key Question at first use.
Peer Reviewer #8	General Comments	The report is clinically meaningful. The target population and audience are explicitly defined. The key questions are appropriate and explicitly stated.	Thank you for your comments.

Reviewer	Section	Comment	Response
TEP #3	General Comments	It will be difficult for clinicians, based on this report, to implement any measures to reduce cesareans since the report concludes nothing has been shown to be clearly effective. Furthermore, it concludes that nothing has been clearly shown to be clearly ineffective, so clinicians will not be able to stop using a useless measure to reduce cesareans. Yes, the target population, audience, and key questions were described explicitly. But the question now arises, can reviews such as these be TOO rigorous, when not a single study is judged sufficient basis for conclusion? is there nothing to be gained by summarizing results of only "good" studies as a place to find something clinically useful? Similarly, if results of a "good" study are not consistent with results of a "poor" study, is it appropriate to conclude that no guidance can be gleaned? As an example, differing results for use of propranolol + oxytocin. Or what about amnioinfusion to reduce cesarean for fetal distress? There is a troubling conflict between rigor and utility of reports like this...is it time to reexamine the approach?	Thank you for your comments.
Peer Reviewer #10	General Comments	The target population is well-defined and the key questions are explicitly stated. The fact that the study did not identify a clear set of interventions that could be used to decrease Cesarean delivery rates is disappointing but not surprising.	Thank you for your comments.
TEP #4	General Comments	Key questions, target population, audience all well stated at the beginning of the report. It is clinically relevant, however, since there are not actionable recommendations I am not sure it would be called meaningful... Like so many things we do however, there are not studies to support our actions.	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #13	General Comments	This important review represents considerable effort and addresses a critical question in maternity care today. It is unfortunate that the quality of the evidence overall is poor or inadequate. The report is organized by Key Questions (KQs) with the harms of interventions addressed separately from their effectiveness. However, clinicians, women, and other stakeholders are likely to want to consider the effectiveness and potential adverse effects of strategies simultaneously. Additionally, this organization scheme biases against strategies that have no or few potential adverse effects, namely continuity of carer and continuous labor support. When faced with uncertainty about the effectiveness of strategies due to poor quality evidence or low external validity, the low likelihood that there are adverse effects may make these strategies much more appealing to women, whereas interventions that include medications or invasive procedures need much more careful study before they can be adopted. One additional note: consider adding “in low risk women” to the title of the report.	ES-1, Page i: We sought to organize the review of this literature by type of strategy. We then systematically reviewed each included study for adverse effects. We have added text to point to the important point that many of the strategies related to labor support have no known adverse effects. We have revised the title to clarify our focus on low-risk women.
TEP #5	General Comments	I am not finding the report to be very meaningful in a clinical context. Too much literature was excluded for not having the AIM of reducing CS. The KQs, targeted populations and audiences are fine, the inclusion and exclusion criteria are not.	Thank you for your comments.
Peer Reviewer #15	General Comments	The report is meaningful in demonstrating the state of the existing literature in cesarean reduction and in pointing directions for future research, The lack of quality research and evidence for beneficial reductions minimizes the public health importance of the report and there are few areas that will change clinical practice. The major impact is on the design and assessment of future research .	Thank you for your comments.

Reviewer	Section	Comment	Response
Peer Reviewer #16	General Comments	Report is clinically meaningful particularly in trying to process the disconnect between practices seen in everyday obstetric practice and population-level data regarding the rapid and sustained increase in the number of cesarean deliveries. The authors carefully document the target population and audience at several key points throughout the document. The key questions are clearly stated. I have some specific feedback re: KQ4, but I don't feel my thoughts invalidate the careful work of the authors and their TEP in designing these KQ. These KQ appropriately address the necessary questions re: this topic.	Thank you for your comments.
Peer Reviewer #18	General Comments	In general, the report is clear, consitent, and well-written. The target population is explicitly defined. The report is also clinically important and presented in a way that will resonate with clinicians. However, I always struggle with samples of mixed parity with the outcome of primary c/s. It is possible that the effect of interventions that may help lower cesarean rate in nulliparous women is washed out with mixed parity samples. This issue was not addressed in the review. The issue of adequate sample size in individual studies was not well described, e.g. notation of whether or not each study's sample size was base on an appropriate power analysis. The focus on over sample size vs a criterion of power analysis base on primary outcome should be rethought. The 2 issues of mixed parity and sample size determination via power analysis were appropriately addressed in the section on Future Research: Methodological issues. Thank you!	Thank you for your comments.