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Strategies to Reduce Cesarean Birth

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting comparative effectiveness reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see http://www.effectivehealthcare.ahrq.gov/reference/purpose.cfm

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input from are essential to the Effective Health Care Program. Please visit the Web site (http://www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this CER. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to epc@ahrq.hhs.gov.

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Strategies to Reduce Cesarean Birth

Structured Abstract

Structured abstract.

Objectives: The Evidence-based Practice Center systematically reviewed evidence addressing strategies to reduce cesarean birth.

Data Sources: We searched MEDLINE® and CINAHL® for articles published in English from 1968 to July 2011.

Review Methods: We excluded 6016 publications because they did not address a key question, were not an eligible study design or did not aim to reduce cesarean birth. Of the 92 studies included, 16 were good quality, 26 fair, and 50 poor.

Results: In this review, all studies compared the novel strategy to usual care or to variations in the same intervention. Few studies addressed prenatal strategies; the one intervention that reduced cesarean was treatment of the cervix with hyaluronidase in the clinic at term to promote cervical softening. Four trials favored active management of labor, with 2.8 to 7.4 percent decreases in cesarean, one was significant. Doula support in labor was associated with significant reductions in cesarean (5.0 to 22.0 percent) in three studies. One of six trials of fetal assessment reported a significant reduction in total cesareans (20.6 percent). Three of eight trials of amnioinfusion reported a significant reduction in total cesareans (15 to 34.2 percent).

Within health care systems that changed policies or procedures, virtually all evaluated strategies with more than one component. Seventeen of 31 studies reported statistically significant reductions in cesarean from 1.6 to 17.0 percent. Ten of the 17 effective strategies included audit and feedback of cesarean trend data to participating units and/or care providers, seven included protocols for vaginal birth after prior cesarean, six included agreement on overarching labor and delivery guidelines, and five included active management of labor protocols. Overall it is not possible to determine which components are definitively associated with reductions.

Conclusions: No single intervention strategy was uniformly successful in reducing cesareans. Strength of evidence was low to insufficient for all interventions. No approach dominated as a strategy appropriate to reduce use of cesarean in low-risk women in the United States.

Contents

Executive Summary ES-1
Introduction 1
Background 1
Objectives 2
Interventions 2
Goal of this CER 2
Scope and Key Questions 2
Scope of the Report 2
Key Questions 3
Organization of this Evidence Report 3
Uses of this Report 3
Methods 5
Topic Development and Refinement 5
Analytic Framework 5
Literature Search Strategy 6
Databases 6
Search Terms 6
Process for Study Selection 7
Inclusion and Exclusion Criteria 7
Screening of Studies 8
Data Extraction and Data Management 9
Individual Study Quality Assessment 9
Data Synthesis 10
Strength of Evidency for each Key Question 10
Applicability 10
Results 13
Article Selection 13
Studies of Strategies used During Pregnancy 18
Overview of the Literature 18
Key Points 18
Detailed Synthesis 19
Studies of Strategies used During Labor 22
Management of Labor 22
Overview of the Literature 22
Key Points 23
Detailed Synthesis 23
Psychosocial Support 31
Overview of the Literature 32
Key Points 32
Detailed Synthesis 32
Pain Management 36
Overview of the Literature 36
Key Points 37
Detailed Synthesis 37
Fetal Assessments 39

Overview of the Literature 40
Key Points 41
Detailed Synthesis 41
Amnioinfusion 46
Overview of the Literature 46
Key Points 47
Detailed Synthesis 47
Unique Interventions 51
Overview of the Literature 51
Key Points 51
Detailed Synthesis 52
Systems Level Interventions 54
Overview of the Literature 54
Key Points 55
Detailed Synthesis 55
Head-to-Head Comparisons 62
Studies of Adverse Effects of Strategies used to Reduce Cesarean 63
Overview of the Literature 63
Key Points 63
Detailed Synthesis 63
Discussion 67
State of the Literature 67
Summary of Outcomes 67
Studies of Strategies used During Pregnancy 67
Studies of Strategies used During Labor 67
Head-to-Head Comparisons of Strategies to Reduce Cesarean 70
Studies of Harms of Strategies to Reduce Cesarean 70
Strength of the Evidence for Effectiveness of Strategies 71
Overview 71
Strength of the Evidence by Key Question 71
Applicability 73
Future Research 74
State of the Science 74
Methodologic Issues 74
Gaps in Areas of Research 75
Conclusions 76
References 77
Acronyms and Abbreviations 85

Tables

Table 1: Inclusion/exclusion criteria.....7
Table 2. Summary of effectiveness of cesarean reduction strategies from greatest to least change 14
Table 3. Summary of effectiveness of cesarean reduction strategies during pregnancy 18
Table 4: Maternal outcomes for antenatal strategies to reduce cesarean births.....20
Table 5: Neonatal outcomes for antenatal management strategies to reduce cesarean births 21
Table 6. Summary of effectiveness of labor management cesarean reduction strategies: early labor assessment.....24
Table 7. Summary of effectiveness of labor management cesarean reduction strategies: measurement of labor progress 25
Table 8. Summary of effectiveness of labor management cesarean reduction strategies: active management of labor.....27
Table 9. Summary of effectiveness of labor management cesarean reduction strategies: management of abnormal labor 28
Table 10: Maternal outcomes for labor management strategies to reduce cesarean births 30
Table 11: Neonatal outcomes for labor management strategies to reduce cesarean births 31
Table 12. Summary of effectiveness of cesarean reduction strategies using doula support.....33
Table 13. Maternal outcomes for psychosocial/labor support strategies to reduce cesarean births.....33
Table 14. Neonatal outcomes for psychosocial/labor support strategies to reduce cesarean births.....34
Table 15. Summary of effectiveness of cesarean reduction strategies: labor support by nurses and midwifery students.....35
Table 16. Summary of effectiveness of cesarean reduction strategies of pain management.....37
Table 17. Maternal outcomes for pain management strategies to reduce cesarean births 39
Table 18. Neonatal outcomes for labor management strategies to reduce cesarean births.....39
Table 19. Summary of effectiveness of cesarean reduction strategies: fetal pulse oximetry 41
Table 20. Maternal outcomes for fetal assessment strategies to reduce cesarean births 44
Table 21. Neonatal outcomes for fetal assessment strategies to reduce cesarean births 44
Table 22. Summary of effectiveness of fetal assessment cesarean reduction strategies: fetal STAN 45
Table 23. Summary of effectiveness of cesarean reduction strategies: amnioinfusion for meconium.....47
Table 24. Maternal outcomes for amnioinfusion strategies to reduce cesarean births 48
Table 25. Neonatal outcomes for amnioinfusion to reduce cesarean births 48
Table 26. Summary of effectiveness of cesarean reduction strategies: amnioinfusion for fetal distress.....50
Table 27. Summary of effectiveness of cesarean reduction strategies: unique strategies 52
Table 28. Maternal outcomes for unique strategies to reduce cesarean births 53
Table 29. Neonatal outcomes for unique strategies to reduce cesarean births 53
Table 30. Summary of systems level strategies to reduce cesarean births 56
Table 31. Components of interventions in the United States with at least five percent reduction of cesarean.....61
Table 32. Components of interventions in the United States with least success in reduction of cesarean.....62
Table 33. Overview of harms reported in studies of strategies to reduce cesarean birth 63
Table 34. Strength of evidence for various strategies to reduce cesarean birth.....71

Figures

ES-Figure 1. Analytic framework strategies to reduce cesarean birth.....ES-4
ES-Figure 2. Disposition of articles identified by the search strategy.....ES-6
Figure 1. Analytic framework strategies to reduce cesarean birth.....6
Figure 2. Disposition of articles identified by the search strategy.....13

Appendices

Appendix A: Search Strategy
Appendix B: List of Excluded Studies
Appendix C: Evidence Tables
Appendix D: Data Extraction Forms
Appendix E: Quality of the Literature
Appendix F: Applicability Summary Tables
Appendix G: Strength of the Evidence Calculator

Effective Health Care

Strategies to Reduce Cesarean Birth

Executive Summary

Effective Health Care Program

The Effective Health Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders including consumers.

The full report and this summary are available at www.effectivehealthcare.ahrq.gov/reports/final.cfm

Background

Thirty two percent of pregnancies in the United States conclude with a cesarean birth.[1] This record high rate reflects a relative increase of 53 percent in use of cesarean from 1991 to 2007.[1] The pattern of increasing use of cesarean has been concerning for decades, with the last decline of two to three percent occurring in the mid-1990s being fully reversed by 1999 and increasing over 50 percent from 1996 to 2007.[2] Nearly one in three births by cesarean translates to a total of 1.4 million cesarean births each year making cesarean the most commonly performed major surgery in the United States.[1]

The Joint Commission has expressed concern about U.S. cesarean birth rates in its *Specifications Manual for Joint Commission National Quality Core Measures*, noting that, "There are no data that higher rates improve any outcomes, yet the CS [cesarean section] rates continue to rise."[3] Cesarean birth is not without consequences. In general, cesarean is more costly to the healthcare system, is associated with increased risk for both mother and infant, and has potential to complicate subsequent pregnancies.[4-5] Previously extraordinarily rare complications like uterine rupture and abnormalities in placental attachment to the uterus, such as placenta accreta and percreta, are becoming more common modern obstetric care challenges.[6-7] Indeed, because the effects of these complications can be devastating and include fetal death, emergent hysterectomy, and maternal mortality from associated bleeding, labor and delivery units have created "code teams" that conduct practice drills to be prepared for such emergencies.

Cesarean birth rates vary considerably by geographic region, ranging from 25 to 38 percent among different states with the highest rates in the southeastern states.[1] One research group examining differences across hospitals documented a span from 9 percent to 37 percent for primary cesarean births.[8] While health care providers and health systems initially viewed such variation as a reflection of underlying differences in the risk profile of the women receiving care at the hospitals, it has become increasingly clear, through use of techniques like risk adjustment,

that a large proportion of variation is not explained by some facilities having much higher or lower risk patients than others. Provider and patient preference appear to be an important driver of these differences.[9]

Goals to reduce cesarean in the U.S. have become less ambitious. The Healthy People 2000 goal was to reduce cesarean to 15 percent of all births.[10] For Healthy People 2010 this goal was revised to 15 percent among women who had not had a prior cesarean, and in Healthy People 2020 the new target for cesarean among low risk women in a first pregnancy with full-term singleton pregnancies and vertex presentation is 23.9 percent.[11-12] The moving target reflects ambivalence in knowing what the right rate is for optimal maternal and infant outcomes and doubts about what interventions can safely reduce use of cesarean.[13-14]

Commentary on the factors driving change in cesarean use has been robust. Putative influences include:

- Changes in reimbursement for births that favor interventions like cesarean[15]
- Amplified perception of risk of medico-legal liability claims for less than perfect infant outcomes or for failing to intervene[16]
- Shifts in consumer attitude that include less fear of or regret about cesarean[17]
- Lower psychosocial or emotional value placed on the experience of vaginal birth[18]
- Concerns about pelvic floor damage and future continence[19-20]
- Maternal desire for greater control over the timing and circumstances of birth[21] including maternal request for elective induction and cesarean.[22]

Research has addressed predictors of cesarean such as the shift toward older maternal age, higher body mass index, greater maternal comorbidity, use of assisted reproductive technology, and increased incidence of multiple gestations.[23-24]

Nonetheless relatively little focus has been placed on research specifically designed to assess strategies to reduce use of cesarean. The notable exception is study of approaches to promote trial of vaginal birth after prior cesarean (VBAC). Systematic reviews of VBAC interventions report increases in vaginal births from 6 to 70 percent with strategies to support a trial of labor.[25-26] The state of general knowledge about evidence-based approaches to reduce cesarean overall is uncharted. In this review we aim to bring that literature to the forefront by systematically examining the outcomes of interventions intended to reduce use of cesarean among low risk women.

Objectives

The goal of this review is to examine the effects of available strategies to reduce cesarean birth among low-risk pregnant women who have a singleton pregnancy focusing on the following outcomes: route of birth, maternal morbidity and mortality, and neonatal morbidity and mortality.

Population

Low-risk pregnant women who have a singleton pregnancy, a vertex presentation, are at term, and have not had a prior cesarean birth.

Strategies

Studies assessed strategies implemented specifically with the goal of reducing cesarean birth, including interventions used during prenatal care, during labor, and as part of health systems interventions (quality assurance, audit and feedback, implementation of guidelines, etc.).

Comparators

Comparators included usual care, placebo, and comparative strategies or combinations of strategies.

Outcomes Measures for each KQ

Outcomes included route of birth, maternal morbidity and mortality, and neonatal morbidity and mortality. We also assessed the harms of the strategies used, defined by the Evidence-based Practice Center Program as all possible adverse consequences of an intervention, including adverse events (Figure ES-1).[27]

Timing

Strategies used during pregnancy and during labor.

Setting

Strategies used in all health care settings, including the home, hospital, provider offices, clinics, and community.

ES-Table 1: Inclusion/exclusion criteria

Category	Criteria
Study population	Low-risk pregnant women who have a singleton pregnancy, a vertex presentation as defined by the authors where reported, term birth, and no previous cesarean birth
Time period	All years
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs Randomized controlled trials of interventions (KQ1-4) Pre- and post-studies related to large-scale health systems changes (KQ2 only) Other criteria Original research studies that provide sufficient detail regarding methods and results to enable interpretation of the data and results Studies must include extractable data for one or more relevant outcomes listed in the PICOTS

PICOTS, population, intervention, comparator, outcome, timing, and setting
KQ, key question

Key Questions

We have synthesized evidence in the published literature to address these key questions (KQs):

KQ1: What strategies during pregnancy are effective to reduce the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

KQ2: What strategies during labor are effective to reduce the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

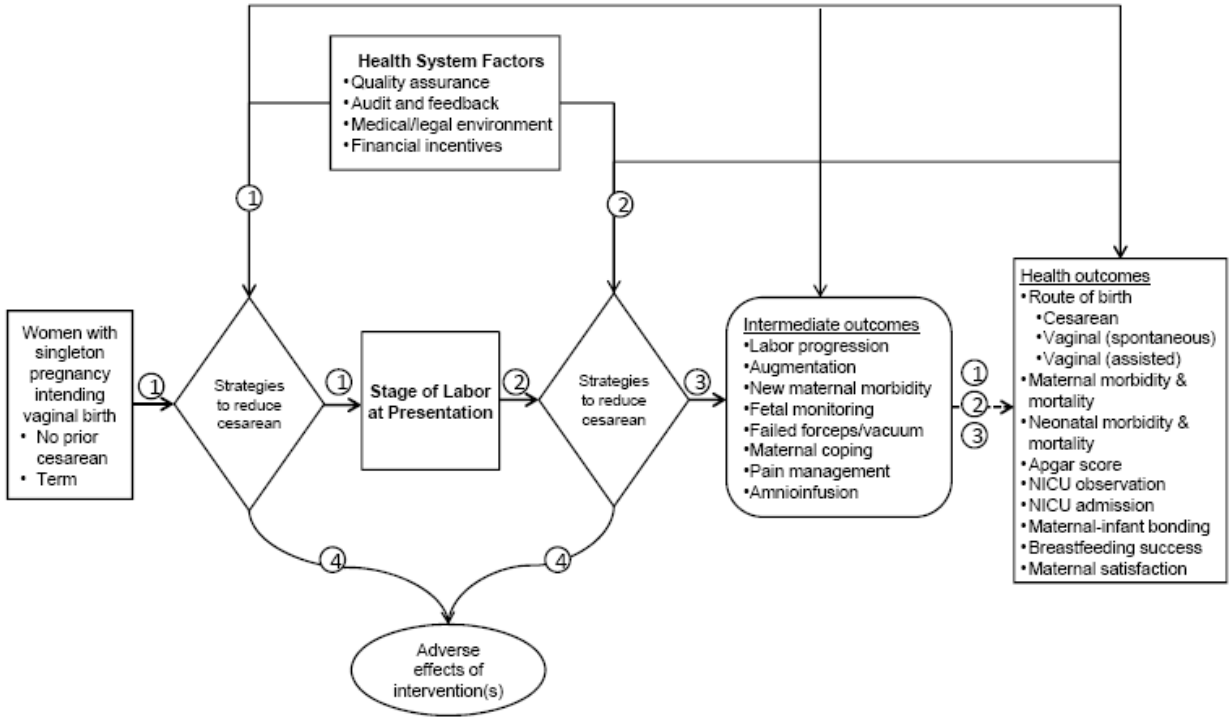
KQ3: Where head-to-head comparisons are available, what strategies are shown to be superior in reducing the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

KQ4: What are the nature and frequency of adverse effects resulting from strategies used to reduce cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

Analytic Framework

We developed the analytic framework (Figure ES-1) based on the literature and clinical expertise and refined it with input from our key informants and Technical Expert Panel members. The framework summarizes how strategies to reduce cesarean before and/or during labor may mediate intermediate outcomes such as labor progression, maternal coping, and pain management and result in long-term outcomes such as route of birth, maternal morbidity and mortality, or neonatal morbidity and mortality. Also, adverse events may occur at any point after the strategy has been implemented.

ES-Figure 1. Analytic Framework for Strategies to Reduce Cesarean Birth



Methods

Input from Stakeholders

The topic for this report was nominated by a physician and health benefits plan/insurance carrier in a public process using the Effective Health Care website. Working from the nomination we drafted the initial key questions and analytic framework and refined them with input from key informants representing the fields of obstetrics and gynecology, midwifery, nursing, pediatric care, primary care, and patient advocacy to provide assistance during the project, which were reviewed by the Agency for Healthcare Research and Quality (AHRQ) and posted to a public website for public comment. Using public input, we submitted final key questions, which were reviewed by AHRQ. We convened a technical expert panel representing the fields of obstetrics and gynecology, midwifery, nursing, pediatric care, primary care, and patient advocacy to provide input during the project on issues such as setting inclusion/exclusion criteria and refining the analytic framework

Literature Search

Our search included MEDLINE® via the PubMed interface and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). We also hand-searched references of included articles to identify additional studies. Controlled vocabulary terms served as the foundation of our search, complemented by additional keyword phrases to represent the myriad ways in which cesarean is referred to in the clinical literature. We also employed indexing terms within each database to exclude undesirable publication types and articles in languages other than English.

Inclusion and Exclusion Criteria

We excluded studies that:

- Were not original research
- Did not report information pertinent to the key questions
- Did not describe an intention to reduce cesarean in low-risk women
- Did not include aggregate data or presented data only in graphics/figures
- Were not randomized controlled trials (RCTs) or pre-post studies of changes in policies or procedures within a healthcare system
- Were not published in English.

Article Selection Process

We examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts for inclusion or exclusion. If one reviewer concluded the article could be eligible for the review based on the abstract, we retained it. Full publications were then jointly reviewed for final inclusion, with disagreements resolved via adjudication by an independent third reviewer. Reasons and process for exclusions are described in the full report.

Data Extraction

All team members shared the task of entering information into evidence tables. After initial data extraction, another member checked table entries for accuracy, completeness, and consistency. Abstractors reconciled inconsistencies.

Quality Assessment

The quality of individual studies was assessed using specific, established tools for each type of study. For RCTs, the Cochrane Collaboration's tool for assessing risk of bias was employed. Fundamental domains include: adequate sequence generation, allocation concealment, blinding, incomplete outcome data addressed, and free of selective reporting bias. For nonrandomized and observational studies, the Newcastle-Ottawa scale was utilized. The scale assesses three broad perspectives: (1) selection of study groups; (2) comparability of the groups; and (3) the ascertainment of the outcome of interest. Both quality assessment tools are commonly used tools accepted by AHRQ.

Evidence Synthesis

Text that summarizes the research evidence is organized by key question. Within each key question evidence is organized by aspects of the question, such as the type of strategy used and the outcomes. In the full report, we include evidence tables, summary tables of common outcomes, and provide extended analysis.

Strength of Evidence

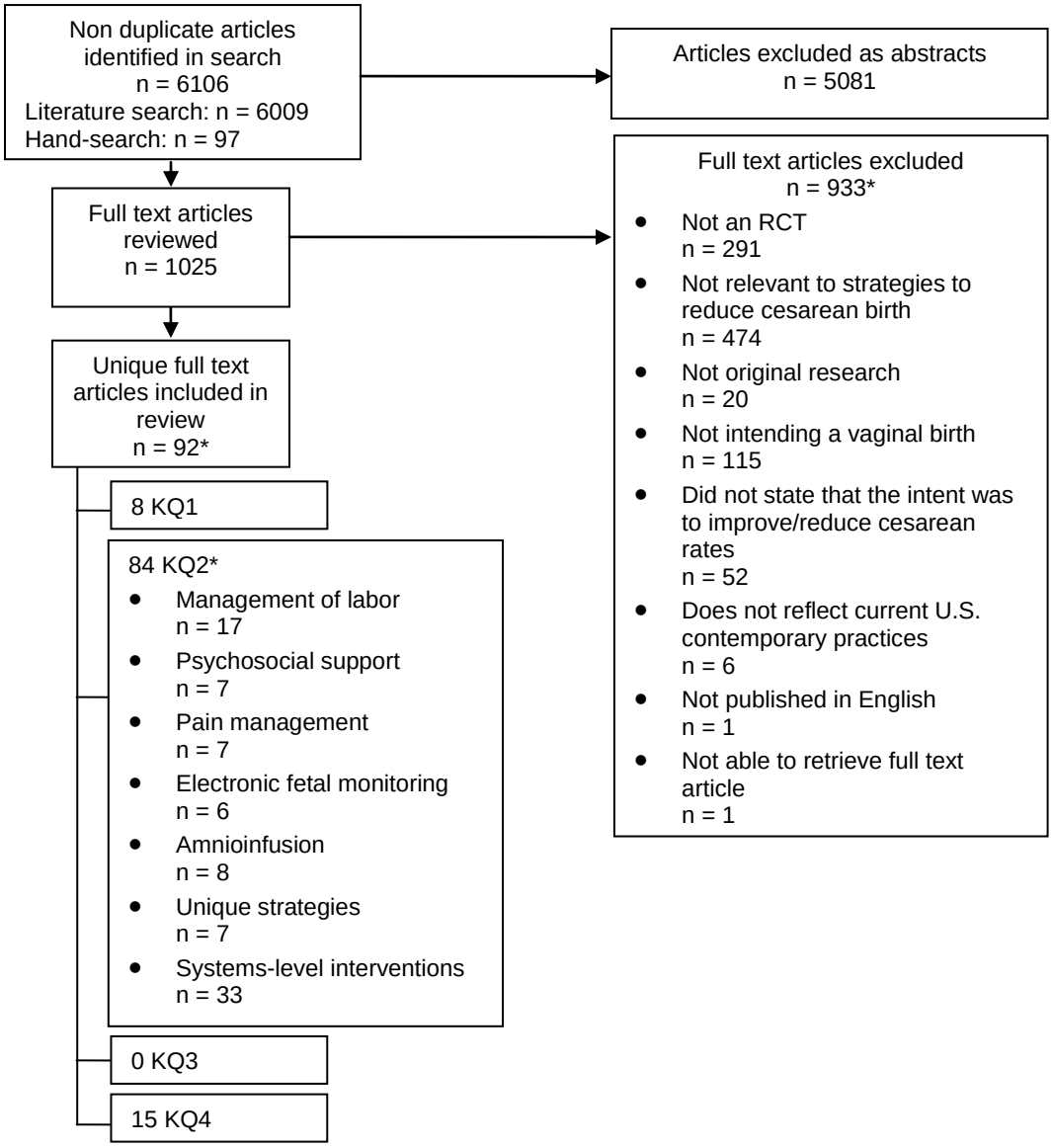
The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence. The overall strength of evidence could be graded as "high", "moderate", "low", or "insufficient". It describes the adequacy of the current research, in quantity and quality, and the degree to which the entire body of current research provides a consistent and precise estimate of effect. We evaluated the overall strength of the evidence for the primary outcomes. We used the approach to strength of evidence as described in the Evidence-based Practice Centers' (EPC) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (Appendix G).[28]

Results

Literature Search Yield

We identified 6106 non-duplicate publications. Ninety-two were included in the review (Figure ES-2). They represent 90 distinct study populations: 63 RCTs and 29 pre-post-studies of health system changes. The most common reasons for exclusion were ineligible study design and irrelevance to the topic. Eight articles pertain to KQ1, 84 articles to KQ2, no articles to KQ3, and 15 articles to KQ4.

ES-Figure 2. Disposition of articles identified by the search strategy



KQ = key question
*The number of articles addressing key questions and those excluded exceed the total number of articles in each category because some articles fit multiple exclusion categories or addressed more than one key question.

KQ1. Effectiveness of Strategies Used During Pregnancy

Eight studies of strategies used during pregnancy were included in the review. [29-36] Six trials were rated as fair,[29, 31-32, 34-36] and two as poor.[30, 33] Care by members of a midwifery practice team who provide both prenatal and birth care demonstrated a modest 4.5 percent reduction in cesarean births with no difference reported in two similar studies. Injection of hyaluronidase into the cervix in the outpatient clinic for patients at term with a low Bishop score promoted cervical softening. This intervention of cervical preparation or "ripening" reduced cesarean births by 31 percent. This study was small (n=168) and no other studies were found that investigated this intervention. Light exercise, intervention to reduce fear of labor, education about how to push in labor, and preemptive management of specific risks detected during antenatal care were among the ineffective outpatient interventions reported in individual studies.

The evidence about reducing cesarean through antenatal care models designed to enhance continuity is based on three RCTs with 4134 participants. These fair[29,31] and poor[30] quality studies have inconsistent findings and provide insufficient evidence. Each of the other approaches used during pregnancy is represented by a single trial with fewer than 300 participants and provides insufficient evidence to guide care.

KQ2. Effectiveness of Strategies Used During Labor

Management of labor. Seventeen studies on labor management strategies were included.[37-53] Three labor management strategies that significantly reduced the use of cesarean in individual studies, all of good quality, were 1) use of a partogram, a graphic representation of the progress of labor to plot labor progress over a four hour versus a three hour window (5.8 percent, odds ratio (OR)=1.8, 95 percent confidence interval (CI): 1.1, 3.2,[42] 2) a combined strategy of using a partogram to graph labor progress along with active management to augment labor (7.4 percent, relative risk (RR)=0.68, 95 percent CI: 0.50, 0.93),[44] and 3) administration of the beta-blocker propranolol in addition to oxytocin for treatment of labor that was not progressing normally (24.6, RR=0.58, 95 percent CI: 0.35, 0.93; p=0.02).[49]

Home-based triage of when a woman in labor should leave for the hospital, compared to telephone triage, did not reduce use of cesarean.[37] Neither did early labor assessment done to delay hospital admission until active labor, compared with direct admission of women in labor.[38] Cesarean rates were identical in women who did and did not have amniotomy, which is artificial rupture of the membranes, at the time of hospital admission.[52] Increased intravenous fluids during labor did not reduce the use of cesarean.[53] Each of these strategies was assessed to provide insufficient evidence.

Evidence about partograms and other interventions in labor is conflicted in one study of good quality,[40] two studies of fair quality[39, 48] and four of poor quality.[41, 43, 45-46] In contrast to the two trials above that noted benefit for specific uses of partograms, adding a partogram with a two-hour alert line and no action line to the usual written labor progress notes did not reduce the use of cesarean in two units in a tertiary care perinatal complex,[39] and the proportion of births by cesarean among women randomized to a two-hour versus a four-hour partogram were equivalent.[40] Thus from these four studies of partograms, that enrolled more than 10,832 women, there is low strength of evidence for lack of benefit of partograms for reducing cesarean.

Providing a computerized reference range for assessing labor progress also did not reduce the use of cesarean.[41] Active management of labor did not reduce the use of cesarean in three studies,[43, 45-46], and a second study of propranolol administered simultaneously with oxytocin for arrested first stage of labor did not find a significant reduction in cesarean.[48] The four RCTS of

active management have conflicting findings but as fair and good quality studies of more than 2500 women, they provide low strength of evidence for lack of evidence of benefit. Single studies of strategies used during labor provide insufficient evidence to inform care.

Psychosocial support. We identified seven studies[54-60] that examined the effect of psychosocial support interventions on cesarean births. One trial was of fair quality[56] and six of poor quality.[54-55, 57-60] The three doula support studies showed a reduction in cesarean births for women in the doula support groups ranging from five to 22 percent. A doula is a woman experienced in childbirth who provides continuous physical and emotional support throughout labor and birth. These studies used women unfamiliar to the study participant who had experience and training in childbirth and support of women in labor. A study using female family members or friends, who received four hours of training, to provide labor support showed no reduction in cesarean. In other models of one-to-one support, there was no advantage in reducing cesarean among women who received continuous labor support from nurses or midwifery students compared to women who received usual labor care. For traditional trained doula support there is low strength of evidence favoring benefit from this intervention. The lay model of support provides insufficient evidence and nursing models of one-to-one support in three trials with 7,568 participants, provide low strength of evidence for benefit.

Pain management. We identified seven trials of pain management that aimed to reduce cesarean by optimizing the pain management approach predominantly through varied dosing strategies.[61-67] A single study, judged to be poor quality due to lack of description of the randomization allocation and concealment procedures, reported a three-fold reduction in cesareans among women who received intermittent epidural (5 percent) as compared to continuous epidural (15 percent, $p=0.03$).[65] A larger good quality study that compared high versus low dose epidural reported significantly fewer instrumental births (vacuum extraction and cesarean) in women who received the lower dose of analgesia (30 percent compared to 49 percent, $p<0.00001$).[64] The proportion of cesareans for the two groups was 10.2 percent and 14.7 percent for low and high dose, respectively, but no statistical analysis was reported. None of the remaining five studies reported a significant difference in use of cesarean. These studies varied in quality, sample size, comparison of anesthetics used, parity of the study population, and overall rate of cesarean birth. None examined the same intervention. Results across these studies are inconsistent. In total they provide low strength of evidence for lack of benefit of pain management strategies as an approach to reduce cesarean.

Fetal assessments. Six studies of approaches to assessing fetal well-being in labor were included in this review.[68-73] Of these, one was good quality,[71] and five were fair.[68-70, 72-73] 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. There was no evidence that fetal pulse oximetry slowed or interfered with labor. Use of ST analysis in conjunction with fetal heart rate monitoring did not reduce cesarean rates overall, or cesarean rates for nonreassuring fetal heart tracing when compared to routine fetal heart rate monitoring alone. Across these categories of fetal assessment strategies there is low strength of evidence for lack of benefit, from six studies including more than 9,700 women.

Amnioinfusion. Eight studies of fetal interventions during labor were included.[74-81] Three were rated as fair quality[76, 78, 80] and five poor quality.[74-75, 77, 79, 81] When amnioinfusion, which is instilling sterile fluid into the uterus to surround the fetus, is performed for fetal heart tracings

indicating potential distress, four of eight studies found a significant reduction ranging from 12 to 20 percent in cesareans for fetal distress, however these studies did not find a consistent overall decrease in use of cesarean.[75-77, 80]

Amnioinfusion to dilute moderate or heavy meconium when performed in under-resourced hospital settings, where electronic monitoring was limited or absent, improved neonatal outcomes.[74, 76] Prophylactic amnioinfusion for oligohydramnios, which is low levels of fluid surrounding the fetus, did not reduce use of cesarean. The data are conflicted about its effectiveness for preventing cesarean. Overall amnioinfusion did decrease cesarean and strength of evidence is insufficient to support use to prevent cesarean.

Unique strategies. Seven studies not amenable to grouping, focused on unique strategies to reduce cesarean births.[82-88] These studies varied in quality with two good quality,[84, 88] two fair quality,[82-83] and three poor quality studies.[85-87] Large single studies, comprising approximately 500 to 2400 participants each, of encouraging walking, allowing eating, or using an inflatable obstetric belt to augment contractions during labor showed no effect on the incidence of cesarean as compared with usual care.[84, 87-88] Small studies of other interventions such as acupuncture, a molded dental device for use during pushing, or a single intravenous dose of propranolol given after admission did not reduce risk of cesarean when compared with standard care approaches.[82-83, 85-86] As unique studies these provide insufficient evidence to guide care.

Systems level interventions. Thirty-three publications in 31 study settings, described the findings of systems-level interventions that included changes in policies, procedures, or protocols intended to reduce cesarean births.[41, 89-120] From baseline to followup, 18 of 31 studies achieved statistically significant reductions in cesarean with a range of 1.6 to 17.0 percent decreases. None of the four systems-level RCTs demonstrated effectiveness. Three of these trials were poor quality and one fair.

More than16 different types of intervention components have been used in various combinations in these reports of systems-level changes. This makes interpretation challenging because when multiple components are put into place and no two studies compare the exact same components, the data cannot be directly aggregated and effective components cannot be identified with certainty.

Twelve observational studies reported achieving a reduction in cesarean of five percent or more. Ten of these pre-post studies documented reductions in cesarean with interventions that included varied forms of auditing of individual or group cesarean use trends with regular feedback of data to either the organizational unit (hospital, department, and labor and delivery staff) or the individual care providers or both. Across these studies audit and feedback data was most often provided at both the unit and individual level. The next most common components of successful interventions, with a five percent or greater reduction, were tracking of progress in labor using partogram often implemented along with agreed procedures for taking action when labor was not progressing at the rate indicated in the intervention protocols.

When comparing successful to unsuccessful systems level interventions the overall number of components used in any one study is modestly lower among unsuccessful interventions. Successful and unsuccessful interventions shared many components in common. Overall it is not possible to determine which components are definitively associated with reductions. Variation across study interventions, relatively modest effects in U.S. settings, and the observational nature of this data means the evidence is insufficient to determine if systems based interventions reduce cesarean.

KQ3. Head-to-head Comparisons of Strategies

All studies compared the novel strategy to usual care or to variations in the same intervention For instance some studies evaluated variations in the timing of the action line in partograms or dosing of epidurals. None examined direct comparisons of distinct strategies.

KQ4. Harms of Strategies to Reduce Cesarean Birth

Fifteen studies included in the review reported on harms in the populations participating in these studies of strategies to reduce cesarean. [32, 35-36, 47, 51, 61-62, 71, 74-75, 80, 83-84, 86, 88] Few of the harms presented in the reports have a plausible direct correlation to the strategy used to prevent cesarean birth. Most summarized obstetrics outcome measures traditionally reported in the literature such as maternal fever, nausea and vomiting, and anesthesia-related side effects. When a relationship with the intervention was plausible, such as for use of *in utero* monitoring in labor, and risk of infection, there was no systematic evidence of increased risk in the intervention groups.

Discussion

Summary Strength of Evidence and Findings

Overall the strength of evidence to answer the key questions was insufficient to low. Deficiencies in the strength of evidence most often related to a preponderance of studies with inadequate study size, high risk of bias (failure to properly randomize or to conceal allocation), inconsistent findings across studies (no intervention had entirely consistent evidence supporting effectiveness), and variation in reporting of indications for cesarean (Appendix G).

ES-Table 2. Strength of evidence for various strategies to reduce cesarean birth

Strategy n total studies(n total participants)	Risk of Bias	Consistency	Directness	Precision	**Strength of Evidence**
KQ1. Effectiveness of strategies during pregnancy to reduce cesarean birth					
Antenatal Care Model **3 (4143)**	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 2 studies of fair quality, 1 poor quality
Exercise training **1 (160)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality
Management of fear of childbirth **1 (176)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of poor quality
Induction of labor for at-risk **1 (270)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality
Education on pushing **1 (100)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality
Hyaluronidase **1 (168)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality

ES-Table 2. Strength of evidence for various strategies to reduce cesarean birth (continued)

Strategy n total studies (n total participants)	Risk of Bias	Consistency	Directness	Precision	**Strength of Evidence**
KQ2: Effectiveness of strategies during labor to reduce cesarean birth					
Early labor assessment **2 (1,668)**	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 2 studies of fair quality with conflicting findings
Measurement of labor progress **4 (10,823)**	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 studies of good quality, 1 fair and 1 poor quality
Active management of labor **4 (2,764)**	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 studies of good quality, 2 of fair quality
Management of abnormal labor **5 (2,764)**	Moderate	Inconsistent	Direct	Imprecise	Insufficient; two studies of good quality, two of fair quality, one of poor quality
Amniotomy **1 (128)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality
Increased IV fluids **1 (195)**	Low	N/A	Direct	Imprecise	Insufficient; 1 study of good quality
Doula support **3 (1,136)**	High	Consistent	Direct	Precise	Low strength of evidence; 3 poor quality studies
Trained friend or family as labor support **1 (598)**	High	N/A	Direct	Imprecise	Insufficient; 1 poor quality study
Nursing and midwifery student support **3 (7,568)**	High	Consistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 poor and 1 fair studies
Pain management **7 (5,525)**	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 4 poor, 2 fair, 1 good study
Fetal pulse oximetry **4 (7,098)**	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 1 good, 3 fair studies
Fetal assessment by STAN **2 (2,271)**	Moderate	Consistent	Direct	Imprecise	Low or moderate evidence for lack of benefit; 2 fair quality studies

ES-Table 2. Strength of evidence for various strategies to reduce cesarean birth (continued)

Strategy n total studies (n total participants)	Risk of Bias	Consistency	Directness	Precision	**Strength of Evidence**
KQ1. Effectiveness of strategies during pregnancy to reduce cesarean birth					
Amnioinfusion for fetal distress **2 (588)**	High	Inconsistent	Direct	Imprecise	Insufficient; 1 fair and 1 poor study
Amnioinfusion for meconium **5 (1565)**	High	Inconsistent	Direct	Imprecise	Insufficient; 3 poor and 2 fair studies
Amnioinfusion for oligohydramnios **1 (60)**	High	NA	Direct	Imprecise	Insufficient; 1 fair quality study
Other strategies (acupuncture) **2 (145)**	High	Inconsistent	Direct	Imprecise	Insufficient; two fair studies
Dental device **1 (64)**	High	N/A	Direct	Imprecise	Insufficient; one poor study
Allowing eating **1 (2426)**	Low	N/A	Direct	Precise	Insufficient; one good study
Inflatable obstetric belt **1 (500)**	Low	N/A	Direct	Imprecise	Insufficient; one good study
Propranolol **1 (57)**	High	N/A	Direct	Imprecise	Insufficient; one poor study
Allowing walking **1 (916)**	High	N/A	Direct	Precise	Insufficient; one poor study
Systems level strategies **33**	High	Inconsistent	Indirect	Precise	Insufficient
Adverse effects of strategies to reduce cesarean birth					
Harms **17 (14,403)**	Moderate	Inconsistent	Indirect	Imprecise	Insufficient; fair to poor quality studies with inconsistent reporting of multiple adverse events

Applicability

In this report, the study populations were, by design of the review, intended to be low-risk pregnant women with a singleton pregnancy, a vertex presentation, at term, and without a history of previous cesarean birth. However, authors did not always provide sufficient detail to ensure the entire study population met this low risk definition. It is likely that overall we have captured studies with predominantly low risk groups that can inform the question of how best to prevent cesarean in low risk women at term. The strategies used during pregnancy and in labor varied widely, and few interventions were duplicated in more than one setting. For all of the studies included in this review the comparators were standard obstetric care or comparisons to pain medications in the same drug class, but standards and patterns of care vary. The primary outcome of interest was route of birth, including vaginal, vaginal assisted, and cesarean.

However, the reporting of each category was incomplete among the studies reviewed so it was not always possible to assess if reductions in cesarean were achieved at the expense of an increase in assisted or complicated vaginal births. Most importantly, fewer than half of the studies included were conducted in the United States (41 of 93), so outcomes reflect data from many countries and settings that may not directly apply. We have taken care to indicate in detailed tables when this is the case.

Conclusions

No particular intervention strategy was uniformly successful in reducing cesareans. Strength of evidence was low to insufficient across all interventions. While certain components of systems-level interventions were common among successful interventions, none were supported by a randomized trial.

This literature contains intriguing examples of single studies that deserve further exploration. They include outpatient use of agents to promote cervical softening, further exploration of what elements of doula support were common across successful trials in order to conduct larger scale replications, use of amnioinfusion to reduce fetal distress and thereby reduce cesareans for this indication, and evaluations of whether components of systems interventions succeed because of the components themselves or because the interventions selected reflect the will of the health system and care providers to promote decreased use of cesarean.

In conclusion, no approach dominated as a strategy appropriate to reduce use of cesarean in low risk women in the United States.

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Introduction

Background

Thirty two percent of pregnancies in the United States conclude with a cesarean birth.[1] This record high rate reflects a relative increase of 53 percent in use of cesarean from 1991 to 2007.[1] The pattern of increasing use of cesarean has been concerning for decades, with the last decline of two to three percent occurring in the mid-1990s being fully reversed by 1999 and increasing over 50 percent from 1996 to 2007.[2] Nearly one in three births by cesarean translates to a total of 1.4 million cesarean births each year making cesarean the most commonly performed major surgery in the United States.[1]

The Joint Commission has expressed concern about U.S. cesarean birth rates in its *Specifications Manual for Joint Commission National Quality Core Measures*, noting that, "There are no data that higher rates improve any outcomes, yet the CS [cesarean section] rates continue to rise."[3] Cesarean birth is not without consequences. In general, cesarean is more costly to the healthcare system, is associated with increased risk for both mother and infant, and has potential to complicate subsequent pregnancies.[4-5] Previously extraordinarily rare complications like uterine rupture and abnormalities in placental attachment to the uterus, such as placenta accreta and percreta, are becoming more common modern obstetric care challenges.[6-7] Indeed, because the effects of these complications can be devastating and include fetal death, emergent hysterectomy and maternal mortality from associate bleeding, labor and delivery units have created "code teams" that conduct practice drills to be prepared for such emergencies.

Cesarean birth rates vary considerably by geographic region, ranging from 25 to 38 percent among different states with the highest rates in the southeastern states.[1] One research group examining differences across hospitals documented a span from 9 percent to 37 percent for primary cesarean births.[8] While health care providers and health systems initially viewed such variation as a reflection of underlying differences in the risk profile of the women receiving care at the hospitals, it has become increasingly clear, through use of techniques like risk adjustment, that a large proportion of variation is real. It is not explained by some facilities having much higher or lower risk patients than others. In medical care, when there is variation of the magnitude we see in use of cesarean after taking into account differences in patient characteristics, the conclusion is that provider and patient preferences are important drivers of variation.[9, 121]

Goals for reducing cesarean in the U.S. have become less ambitious over time The Healthy People 2000 goal was to reduce cesarean to 15 percent of all births.[10] For Healthy People 2010 this goal was revised to 15 percent among women with had not had a prior cesarean, and in Healthy People 2020 the new target for cesarean among low risk women in a first pregnancy with full-term singleton pregnancies and vertex presentation is 23.9 percent.[11-12] The moving target for both numerator and denominator in these goals reflects ambivalence in knowing what the right rate is for optimal maternal and infant outcomes and doubts about what interventions can safely reduce use of cesarean.[13-14]

Commentary on the factors driving change in cesarean use have been robust. Putative influences include:

- Changes in reimbursement for births that favor interventions like cesarean[15]
- Amplified perception of risk of medico-legal liability claims for less than perfect infant outcomes or for failing to intervene[16]

- Shifts in consumer attitude that include less fear of or regret about cesarean[17]
- Lower psychosocial or emotional value placed on the experience of vaginal birth[18]
- Concerns about pelvic floor damage and future continence[19-20]
- Maternal desire for greater control over the timing and circumstances of birth[21] including maternal request for elective induction and cesarean.[22]

Research has addressed predictors of cesarean such as the shift toward older maternal age, higher body mass index, greater maternal comorbidity, use of assisted reproductive technology, and increased incidence of multiple gestations.[23-24]

Nonetheless relatively little focus has been placed on research specifically designed to assess strategies to reduce use of cesarean. The notable exception is study of approaches to promote trial of vaginal birth after prior cesarean (VBAC). Systematic reviews of VBAC interventions report increases in vaginal births from 6 to 70 percent with strategies to support a trial of labor.[25-26] The state of general knowledge about evidence-based approaches to reduce cesarean overall is uncharted. In this review we aim to bring that literature to the forefront by systematically examining the outcomes of interventions intended to reduce use of cesarean among low risk women.

Objectives

The goal of this review is to examine the effects of available strategies to reduce cesarean birth among low-risk pregnant women who have a singleton pregnancy focusing on the following outcomes: route of birth, maternal morbidity and mortality, and neonatal morbidity and mortality.

Interventions

Low-risk pregnant women who have a singleton pregnancy, with a vertex presentation, at term, and no previous cesarean births are the focus of this review. Various strategies can be used during pregnancy and labor in order to reduce the risk of a cesarean birth. Those used during pregnancy include, but are not limited to childbirth education and health education approaches. Those interventions during labor include, but are not limited to timing of admission, pain management, style of labor management, and support in labor.

Goal of this Comparative Effectiveness Review (CER)

The overall goal of this CER is to inform clinician and patient decisions about the strategies that could be used to reduce cesarean births. This CER summarizes evidence for the effectiveness of strategies before and during labor to prevent a birth by cesarean. We also address any harms of strategies employed by pregnant women or their healthcare providers as reported in the literature. “Harms” are defined by the Evidence Based Practice Center program as the totality of all possible adverse consequences of an intervention.[27]

Scope and Key Questions

Scope of the Report

Evidence reviews of interventions seek to identify and systematically summarize objective information about the evidence related to factors including the:

- Effectiveness of specific strategies
- Relative benefit of one strategy over another
- Common side effects and serious risks of a strategy

We focused this review on strategies to reduce cesarean birth in low-risk pregnant women who have a singleton pregnancy, a vertex presentation, term birth, and no previous cesarean births.

Key Questions

We have synthesized evidence in the published literature to address the following key questions (KQs):

KQ1: What strategies during pregnancy are effective to reduce the use of cesarean birth among women with a singleton pregnancy, who are intending a vaginal birth?

KQ2: What strategies during labor are effective to reduce the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

KQ3: Where head-to-head comparisons are available, what strategies are shown to be superior in reducing the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

KQ4: What are the nature and frequency of adverse effects resulting from strategies used to reduce cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

Organization of this Evidence Report

The Methods Chapter describes our processes including our search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, and methods for extraction of data into evidence tables, and compiling evidence. We also describe our approach to grading the quality of the literature and to describing the strength of the body of evidence.

The Results Chapter presents the findings of the literature search and the review of the evidence by key question, synthesizing the findings across strategies.

The final section of the report discusses the results and enlarges on the methodologic considerations relevant to each key question. We also outline the current state of the literature and challenges for future research on the strategies to reduce cesarean birth.

The report includes a number of appendices to provide further detail on our methods and the studies assessed. The appendices are as follows:

- Appendix A: Search Strategy
- Appendix B: List of Excluded Studies
- Appendix C: Evidence Tables
- Appendix D: Data Extraction Forms
- Appendix E: Quality of the Literature
- Appendix F: Applicability Summary Tables

We also include a list of abbreviations and acronyms at the end of the report.

Uses of this Report

We anticipate this report will be of value to all healthcare providers who take care of women of childbearing age, including members of the American Congress of Obstetricians and

Gynecologists; the Association of Women's Health; Obstetric and Neonatal Nurse; the American College of Nurse-Midwives; the American Academy of Family Physicians; the National Association of Nurse Practitioners in Women's Health; and other clinical professional organizations. In addition, this review will be of use to the National Institutes of Health, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, and the Health Resources and Services Administration – all of which have offices or bureaus devoted to women's health issues. This report can bring providers up to date about the current state of evidence, and it provides an assessment of the quality of studies that aim to determine the outcomes of strategies to reduce cesarean birth. It will be of interest to individual women and the general public because of the continuing increase in cesarean births, and the recurring need for women and their health care providers to make the best possible decisions and choices from among numerous options. We also anticipate it will be of use to private sector organizations concerned with women's health, such as Childbirth Connection, the March of Dimes, the National Women's Health Network, and Our Bodies Ourselves.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to advance research methods, understand risk factors, develop prevention strategies, develop new treatment options, and optimize the effectiveness and safety of clinical care for those women.

Methods

Topic Development and Refinement

The topic for this report was nominated by a physician and health benefits plan/insurance carrier in a public process using the Effective Health Care website. Working from the nomination we drafted the initial key questions and analytic framework and refined them with input from key informants representing the fields of obstetrics and gynecology, midwifery, nursing, pediatric care, primary care, and patient advocacy. After review from the Agency for Healthcare Research and Quality (AHRQ), the questions and framework were posted online for public comment. All members of the research team were required to submit information about potential conflicts of interest before initiation of the work. No members of the review team have any conflicts.

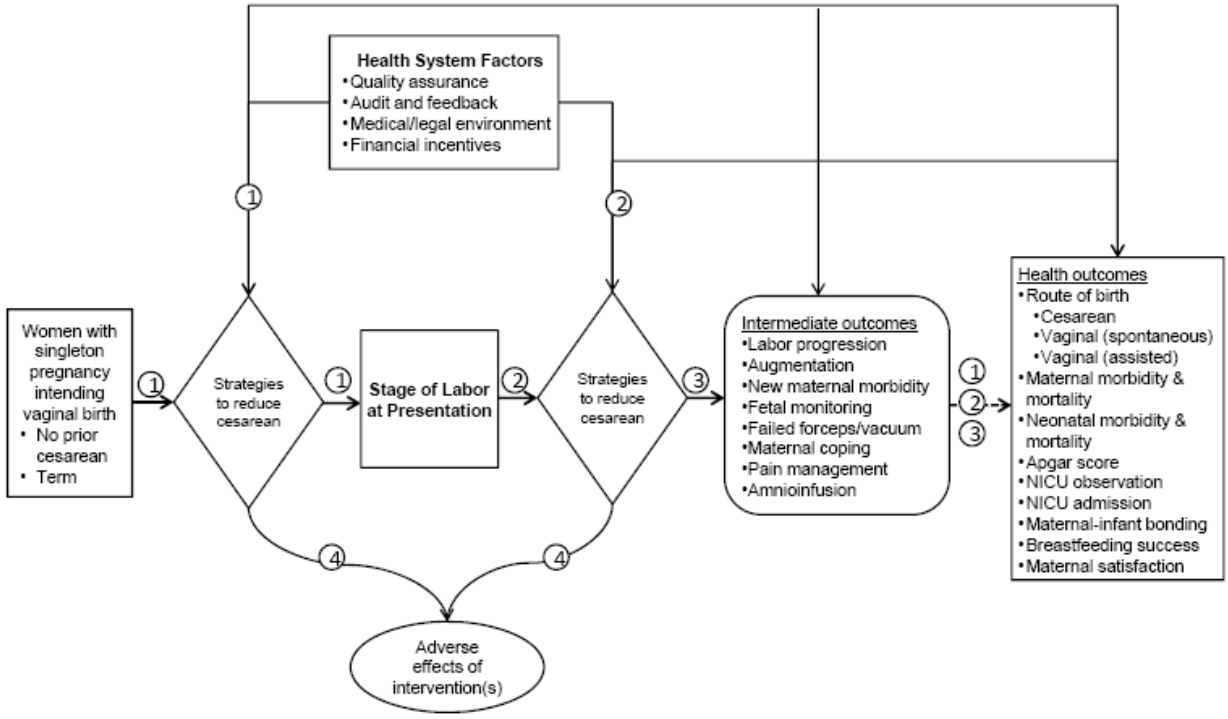
After reviewing the public commentary, we prepared final key questions (KQ) and submitted them to AHRQ for review. The primary change in response to public comments was to broaden the terminology from 'interventions' to 'strategies' to more clearly indicate interest in all approaches to reduce cesarean. We identified technical experts on the topic in the fields of maternal and child health, obstetrics, nursing, and midwifery to provide assistance during the project. The Technical Expert Panel (TEP), representing the fields of obstetrics and gynecology, midwifery, nursing, pediatric care, primary care, and patient advocacy, contributed to the AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included 12 members serving as technical or clinical experts. To ensure robust, scientifically relevant work, we called on the TEP to review and provide comments as our work progressed. TEP members participated in conference calls and discussions through e-mail to:

- Refine the analytic framework and key questions at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria

Analytic Framework

We developed the analytic framework (Figure 1) based on clinical expertise and refined it with input from our key informants and TEP members. The framework summarizes how strategies to reduce cesarean before and/or during labor may result in intermediate outcomes such as labor progression, maternal coping, and pain management and/or long-term outcomes such as route of birth, maternal morbidity and mortality, or neonatal morbidity. Also, adverse events may occur at any point after the strategy has been implemented.

Figure 1. Analytic framework strategies to reduce cesarean birth



NICU= Neonatal intensive care unit
Numbers in circles indicate the position of key questions in the intervention process.

Literature Search Strategy

Databases

We employed search strategies provided in Appendix A to retrieve research on interventions to reduce the incidence of cesarean. Our primary literature search used two databases, MEDLINE® via the PubMed interface and the Cumulative Index to Nursing and Allied Health Literature (CINAHL®). We also hand-searched the reference lists of all included articles and relevant reviews to identify additional studies for review.

Search Terms

Our search used a combination of keywords and controlled vocabulary terms used to represent cesarean birth in the medical, nursing, and allied health fields. To refine the search in line with our focus on randomized controlled trials (RCTs) and systems-level interventions, we employed an adapted version of the Cochrane highly sensitive search strategy.[122] We also used a variety of indexing terms to exclude undesired publication types (e.g. reviews, case reports, letters) in each database.

Our searches were executed between October 2010 and July 2011. Appendix A provides our search terms and yield for each database.

Process for Study Selection

For this review, the relevant population for all key questions were low-risk pregnant women who have a singleton pregnancy, a vertex presentation, term birth, and with no previous cesarean births.

Inclusion and Exclusion Criteria

Table 1 lists the inclusion/exclusion criteria we selected based on our understanding of the literature, the topic-refinement phase, input from the TEP, and established principles of methodological quality.

Table 1: Inclusion and exclusion criteria

Category	Criteria
Study population	Low-risk pregnant women who have a singleton pregnancy, a vertex presentation, term birth, and no previous cesarean birth
Time period	All years
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs Randomized controlled trials of interventions (KQ1-4) Pre- and post-studies related to large-scale health systems changes (KQ2 only) Other criteria Original research studies that provide sufficient detail regarding methods and results to enable interpretation of the data and results Studies must include extractable data for one or more relevant outcomes listed in the PICOTS

PICOTS, population, intervention, comparator, outcome, timing, and setting
KQ, key question

Study Population

For this review, the relevant population for all key questions was low-risk pregnant women who have a singleton pregnancy, a vertex presentation, at-term birth, and no previous cesarean births.

Language

We did not have translation services available to us to review non-English papers and our TEP agreed that the vast majority of the relevant literature would be published in English. Furthermore, this review is intended to inform U.S. health care, and most research in the population of pregnant women in the United States is published in English language journals. Empirical evidence on the potential for bias created by excluding non-English studies also suggests little effect.[123] We did not review 170 abstracts of probable RCTs that appeared in non-English literature; based on the proportion of includes in the English language materials reviewed, this suggests we excluded fewer than five studies that could have had relevance.

Time Period

No time limits were set in this review.

Sample Size

No limits on sample size were set in this review.

Study Design

We only reviewed published RCTs of strategies to reduce the rate of cesarean births or those pre- and post-studies related to health system changes (KQ2) to decrease the number of cesareans. In addition, studies were included if the stated or implied aim of the study was 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 under study.
- The stated primary or secondary aims indicate intention to examine influence of the intervention on cesarean risk/rate or route of birth.
- The analytic models indicate the authors conducted data analysis of the effect of the intervention as it relates to cesarean risk/rate or route of birth.
- The results feature data about the relationship of the intervention 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.

Outcomes

KQ1 through KQ3 seek to identify strategies that reduce the number and/or proportion of cesarean births between comparison groups. The intermediate outcomes include labor progression, need for augmentation, onset of maternal morbidity, and maternal coping and pain management. The final outcomes of most interest include route of birth (comparing number and/or proportion of cesarean births to those that are spontaneous and assisted vaginal). Additional final outcomes included maternal and neonatal morbidity and mortality, Apgar scores, NICU admission, maternal satisfaction, maternal-infant bonding, and breastfeeding success.

KQ4 seeks to identify any harms resulting from the use of strategies to reduce cesarean birth. Harms include onset of maternal morbidity, need for additional intervention, and fetal distress.

Screening of Studies

Once we identified articles through the electronic database searches, review articles, and bibliographies (discussed above), we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated each abstract for inclusion or exclusion, using an Abstract Review Form (Appendix D). If at least one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it for full text assessment.

Two reviewers independently assessed the full text of each included study using a standardized form (Appendix D) that included questions stemming from our inclusion/exclusion

criteria. Disagreements between reviewers were resolved by a third-party adjudicator. The group of abstract and full text reviewers included expert clinicians and health services researchers.

Data Extraction and Data Management

Evidence tables, jointly developed and tested by the team, were used as data extraction tools. All data were extracted by one team member and checked by a second. Evidence tables collected descriptive information related to the strategy used to reduce cesarean birth as well as key study design and comparator data. When possible to identify, analyses resulting from the same study were grouped into a single evidence table. The final evidence tables are presented in their entirety in Appendix C.

Individual Study Quality Assessment

We followed the methods outlined in the Evidence-based Practice Centers' (EPC) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*[28] and the *Cochrane Handbook for Systematic Reviews of Interventions*[124] to assess the quality of individual RCTs. Decision rules regarding application of the tools were developed *a priori* by the research team. We developed separate quality assessment approaches for RCTs and the pre- and post-studies related to large-scale health systems changes studies. Two reviewers independently assessed each study, with disagreements between assessors resolved by a third adjudicator. For all RCTs we assessed each of the following domains, using the Cochrane Risk of Bias (ROB) tool, as having "low risk," "high risk," or "unclear risk" of bias:

- Selection bias
  - Random sequence generation
  - Allocation concealment
- Performance bias
  - Blinding of participants and personnel
- Detection bias
  - Blinding of outcome assessment
- Attrition bias
  - Incomplete outcome data
- Reporting bias
  - Selective reporting
- Other bias
  - Other sources of bias

We used the Newcastle-Ottawa Quality Assessment Scale (NOQAS) to assess the quality of all nonrandomized studies (pre- and post-studies). This scale assesses three broad perspectives: the selection of study groups, the comparability of study groups, and the ascertainment of the outcome of interest. We describe the individual quality components below and report individual quality assessments for each study in Appendix E.

Determining Risk of Bias Levels

For RCTs, according to the criteria determined by Cochrane, we considered a "low risk" of bias study as one that had low risk of bias for all domains.[124] We considered studies that were assessed to have unclear risk of bias for one or more key items as having "unclear risk" of bias.

Studies with a high risk of bias for one or more domains were considered to have a "high risk" of bias.

Data Synthesis

There was significant heterogeneity among studies reporting results of strategies to reduce cesarean birth, including heterogeneity of population inclusion criteria, heterogeneity of strategy, and heterogeneity of outcome measures. Therefore, it was not appropriate to perform meta-analysis.

Strength of Evidence for each Key Question

We evaluated the overall strength of the evidence for the primary outcome of reduction of cesarean use for each category of intervention (Table 34). We used the approach to strength of evidence as described in the EPCs' *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[28]

We examined the following four major domains using a standardized strength of evidence evaluation sheet with scoring algorithm (see appendix):

- risk of bias (low, medium, or high),
- consistency of findings (inconsistency not present, inconsistency present, or unknown or not applicable),
- directness (direct comparison of influence on outcomes in RCT, or indirect information from observational research, and
- precision (precise or imprecise based on outcomes rates, size of the indivudal studies and the total number of women in the studies for the category of intervention).

The key outcome for each category of intervention in the body of literature was use of cesarean.

The overall strength of evidence could be graded as "high" (indicating high confidence that the evidence reflects the true effect and further research is very unlikely to change our confidence in the estimate of effect); "moderate" (indicating moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of effect and may change the estimate); "low" (indicating low confidence that the evidence reflects the true effect and further research is likely to change our confidence in the estimate of effect and is likely to change the estimate); or "insufficient" (indicating that evidence is either unavailable or does not permit estimation of an effect).These overall grades resulted from use of the scoring algorithm.

Strength of evidence was applied both to evidence of benefit and to evidence of lack of benefit. This means for instance that for a category of intervention in which there are multiple studies, with moderate bias and direct evidence showing no effect, and a single study reporting a insignificant reduction, the body of literature for the category of intervention could be scored as low evidence of lack of benefit. Two reviewers independently graded the body of evidence and calculate assigned strength of evidence using the scoring algorithm; disagreements were resolved through discussion or a third reviewer adjudication.

Applicability

Finally, it is important to consider the ability of the findings to apply both to other populations and to other settings. Our assessment of applicability included determining the

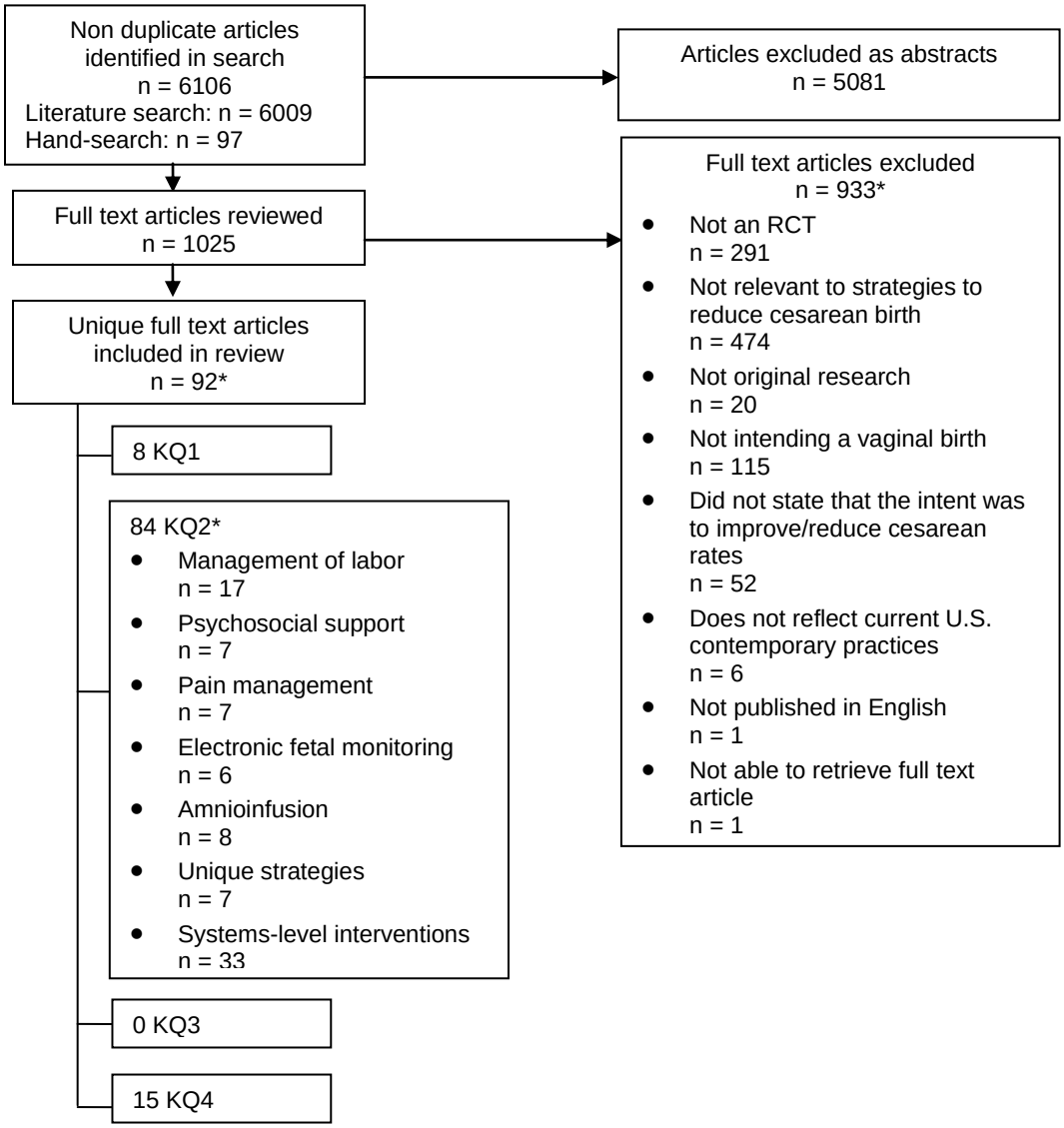
population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category (Appendix F).

Results

Article Selection

We identified 6106 non-duplicate publications through the search process, with 1025 proceeding to full text review (Figure 2). Sixty-three RCTs were included in the review, representing 63 distinct study populations. Fifty-nine RCTs were conventional intervention trials and four were RCTs of systems interventions. Twenty-nine pre- post-studies of large scale health systems changes were also identified. The most common reasons for exclusion were irrelevance to the topic and ineligible study design. Eight articles pertain to KQ1, 84 articles to KQ2, zero articles to KQ3, and 15 articles to KQ4. Tables 2 and 30 provide a summary of the strategies to reduce cesarean represented in this review in ordered from greatest to least reduction in cesarean.

Figure 2. Disposition of articles identified by the search strategy



KQ = key question

*The number of articles addressing key questions and those excluded exceed the total number of articles in each category because some articles fit multiple exclusion categories or addressed more than one key question.

Table 2. Summary of effectiveness of cesarean reduction strategies from greatest to least change

Author, Year Country	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Choudhary et al., 2010[74] India	Standard obstetric care without amnioinfusion (146)	63.7	34.2 lower
	Transcervical amnioinfusion (146)	29.5	
Spallicci et al., 2007[36] Brazil	Placebo cervical injection (85)	49.0	31.0 lower
	Hyaluronidase injection in cervix (83)	18.0	
Sanchez-Ramos et al., 1996[49] US	Oxytocin plus placebo (47)	51.1	24.6 lower
	Oxytocin plus propranolol (49)	26.5	
Trueba et al., 2000[59] Mexico	Standard care (50)	24.0	22.0 lower
	Childbirth educator trained as doula (50)	2.0	
Kuhnert et al., 2004 [68] Germany	Fetal monitoring with cardiotocography and fetal scalp blood sampling only (73)	37.0	20.6 lower
	Fetal monitoring with cardiotocography and fetal pulse oximetry and fetal scalp blood sampling (73)	16.4	
Abdel-Aleem et al., 2005[80] Egypt	Standard obstetric care without amnioinfusion (219)	68.0	20.1 lower
	Transcervical amnioinfusion (219)	47.9	
Rathor et al., 2002[76] India	Standard obstetric care without amnioinfusion (100)	36.0	15.0 lower
	Transcervical amnioinfusion (100)	21.0	
McGrath and Kennell, 2008[54] US	Routine Care (196)	25.0	11.6 lower
	Doula Support (224)	13.4	
Kennell et al., 1991[58] US	Control group assigned after birth (204)	18.0	10.0 lower 5.0
	Received support of a doula (212)	8.0	
	Observed by an inconspicuous observer (200)	13.0	
Skrablin et al., 2011[65] Croatia	Continuous epidural (104)	14.4	9.4 lower
	Intermittent epidural (101)	5.0	
Pattinson et al., 2003[44] South Africa	Expectant management (350)	23.4	7.4 lower
	Aggressive management (344)	16.0	
Lavender et al., 1998[42] UK	3-hour partogram (302)	14.2	5.8 (4-hour vs. 3-hour) lower
	4-hour partogram (311)	8.4	
	2-hour partogram (315)	11.1	
Homer et al., 2001[30] Australia	Standard hospital-based care(539)	17.8	4.5 lower
	Community-based model care (550)	13.3	
Harper et al., 2006[82] US	Usual care (26)	39.0	22.0 same
	Acupuncture sessions (30)	17.0	
Bidgood et al., 1987[51] UK	Observation (20)	45.0	18.7 (high-dose vs. obs.) same
	High-dose oxytocin (19)	26.3	
	Low-dose oxytocin (21)	33.3	
Matsuo et al., 2009[85] US	Usual care (32)	25.0	12.5 same
	Dental support device during active pushing (32)	12.5	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Table 2. Summary of effectiveness of cesarean reduction strategies (continued)

Author, Year Country	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Garite et al., 2000[53] US	Standard intravenous fluids of 125 ml/hr (94)	17.0	7.1 same
	Increased intravenous fluids (101)	9.9	
Moodley et al., 1998[77] South Africa	Standard obstetric care without amnioinfusion (30)	47.0	7.0 same
	Transcervical amnioinfusion (30)	40.0	
Karraz, 2003[63] France	Intermittent epidural bolus injections of 0.1% ropivacaine with 0.6 μg/ml sufentanil, non-ambulatory (74)	16.2	7.0 same
	Intermittent epidural bolus injections of 0.1% ropivacaine with 0.6 μg/ml sufentanil, ambulatory (141)	9.2	
Strong et al., 1990[81] US	Standard care (30)	20.0	7.0 same
	Amnioinfusion (30)	13.0	
Adamsons et al., 1999[86] Puerto Rico	Usual care (23)	17.4	5.7 same
	Propranolol during labor (34)	11.7	
Saisto et al., 2001[33] Finland	Conventional therapy (91)	48.4	4.9 same
	Intensive therapy (85)	43.5	
Nicholson et al., 2009[34] US	Standard care (134)	14.9	4.6 same
	Induction of labor (136)	10.3	
Olofsson et al., 1998[64] Sweden	Epidural anesthesia with high dose local anesthetic (0.25% bupivacaine with adrenaline) (435)	14.7	4.5 same
	Epidural anesthesia with low dose (0.125% bupivacaine with sufentanil 10 μg (422)	10.2	
Rogers et al., 1997[45] US	Usual care (205)	11.7	4.2 same
	Active management (200)	7.5	
Phipps et al.,2009[35] Australia	Standard care (50)	26.0	4.0 same
	Structured education for pushing (50)	22.0	
Lopez-Zeno et al., 1992[46] US	Traditional management (354)	14.1	3.6 same
	Active management (351)	10.5	
Hemminki et al., 1990[60] Finland	Usual Care (118)	5.0	3.0 same
	Midwifery student support (122)	2.0	
McNiven et al., 1998[38] Canada	Direct admission (104)	10.6	3.0 same
	Early labor assessment (105)	7.6	
Mahomed et al., 1998[78] Zimbabwe	Standard obstetric care without amnioinfusion (336)	11.3[a]	1.8 same
	Transcervical amnioinfusion (325)	9.5	
Vayssiere et al., 2007[72] France	Fetal monitoring with cardiotocography only (400)	16.3	2.8 same
	Fetal monitoring with cardiotocography and STAN (399)	13.5	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Table 2. Summary of effectiveness of cesarean reduction strategies (continued)

Author, Year Country	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Somprasit et al., 2005[43] Thailand	Conventional management (640)	14.7	2.8 same
	Active management (320)	11.9	
Gagnon et al., 1997[57] Canada	Usual nursing care (204)	16.2	2.3 same
	One-to-one nursing care (209)	13.9	
East et al., 2006[70] Australia	Fetal monitoring with cardiotocography only (295)	48.1	2.2 same
	Fetal monitoring without cardiotocography and fetal pulse oximetry (306)	45.9	
Bloom et al., 1998[87] US	Usual care (531)	6.0	2.0 same
	Walking during 1st stage of labor (536)	4.0	
Mehrangiz et al., 2004[67] Iran	Promethazine only (50)	4.0	2.0 same
	Paracervical block with promethazine (50)	2.0	
Waldenstrom et al., 1997[31] Sweden	Standard maternity care (932)	8.9	1.8 same
	Birth center care (928)	7.1	
World Health Organization, 1994[98] Indonesia, Thailand, Malaysia	Baseline: (n=10,049)	6.2	1.7 same
	Intervention: Use of WHO partogram to guide active management of labor and decisions about cesarean (n=9,130)	4.5	
Cohen et al., 1987[50] US	Control (75)	14.6	1.3 same
	Early aggressive management (75)	13.3	
Bloom et al., 2006[71] US	Fetal pulse oximetry with oxygen saturation not displayed to clinician (2712)	27.5	1.2 same
	Fetal pulse oximetry with oxygen saturation displayed to clinician (2629)	26.3	
Hofmeyr et al.,1998[79] South Africa	Standard obstetric care without amnioinfusion (176)	43.0	1.0 same
	Transcervical amnioinfusion (176)	42.0	
Windrim et al., 2007[39] Canada	Labor progress documented by standard sequential notes (962)	25.4	0.7 same
	Partogram added to standard written labor progress notes (970)	24.7	
Barakat et al., 2009[32] Spain	No exercise training (80)	15.7	0.4 same
	Exercise training (80)	15.3	
Althabe et al.,[93] South America	Control Group: Usual care (n=39,175)	24.9	0.2 same
	Intervention: Mandatory second opinion driven by evidence-based guidelines for indications (n=34,735)	24.7	
Hodnett et al., 2002[56] US & Canada	Usual care (3461)	12.6	0.1 same
	Nurse support (3454)	12.5	
Ajadi et al., 2006[52] Nigeria	No amniotomy on admission (64)	1.6	0.0 same
	Amniotomy on admission (64)	1.6	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Table 2. Summary of effectiveness of cesarean reduction strategies (continued)

Author, Year Country	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Elferink-Stinkens et al., 2004[94] Netherlands	Control Group: Usual care (n>130,000)	NR	0.0 same
	Intervention: Report of departmental data in table and graph form with follow-up (n>130,000)	NR	
Hinshaw et al., 2008[47] UK	Delayed oxytocin (204)	13.7	0.0 same
	Early oxytocin (208)	13.7	
Lavender et al., 2006[40] UK	4-hour partogram (1485)	9.1	0.0 same
	2-hour partogram (1490)	9.1	
O'Sullivan et al., 2009[88] UK	Usual care (1216)	30.0	0.0 same
	Allowed to eat during labor (1227)	30.0	
Waldenstrom et al., 2001[29] Sweden	Standard care (505)	11.9	0.0 same
	Team midwife care (495)	11.9	
Hamilton et al., 2004[41] US & Canada	Labor progress evaluated by plotting cervical dilatation against time (2514)	16.9	-0.7 same
	Computerized reference range used to evaluate labor progress (2474)	17.6	
Gambling et al., 1998[62] US	Intravenous meperidine analgesia (607)	5.6	-0.7 same
	Combined spinal-epidural anesthesia (616)	6.3	
Campbell et al., 2006[55] US	Standard care (300)	17.9	-1.0 same
	Lay doula support (298)	18.9	
Norris et al., 2001[61] US	Epidural analgesia (1112)	13.4	-1.1 same
	Combined spinal-epidural anesthesia (1071)	14.5	
Regi et al., 2009[75] India	Standard obstetric care without amnioinfusion (75)	37.3	-1.1 same
	Transcervical amnioinfusion (75)	38.4	
Ojala et al., 2006[73] Finland	Fetal monitoring with cardiotocography only (739)	4.7	-1.7 same
	Fetal monitoring with STAN (733)	6.4	
Cox et al., 1999[84] UK	Usual care (240)	3.8	-2.0 same
	Inflatable obstetric belt (260)	5.8	
Garite et al., 2000[69] US	Fetal monitoring with cardiotocography only (502)	26.0	-3.0 same
	Fetal monitoring with cardiotocography and fetal pulse oximetry (508)	29.0	
Janssen et al., 2006[37] Canada	Telephone triage (731)	25.4	-3.2 same
	Home-based triage (728)	28.6	
Jalil et al., 2009[66] Malaysia	IM pethidine analgesia (98)	7.1	-4.6 same
	Epidural ropivacaine 0.2% with fentanyl 2μg/ml (94)	11.7	
Palomäki et al., 2006[48] Finland	Oxytocin plus placebo (55)	4.0	-7.0 same
	Oxytocin plus propranolol (55)	11.0	
Asher et al., 2009[83] US	Acupuncture (30)	20.0	-10.0 3.0 same
	Usual care (no acupuncture) (30)	10.0	
	Sham acupuncture (29)	7.0	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Key Question 1. What strategies during pregnancy are effective to reduce the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

Overview of the Literature

Eight studies of strategies used during pregnancy were included in the review (Table 3).[29-36] One study of identifying women at high risk of cesarean and preemptively conducting cervical ripening and induction of labor was done in the United States,[34] one study of cervical ripening with injection of hyaluronidase in clinic was conducted in Brazil,[36] and the balance were conducted in Europe and Australia. Six trials were rated as fair,[29, 32, 34-36, 125] and two as poor.[30, 33]

Key Points

- Evidence about reducing cesarean through antenatal care models designed to enhance continuity is based on three RCTs with 4,134 participants. These studies have inconsistent findings and provide insufficient evidence. Each of the other approaches used during pregnancy is represented by a single trial with fewer than 300 participants and provides insufficient evidence to guide care (Table 34).
- Care from members of a midwifery practice team who provided both prenatal and birth care compared to conventional care demonstrated a modest 4.5 percent reduction in cesarean births in one study (n = 1283). Two other studies of team midwifery and birth center prenatal care did not document reductions.
- Injection of hyaluronidase into the cervix, in patients at term with a low Bishop score demonstrated a 31 percent reduction in risk of cesarean birth in one small study (n = 168). No other studies were found that repeated evaluation of this intervention.

Table 3. Summary of effectiveness of cesarean reduction strategies during pregnancy

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Spallicci et al., 2007[36] Brazil; Fair	Placebo cervical injection (85)	49.0	31.0 lower
	Hyaluronidase injection in cervix (83)	18.0	
Homer et al., 2001[30] Australia, Poor	Standard hospital-based care(539)	17.8	4.5 lower
	Community-based model care (550)	13.3	
Saisto et al., 2001[33] Finland; Poor	Conventional therapy (91)	48.4	4.9 same
	Intensive therapy (85)	43.5	
Nicholson et al., 2009[34] US; Fair	Standard care (134)	14.9	4.6 same
	Induction of labor (136)	10.3	
Phipps et al., 2009[35] Australia; Fair	Standard care (50)	26.0	4.0 same
	Structured education for pushing (50)	22.0	
Waldenstrom et al., 1997[31] Sweden; Fair	Standard maternity care (932)	8.9	1.8 same
	Birth center care (928)	7.1	

Table 3. Summary of effectiveness of cesarean reduction strategies during pregnancy (continued)

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Barakat et al., 2009[32] Spain; Fair	No exercise training (80)	15.7	0.4 same
	Exercise training (80)	15.3	
Waldenstrom et al., 2001[29] Sweden; Fair	Standard care (505)	11.9	0.0 same
	Team midwife care (495)	11.9	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Detailed Synthesis

Antenatal Care Models

Continuity of care and familiarity of the patient with her care provider and her provider with her history and specific pregnancy details has been proposed to reduce uncertainty in decision making and to preempt interventions like cesarean that might otherwise be undertaken in the context of less shared knowledge and experience. Studies examining care models have typically sought to evaluate if continuity from prenatal into birth care can reduce cesarean. An RCT conducted in Australia randomized 1283 pregnant women at their first antenatal visit to either a 'community model of care' with six midwives, and obstetrician, and a registrar providing consistent care with a team continuity model or to a 'standard model of care' with a larger number of midwives, obstetricians, registrars, and general practitioners, without an attempt to have consistency among providers.[30] The RCT used the Zelen model of randomization - the participants were first randomized, and then asked to consent. If a participant randomized to the intervention wished to receive the control care model, she was allowed to do so and was included in the intervention group for intention-to-treat analysis. Cesarean incidence was 13.3 percent in the intervention group and 17.8 percent in the control group. This is an absolute reduction of cesarean use of 4.5 percent among those assigned to team based care compared to usual care (adjusted odds ratio [AOR]=0.6, 95 percent CI: 0.4, 0.9; p=0.02).[30]

Another RCT conducted in Australia, randomized 1000 pregnant women with uncomplicated pregnancies prior to 25 weeks gestation to either team midwifery care or standard obstetric care.[29] Cesarean risk did not differ between the two groups, by intention-to-treat analysis. Of the women receiving team midwife care, 55 of 464 (11.9 percent) had a cesarean, compared to 56 of 471 (11.9 percent) receiving standard care (OR=1.00, 95 percent CI: 0.66, 1.15). There was no difference between the reported neonatal outcomes for the intervention and control groups (mortality 1.1 percent versus 1.5 percent, five-minute Apgar <7 1.9 percent versus 1.5 percent, NICU admission 10.3 percent versus 7.6 percent [OR=1.4, 95 percent CI: 0.87, 2.26]) (Tables 4 and 5).[29]

A Swedish RCT randomized 1860 women at their first or second antenatal visit to either a birth center care model or a standard care model.[31] The birth center care model was comprehensive and integrated antenatal, intrapartum and postpartum care with the same team of midwives. Their practice includes restricted use of medical technology and discharge within 24 hours. The standard care model was the usual form of public maternity care offered to women in

the Greater Stockholm area, with approximately 75 community centers providing antenatal care (two of which were private) and seven hospitals providing intrapartum and postpartum care.

Women were allowed to change groups, but data analysis was by intention to treat so this bias would have tended to lower the measured effect. There was no significant difference in cesarean use: 7.1 percent in the intervention group and 8.9 percent in the control group, an absolute reduction of 1.8 percent (95 percent CI: -4.3, 0.7; p=0.18). Neonatal outcomes for the intervention and control groups did not differ (mortality 0.9 percent versus 0.2 percent, five-minute Apgar less than seven 1.3 percent versus 1.1 percent, and special care nursery admission 11.1 percent versus 9.0 percent).[31]

Table 4: Maternal outcomes for antenatal strategies to reduce cesarean births

Strategy	Fever, % (n studies)	Infection, % (n studies)	Hemorrhage, % (n studies)	Mortality, % (n studies)
Control	3.0[34]	NR	2.6-12.7[29-31] (3)	0[31]
Antenatal care, community model[30], birth center[31], team midwife care[29]	NR	NR	1.6-12.5[29-31] (3)	0[31]
Exercise training[32]	NR	NR	NR	NR
Education on pushing[35]	NR	NR	NR	NR
Hyaluronidase injection[36]	NR	NR	NR	NR
Induction[34]	4.4	NR	NR	NR
Intensive therapy for fear of childbirth[33]	NR	NR	NR	NR

Exercise Training

Physical activity has been associated with reduced maternal complications in pregnancy and may have potential to reduce cesarean risk. An RCT conducted in Spain randomized 160 pregnant women to either light intensity resistance exercise training during the second and third trimesters or to no exercise training.[32]. Inclusion criteria limited participants to women with uncomplicated pregnancies who were sedentary (not exercising more than 20 minutes on more than three days per week). Analysis was not done using an intention-to-treat approach. There was no difference in the cesarean rate between the intervention and control groups (15.3 percent versus 15.7 percent).[32]

Management of Fear of Childbirth

If fear of labor, interventions, or the birth itself impairs progress in labor or ability to work in partnership with care providers, fear could elevate cesarean risk. A community-based RCT, conducted in Finland, randomized 176 pregnant women with fear of childbirth to either intensive intervention or conventional care.[33] The participants were physically healthy with low risk pregnancies. The intensive intervention included written education materials, questionnaires, cognitive behavioral therapy, provider discussions, and creation of a birth plan. There was no statistical difference in use of cesarean between the two groups: 43.5 percent among those in the intervention and 48.4 in the control group.[33]

Table 5: Neonatal outcomes for antenatal management strategies to reduce cesarean births

Strategy	Apgar score <7 at 5-min, % (n studies)	NICU admission, % (n studies)	NICU days, mean ± SD (n studies)	Mortality,% (n studies)
Control	0.8-8.2[29-31, 34, 36] (5)[a]	6.7-18.9[29-31, 34] (4)	10.2-17.2[29, 31] (2)	0.2-1.5[29-31] (3)
Antenatal care, community model[30], birth center[31], team midwife care[29]	1.3-2.2[29-31] (3)	10.4-14.5[29-31] (3)	9.6-11.1[29, 31] (2)	0.7-1.1[29-31] (3)
Exercise training[32]	9.9 ± 0.2[b]	NR	NR	NR
Education on pushing[35]	NR	NR	NR	NR
Hyaluronidase injection[36]	2.4[b]	NR	NR	NR
Induction[34]	0	1.5	NR	0
Intensive therapy for fear of childbirth[33]	NR	NR	NR	NR

NICU, neonatal intensive care unit, [a] Not specified if 1, 5, or 10 minute Apgar score; [b] Mean ± SD; Control group: 9.9 ± 0.3[32]

Induction of Labor for Women at Risk for Cesarean

A multi-site RCT conducted in the U. S. randomized 270 pregnant women to either induction of labor after 37 weeks and 4 days gestation or to usual care.[34] The authors hypothesized that pre-emptive induction of labor rather than spontaneous onset of labor, could prevent cesarean in women who were predicted to be at high risk of cesarean. Between 32 and 37 weeks gestation, pregnant women were assessed for six risk factors for high probability of a cesarean birth: 1) maternal age greater than or equal to 35 at birth, 2) maternal height less than or equal to 62 inches, 3) BMI 30 kg/m^2, 4) blood pressure more than 80 mmHg diastolic or 120 mmHg systolic, 5)hemoglobin less than 11 g/dL in first trimester, 6) history of a prior birthweight more than 8lbs 8oz. If the patient had one or more of these risk factors for cesarean, she was invited to enroll in the study; participants were then randomized. Participants in the intervention group who had not given birth by 37 weeks and 4 days were scheduled for cervical ripening and induction of labor one to four days prior to what was considered by the study algorithm to be the upper limit for optimal timing of birth. Data analysis was not by intention-to-treat. Cesarean risk was the same across groups: 10.3 percent among the intervention group and14.9 percent among those who received standard care, in this study powered to detect a 66 percent relative difference.[34] There was no difference between these reported neonatal outcomes for the intervention and control groups: (mortality 0.0 percent versus 0.8 percent, five minute mean Apgar score 8.9 versus 8.9, five-minute Apgar score less than 7 0.0 percent versus 0.8 percent). NICU admission rates for the intervention were lower for the intervention group (1.5 percent versus6.7 percent: RR=0.22, 95 percent CI: 0.05, 0.99; p=0.03).[34]

Structured Education for Pushing

Second stage, or "pushing," is the final phase of labor before the birth. Maternal exhaustion, fear, or difficulty in coordinating pushing could theoretically result in a dysfunctional second stage and increase cesarean risk. An RCT conducted in Australia randomized 100 low-risk women who had not previously given birth to either structured education about pushing or routine care.[35] The intervention was two 15-minute structured education sessions teaching pushing with observation of the perineum and digital pressure and biofeedback to the levator

muscle. Cesarean risk did not differ between the two groups: 22 percent among those who received structured education for pushing and 26 among those receiving standard care. The study had an inadequate sample size to detect differences in cesarean risk.[35] Use of episiotomy and incidence of perineal tears did not differ between the groups.[35]

Hyaluronidase Injection into the Cervix

Before labor, the cervix typically softens or "ripens" becoming more pliable to allow dilation and effacement during labor. A standardized score, the Bishop Score, can be used to describe whether the cervix is favorable or unfavorable for induction of labor. In this case the investigators used that scoring mechanism in a novel way to identify women with little cervical softening in order to use an agent that could accelerate cervical ripening. An RCT conducted in Brazil randomized 168 women with a Bishop Score of less than five to either injection of hyaluronic acid or injection of a placebo mixture.[36] The intervention consisted of 5ml of 20,0000IU lyophilized hyaluronidase, sodium chloride, mannitol, and thiomersal diluted in distilled water and injected at 12 o'clock and 6 o'clock into the cervix. The control consisted of sodium chloride, mannitol, thiomersal, benzalkonium chloride, and riboflavin phosphate diluted in distilled water and injected at 12 o'clock and 6 o'clock into the cervix. Technically the study compared two interventions: hyaluronidase versus benzalkonium chloride and riboflavin phosphate. Thiomersal contains mercury and could not be given to pregnant women in the United States. Benzalkonium chloride can be toxic in humans and could not be given to pregnant women in the United States. The cesarean rate in the control group of 85 women was 49 percent, and the overall cesarean rate among 2684 women giving birth at the same hospital over the same period of time was 29 percent. Eighteen percent of women in the intervention group compared to 49 percent in the control group had a cesarean. The absolute risk reduction was 31 percent (95 percent CI: 18, 44; $p<0.0001$).[36] Apgar scores were not different between the two groups. This systematic literature review and subsequent hand-searching did not identify a published study that preceded or attempted to replicate this research.[36]

Key Question 2. What strategies during labor are effective to reduce the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

Management of Labor

Overview of the Literature

This section presents results of 17 studies meeting our review criteria and addressing strategies for management of labor. These interventions are used almost exclusively during the first stage of labor, which is the time period in which the cervix is dilating and thinning. The strategies include early labor assessment (2 trials), [37-38] measurement of labor progress with a partogram, a graphic representation of the progress of labor, or computerized reference curve (4 trials),[39-42] active management of labor (4 trials),[43-46] management of abnormal labor (5 trials),[47-51] amniotomy (1 trial),[52] and intravenous (IV) fluids (1 trial).[53] Of the 17 trials, five were conducted in the United States,[45-46, 49-50, 53] four in the UK,[40, 42, 47, 51] three in Canada,[37-39] one in Finland,[48] one in Thailand,[43] one in Nigeria,[52] one in South Africa,[44] and one was multinational (US and Canada)[41]. All but two of the trials[48-49] included only nulliparous women. Two studies were published in the 1980s,[50-51] five studies in the 1990s,[38, 42, 45-46, 49]; and 10 studies in 2000 or

later.[37, 39-41, 43-44, 47-48, 52-53] There were five trials of good quality,[40, 42, 44, 49, 53] six of fair quality, [37-39, 48, 51-52] and six of poor quality. [41, 43, 45-47, 50]

Key Points

- Each of the early labor assessment strategies was assessed to provide insufficient evidence (Table 34). The four studies of partograms, that enrolled more than 10,832 women, provide low strength of evidence for lack of benefit of partograms for reducing cesarean. The three RCTs of active management have conflicting finding but as fair and good quality studies of more than 2,500 women, they provide low strength of evidence for lack of evidence of benefit. Single studies provide insufficient evidence to inform care.
- The only labor management strategies that significantly reduced the use of cesarean were the addition of propranolol to oxytocin for augmentation of dysfunctional labor, a combined strategy of partogram with active management, and use of a four-hour partogram compared with a three-hour partogram (see Table 2). However, a second study did not find a significant reduction in the use of cesarean when propranolol and oxytocin were initiated simultaneously for dysfunctional labor treatment.
- Home-based triage, compared with telephone triage to help a woman judge when to come to the hospital in labor, did not reduce the use of cesarean.
- Early labor assessment to delay hospital admission until active labor defined by cervical change, compared with direct admission of women in labor regardless of progression, did not reduce the use of cesarean.
- Adding a partogram to standard written labor progress notes did not reduce the use of cesarean. Cesarean rates with 2-hour and 4-hour partograms were equivalent.
- A computerized reference range for assessing labor progress did not reduce the use of cesarean.
- Active management of labor did not reduce the use of cesarean.
- Cesarean rates were identical in women who did and did not have amniotomy at the time of hospital admission.
- Increased intravenous fluids did not reduce the use of cesarean.

Detailed Synthesis

Early Labor Assessment

The goal of early labor assessment is to delay hospital admission until a woman is in active labor because early admission is associated with increased rates of obstetric intervention, including cesarean.[126-127] Two Canadian trials of fair quality assessed the effect of early labor assessment strategies (see Table 6 below). [37-38] A trial of 1459 nulliparous women compared home-based triage (n = 728) with telephone triage (n = 731).[37] Women in both groups were evaluated for labor progress and abnormalities, fetal movement, and maternal coping. In addition, those women who had home visits also had maternal vital signs checked, abdominal palpation, fetal heart rate auscultation, assessment of contractions, and cervical examination. Women in the telephone group were given suggestions for coping with contractions while women and their partners in the home visit group received education about comfort measures. Criteria for advising women to proceed to the hospital were the same for both groups except

cervical dilatation, which was used as an additional criterion for the home visit group. The percentage of women who had a cesarean birth was higher in the home-based triage group (28.6 percent) than the telephone triage group (25.4 percent), but this difference was not statistically significant (RR=1.12, 95 percent CI: 0.94, 1.32). Five-minute Apgar scores (RR 1.52, 95 percent CI 0.54-4.23), admission to a Level II nursery (RR=0.93, 95 percent CI: 0.63, 1.37), and admission to a Level III nursery (RR=2.35, 95 percent CI: 0.90, 6.08) were comparable (Tables 10 and 11).

Table 6. Summary of effectiveness of labor management cesarean reduction strategies: early labor assessment

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
McNiven et al., 1998[38] Canada; Fair	Direct admission (104)	10.6	3.0 same
	Early labor assessment (105)	7.6	
Janssen et al., 2006[37] Canada; Fair	Telephone triage (731)	25.4	-3.2 same
	Home-based triage (728)	28.6	

[a] **Same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

In a trial that enrolled 209 women without prior births, participants were randomized to early labor assessment or direct admission when they presented to the hospital in labor.[38] Women in the early labor assessment group were evaluated and only admitted to the labor and delivery unit if they were in active labor. Women who were not in active labor were advised to walk outside or return home until active labor began. Women in the control group were not assessed prior to admission to the labor and delivery unit. The percentage of women who had a cesarean birth was lower in the early labor assessment group (7.6 percent) than the direct admission group (10.6 percent), but this difference was not statistically significant (OR=0.70, 95 percent CI: 0.27, 1.81). As shown in Table 11, the percentage of infants with Apgar scores lower than seven at five minutes was comparable (p=0.318).

Measurement of Labor Progress

The purpose of measuring labor progress is to remain vigilant for and intervene early in abnormal progress, also known as labor dystocia, which is the most common indication for primary cesareans in the United States.[128] When dystocia is identified, strategies to improve labor progress, such as augmentation with oxytocin, can be used. Various methods of tracking labor progress are available including the partogram, which is a paper form used to record labor examination findings such as cervical dilation, fetal descent, and contraction frequency. The partogram provides a graphical representation of labor progress and alerts clinicians to abnormal progress.[129] Four trials investigated strategies to measure labor progress. Three involved partograms,[39-40, 42] and the fourth used a computerized reference range (Table 7).[41]

Table 7. Summary of effectiveness of labor management cesarean reduction strategies: measurement of labor progress

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Lavender et al., 1998[42] UK; Good	3-hour partogram (302)	14.2	5.8 (4-hour vs. 3-hour) lower
	4-hour partogram (311)	8.4	
	2-hour partogram (315)	11.1	
Windrim et al., 2007[39] Canada; Fair	Labor progress documented by standard sequential notes (962)	25.4	0.7 same
	Partogram added to standard written labor progress notes (970)	24.7	
Lavender et al., 2006[40] UK; Good	4-hour partogram (1485)	9.1	0 same
	2-hour partogram (1490)	9.1	
Hamilton et al., 2004[41] US & Canada; Poor	Labor progress evaluated by plotting cervical dilatation against time (2514)	16.9	-0.7 same
	Computerized reference range used to evaluate labor progress (2474)	17.6	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Use of a partogram in conjunction with standard written labor progress notes was compared to documentation of labor progress solely with sequential notes in a Canadian study with 1962 participants.[39] The proportion of women who had a cesarean birth was lower in the group whose labors were assessed with the partogram compared with those who only had standard notes (24.7 percent vs. 25.4 percent), but this difference was not statistically significant (p reported as NS with no specific value given). The differences in rates of maternal fever, five-minute Apgar scores less than seven, and NICU admission were not statistically significant (test result not reported, see Tables 10 and 11).

Partograms typically include pre-printed alert and action lines. The alert line represents the labor progress of the slowest (less than or equal to the 10th percentile) of primiparous women. The action line, which prompts clinicians that intervention may be warranted for slow labor progress, is placed a number of hours (usually two to four) after the alert line.[129] In two trials in the United Kingdom, women whose labor progress crossed the action line had management for prolonged labor (oxytocin augmentation with amniotomy if membranes were intact).[40, 42] In the first trial,[42] 315 women had a partogram with a two-hour action line, 302 women had a partogram with a three-hour action line, and 311 women had a partogram with a four-hour action line. The rate of cesarean birth was lowest in the women in the 4-hour group (8.4 percent) followed by the two-hour group (11.1 percent) and the three-hour group (14.2 percent). When the intervals were compared (two-hour versus three-hour, three-hour versus four-hour, and two-hour versus four hour), only the results for the four-hour versus the three-hour were significant (OR=1.8, 95 percent CI: 1.1, 3.2). In the second trial,[40] 1490 women had a partogram with a two-hour action line, and 1485 women had a partogram with a four-hour action line. The rate of cesarean birth in both groups was identical (9.1 percent). Both trials had rates of postpartum hemorrhage, five-minute Apgar scores less than seven, and NICU admission that did not differ significantly across groups (see Tables 10 and 11).

One trial in 4988 women evaluated the addition of a computerized reference range to standard measurement of labor progress by plotting cervical dilatation against time in primiparous women.[41]The software combined the results of clinical examinations with

contraction frequency from uterine monitoring to produce a percentile comparison to the reference range. Cesareans were performed in 17.6 percent of the experimental group and 16.9 percent of the control group. This difference was not statistically significant (RR= 1.04, 95 percent CI: 0.92, 1.18). The only maternal or neonatal outcome of interest that was reported was the percentage of newborns in each group who had five-minute Apgar scores lower than seven, which was nearly identical (see Table 11).

Active Management of Labor

Active management of labor is a general term for a multifaceted approach to labor care that includes some or all of the following: "patient education, strict criteria for the diagnosis of labor, strict criteria for the determination of abnormal progress of labor, high-dose oxytocin infusion, one-to-one nursing support in labor, strict criteria for interpretation of fetal compromise, and peer review of operative deliveries."[128] The purpose of active management of labor is to decrease the incidence of dystocia, which should in turn decrease the cesarean rate.[46] A Cochrane review of seven active management trials initially did not find a significant reduction in the cesarean rate, but the difference was significant (RR=0.77, 95 percent CI: 0.63, 0.94) when a trial with numerous post-randomization exclusions was removed from the analysis.[130]

Four trials examined use of active management of labor for cesarean reduction (see Table 8 below).[43-46] A trial of good quality in South Africa combined use of a partogram with aspects of active management. [44] Nulliparous women in active labor, defined as regular and painful contractions with cervical dilatation of four or more centimeters, were assigned to aggressive (n = 344) or expectant (n = 350) management. A partogram with a single alert line was used for the aggressive management group who had a repeat vaginal examination two hours after the first examination. If cervical dilatation had progressed on or above the alert line, the cervix was reexamined in two to four hours depending on when complete cervical dilatation was expected. If cervical dilatation crossed the alert line, fetal heart rate was normal, and gross cephalopelvic disproportion was not present, oxytocin was started. The expectant management group had a partogram with an alert line and a four-hour action line. Their cervical examination was repeated four hours after initial examination. If cervical dilatation had progressed on or above the alert line, the cervix was reexamined in two to four hours depending on current dilatation and expected time of complete dilatation. If cervical dilatation had moved to the right of the alert line, the cervix was reexamined at the time it was anticipated the action line would be crossed. If cervical dilatation reached or crossed the action line, fetal heart rate was normal, and gross cephalopelvic disproportion was not present, oxytocin was started. Amniotomy was not performed due to the high prevalence of HIV and thus need to prevent vertical transmission. The cesarean rate was 16.0 percent in the aggressive management group and 23.4 percent in the expectant management group (RR=0.68, 95 percent CI: 0.50, 0.93). As shown in Table 11, three newborns (one of which was a known intrauterine fetal death [IUFD] prior to enrollment) in the aggressive management group and none in the expectant management group had Apgar scores less than eight at 10 minutes. There were three perinatal deaths in the aggressive management group (including the known IUFD) and none in the expectant management group, but this difference was not statistically significant (RR=7.12, 95 percent CI: 0.37, 137.37).

Table 8. Summary of effectiveness of labor management cesarean reduction strategies: active management of labor

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Pattinson et al., 2003[44] South Africa; Good	Expectant management (350)	23.4	7.4 lower
	Aggressive management (344)	16.0	
Rogers et al., 1997[45] US; Good	Usual care (205)	11.7	4.2 same
	Active management (200)	7.5	
Lopez-Zeno et al., 1992[46] US; Poor	Traditional management (354)	14.1	3.6 same
	Active management (351)	10.5	
Somprasit et al., 2005[43] Thailand; Poor	Conventional management (640)	14.7	2.8 same
	Active management (320)	11.9	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

A U.S. trial of poor quality with 705 nulliparous women enrolled participants in spontaneous labor, which was defined as regular, painful contractions at least every five minutes plus complete cervical effacement or spontaneous rupture of membranes.[46] Active management included amniotomy within one hour of labor diagnosis, hourly cervical examinations for the first three hours then examinations every two hours, and high-dose oxytocin augmentation (started at 6 mU per minute and increased by 6 mU per minute every 15 minutes) for cervical dilation of less than one centimeter per hour in the first stage of labor or fetal descent of less than one centimeter per hour in the second stage of labor. In the traditional management group, the physician decided when to perform amniotomy, how often to examine the cervix, and what criteria were used to diagnose inadequate labor progress. When oxytocin augmentation was used, it was typically started at one mU per minute and increased by one or two mU per minute every 15 minutes until there were eight contractions per 20 minutes. The cesarean rate was 10.5 percent in the active management group, and 14.1 percent in the traditional management group ($p=0.18$). As shown in Table 10, the active management group had a significantly lower rate of chorioamnionitis than the traditional management group (4.6 percent versus 9.9 percent, $p<0.01$). Differences in five-minute Apgar scores less than seven and NICU admission rates were not significant (test result not reported, see Table 11). No neonatal deaths occurred in either group.

Another US trial of poor quality enrolled 405 nulliparous women.[45] Participants in the active management group were diagnosed with labor when they had regular, painful contractions every two to five minutes with at least 80 percent cervical effacement, regardless of dilatation. They had amniotomy within two hours of admission, cervical examination every two hours, and high-dose oxytocin augmentation (started at 6 mU per minute and increased every 15 minutes) for cervical dilation of less than one centimeter per hour in the first stage of labor or fetal descent of less than one centimeter per hour in the second stage of labor. Participants in the control group were admitted when they had regular, painful contractions every two to five minutes and three to four centimeters of cervical dilatation, regardless of effacement. Amniotomy was performed at the physician's discretion. If the cervix did not change 1.25 centimeters per hour once the active phase of labor began, low-dose oxytocin was started (1 mU per minute and increased by 1 mU/min every 30 to 40 minutes). The cesarean rate was 7.5 percent in the active management

group and 11.7 percent in the expectant management group, which was not a significant difference. Maternal and neonatal outcomes were similar in both groups (not statistically significant, no test results reported, see Tables 10 and 11).

In a poor quality trial of 960 nulliparous women in Thailand,[43] labor was diagnosed when by regular, painful contractions lasting at least 40 seconds and occurring at least once per five minutes plus spontaneous rupture of membranes or bloody show with cervical dilatation and complete effacement. The active management group had amniotomy within one hour of admission, cervical examination every two hours, and high doses of oxytocin (started at 6 mU per minute and increased by two mU per minute every 30 minutes until there were five contractions per 10 minutes or the rate was 40 mU per minute) if cervical dilatation was less than one centimeter per hour in the first stage of labor. The conventional management group did not have a protocol for amniotomy, cervical examination, or oxytocin initiation. The use of cesarean was lower in the active management group (11.9 percent) than the conventional management group (14.7 percent), but this difference was not significant (p-value not reported). There were no significant differences (test results not reported) between groups in rates of maternal fever, chorioamnionitis, and one-minute Apgar scores less than seven (see Tables 10 and 11).

Management of Abnormal Labor

Five trials assessed strategies for managing abnormal labor (see Table 9).[47-51] A poor quality trial of early versus delayed oxytocin included 412 nulliparous women with primary dysfunctional labor, diagnosed by cervical dilatation of two centimeters or less over four hours from initial dilatation of three to six centimeters.[47] Women with intact membranes had amniotomy prior to randomization. The early oxytocin group started oxytocin within 20 minutes of randomization, while the delayed oxytocin group did not receive oxytocin for eight hours unless intervention was warranted. Cesarean risk was identical in the two groups (14 percent), and there were no significant differences in postpartum hemorrhage (OR=0.87, 95 percent CI: 0.5, 1.4), five-minute Apgar scores (OR=1.6, 95 percent CI: 0.4, 7.0), NICU admission (OR=1.2, 95 percent CI: 0.4, 3.9), or neonatal death (OR=0.98, 95 percent CI: 0.06, 16) (see Tables 10 and 11).

Table 9. Summary of effectiveness of labor management cesarean reduction strategies: management of abnormal labor

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Sanchez-Ramos et al., 1996[49] US; Good	Oxytocin plus placebo (47)	51.1	24.6 lower
	Oxytocin plus propranolol (49)	26.5	
Bidgood et al., 1987[51] UK; Fair	Observation (20)	45.0	18.7 (high-dose vs. obs.) same
	High-dose oxytocin (19)	26.3	
	Low-dose oxytocin (21)	33.3	
Cohen et al., 1987[50] US; Poor	Control (75)	14.6	1.3 same
	Early aggressive management (75)	13.3	
Hinshaw et al., 2008[47] UK; Poor	Delayed oxytocin (204)	13.7	0 same
	Early oxytocin (208)	13.7	
Palomäki et al., 2006[48] Finland; Fair	Oxytocin plus placebo (55)	4.0	-7.0 same
	Oxytocin plus propranolol (55)	11.0	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

One trial of fair quality, done in the United Kingdom, examined three oxytocin protocols in 60 nulliparous women in labor (diagnosed by complete cervical effacement, dilatation greater than or equal to three centimeters, regular contractions with at least one per five minutes, and cervical progress on a partogram) whose cervical dilatation was less than 0.5 centimeters per hour.[51] Amniotomy was performed prior to randomization for women with intact membranes. Participants were randomized into three arms: delayed oxytocin for eight hours (n = 20); automatic infusion system (AIS) oxytocin (2 mU per minute increased by 2 mU every 15 minutes) for women whose uterine activity was less than 700 kPas per 15 minutes (n = 21, 13 received oxytocin); and high-dose oxytocin (7 mU per minute increased by 7 mU every 15 minutes, n = 19). The cesarean rate was 45 percent in the delayed oxytocin group, 33.3 percent in the AIS oxytocin group, and 26.3 percent in the high-dose oxytocin use. Differences across groups were not statistically significant. Five-minute Apgar scores lower than seven (Table 11) did not differ significantly between groups (test result not reported).

A poor quality U.S. trial of early intervention included 150 primigravid women who had been admitted in labor (diagnosed by contractions plus cervical dilatation of three centimeters or ruptured membranes) and had an inadequate contraction pattern (less than 3 contractions lasting 40 seconds each in a 10-minute time period).[50] The early intervention group had amniotomy if membranes were intact, insertion of a fetal electrode and an intrauterine pressure cannula, and initiation of oxytocin infusion, all of which were performed within 30 minutes of admission. The control group had external fetal monitoring and oxytocin infusion if the cervical dilatation did not change for more than two hours or if there was no change in station for one hour during the second stage of labor. The cesarean incidence was 13 percent in the early intervention group and 15 percent in the control group, a difference that was not statistically significant.

Two trials, one of good quality in the U.S.[49] and one of fair quality in Finland,[48] compared oxytocin alone and with propranolol, a beta receptor blocking agent thought to have the potential to enhance uterine activity, for treatment of abnormal labor progress. These were the only trials related to management of labor that included both nulliparous and multiparous women. The first trial defined dysfunctional labor as no cervical dilatation for at least two hours in the active phase of labor or a deceleration phase of at least three hours in nulliparas and one hour in multiparas.[49] All women continued to receive oxytocin. Propranolol (n = 49) or placebo (n = 47) were administered intravenously and repeated after one hour if cervical dilatation did not change. Cesarean was performed if there was no response within an hour after the second dose. The cesarean rate was 26.5 percent in the propranolol group and 51.1 percent in the placebo group (RR=0.58, 95 percent CI: 0.35, 0.93; p=0.02). Differences in Apgar scores and NICU admissions were not significant (Table 11). The second trial defined arrest of labor as hypocontractility with other causes of dystocia, such as disproportion, excluded.[48] At the time of diagnosis of arrested labor, oxytocin was initiated along with a dose of propranolol (n = 55) or placebo (n = 52), which was repeated an hour later if the cervical status was unchanged. The timing of cesarean was not specified as it was in the first trial. The cesarean rate was 11 percent in the propranolol group and 4 percent in the placebo group (p=0.154). The difference in NICU admissions was not significant (see Table 11).

Amniotomy

Amniotomy has been purported to shorten the duration of the first stage of labor although a Cochrane review of 15 studies found no statistical difference in first-stage labor length or the rate of cesarean when amniotomy was performed.[131] A fair quality trial in Nigeria, randomly assigned 128 women to amniotomy or no amniotomy upon presentation in labor.[52] Both groups had identical risk of cesarean (1.6 percent, p>0.05). The only neonatal outcome reported was five-minute Apgar scores, which were comparable between groups (test result not reported, see Table 11).

Increased Intravenous Fluids

One U.S. trial of good quality evaluated the effect of increased intravenous hydration in labor based on the rationale that adequate fluid replacement might improve labor progress, and subsequently reduce the cesarean rate, similar to the effects of adequate hydration on the exercise performance of athletes.[53] Women received increased (250 ml/hour, n = 101) or standard (125 ml/hour, n = 94) rates of lactated Ringer's solution or isotonic sodium chloride solution. The percentage of women who had a cesarean birth was lower in the 250-ml group (9.9 percent) than the 125-ml group (17.0 percent), but this difference was not statistically significant (p=0.22). Maternal and infant outcomes were similar (no test of statistical significance reported, see Tables 10 and 11).

Table 10: Maternal outcomes for labor management strategies to reduce cesarean births

Strategy	Fever, % (n studies)	Infection, % (n studies)	Hemorrhage, % (n studies)	Mortality, % (n studies)
Control	8.1-19.1[39, 43, 53] (3)	0.9-19.1[43, 45-46, 53] (4)	5.3-22.1[40, 42, 45, 47, 53] (5)	NR
Amniotomy at admission[52]	NR	NR	NR	NR
High-dose oxytocin[51]	NR	NR	NR	NR
Low-dose oxytocin[51]	NR	NR	NR	NR
Early aggressive management[44, 50]	NR	NR	NR	NR
Increased IV fluids[53]	14.9	14.9	4.0	NR
Computerized range for labor progress[41]	NR	NR	NR	NR
Early oxytocin[47]	NR	NR	19.7	NR
Home-based triage[37]	NR	NR	NR	NR
2-hour partogram[40, 42]	NR	NR	12.4-12.5	NR
3-hour partogram[42]	NR	NR	12.9	NR
4-hour partogram[40, 42]	NR	NR	12.5	NR
Active management[43, 45-46]	8.1[43]	0-14[a]	4.0[45]	NR
Early labor assessment[38]	NR	NR	NR	NR

Oxytocin plus propranolol[48-49]	NR	NR	NR	NR
Partogram + standard labor progress notes[39]	11.8	NR	NR	NR

[a] P<0.01[46]

Table 11: Neonatal outcomes for labor management strategies to reduce cesarean births

Strategy	Apgar score <7 at 5-min, % (n studies)	NICU admission, % (n studies)	NICU days, mean ± SD (n studies)	Mortality, % (n studies)
Control	0-6.3[37-47, 49, 51-53] (15)	2.0-11.0[37, 39-40, 42, 45-49, 53] (10)	NR	0-0.5[44, 46-47]
Amniotomy at admission[52]	7.8[a]	NR	NR	NR
High-dose oxytocin[51]	0.0	NR	NR	NR
Low-dose oxytocin[51]	4.8	NR	NR	NR
Early aggressive management[44, 50]	0.9[44d]	NR	NR	0.9[44e]
Increased IV fluids[53]	1.0	9.9	NR	NR
Computerized range for labor progress[41]	2.0	NR	NR	NR
Early oxytocin[47]	2.5[b]	2.9	NR	0.5
Home-based triage[37]	1.2	8.1[c]	NR	NR
2-hour partogram[40, 42]	1.5-1.9	1.3-1.4	NR	NR
3-hour partogram[42]	1.3	0.3	NR	NR
4-hour partogram[40, 42]	1.6-2.0	0.6-2.0	NR	NR
Active management[43, 45-46f]	0.3-1.9	0.5-4.0[45-46]	NR	0[46]
Early labor assessment[38]	1.0	NR	NR	NR
Oxytocin plus propranolol[48-49]	2.0[49]	2.0-11.0	NR	NR
Partogram + standard labor progress notes[39]	1.2	3.4	NR	NR

NICU, neonatal intensive care unit; IV, intravenous
[a]One-minute Apgar scores. Five-minute Apgar scores were not provided, but the articles notes were no statistically significant differences in the number of newborns with Apgar scores < 7 at one or five minutes.
[b]Apgar scores ≤ 7
[c]Includes admission to Level II or Level III nursery
[d]Apgar < 8 at 10 minutes
[e]Includes an intrauterine death known prior to trial enrollment
[f]One-minute Apgar scores (five-minute not reported)

Psychosocial Support

"Doula" is a Greek word that refers to a woman caregiver[55] or an experienced woman who helps another woman or a new mother.[54, 58, 132] Today, the word has come to mean a woman experienced in childbirth who provides continuous physical and emotional support throughout

labor and birth.[54-55, 58-59, 132] Continuous one-on-one nursing support refers to uninterrupted support by staff nurses with training in labor support.[56] Labor support refers to "the presence of an empathetic person who offers advice, information, comfort measures, and other forms of tangible assistance to help a woman cope with the stress of labor and birth."[56] Unlike standard maternity care for women in labor, with continuous one-on-one nursing, one nurse is assigned to provide uninterrupted care for one laboring patient throughout labor and childbirth.

Overview of the Literature

We identified seven RCTs[54-60, 132] that examined the effect of psychosocial support interventions on cesarean births. One study added a non-randomized control group after randomizing participants into two other groups.[58] Three studies were conducted in the United States,[54-55, 58] one in Mexico,[59] one study in the United States and Canada,[56] one in Canada,[57] and one in Finland.[60] All interventions took place in labor and delivery. Three studies were conducted in community practices.[54, 58-59] and three were conducted in academic single sites.[55, 57, 60] One study was conducted in multiple settings, including nine academic and four non-academic sites.[56] Five of the studies were restricted to nulliparous women, two included nulliparous and parous women.[56, 60] We separated the seven studies into three categories: doulas as providers of labor support,[54, 58-59] a female friend or family member as a provider of labor support,[55] and nurses and midwifery students as providers of labor support.[56-57, 60] There was one trial of fair quality,[56] and six of poor quality.[54-55, 57-60]

Key Points

- Low strength of evidence favors benefit of trained doula support for reducing cesarean. The single model in which female friends and family give labor support provides insufficient evidence and nursing models of one-to-one support in three trials with 7,568 participants, provide low strength of evidence of lack of benefit (Table 34).
- The three doula support studies showed a reduction in cesarean births for women in the groups who received doula support. The absolute reduction in cesarean ranged from five to 22 percent.
- Cesarean was not reduced by support from a female friend or family member trained to provide labor support.
- Cesarean rates were not lower for women who received continuous labor support from nurses or midwifery students compared to women who received usual labor care.

Detailed Synthesis

Doulas as Providers of Labor Support

Three doula support studies were included (Table 12).[54, 58-59] All studies of doula support were conducted with participants in labor who had uncomplicated pregnancies at term and were having their first birth. One RCT in Mexico[59] compared 50 women who received labor support from childbirth educators who had doula training to 50 women who received usual labor care. The study was conducted at a public hospital with an overall cesarean rate of 40 percent. Doulas were Lamaze trained childbirth educators, who received doula training as part of the Lamaze Childbirth Education curriculum. During labor and childbirth, doulas provided advice and

information, physical assistance and emotional support to the study participants and worked actively to promote natural childbirth.

Table 12. Summary of effectiveness of cesarean reduction strategies using doula support

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Trueba et al., 2000[59] Mexico; Poor	Standard care (50)	24.0	22.0 lower
	Childbirth educator trained as doula (50)	2.0	
McGrath and Kennell, 2008[54] US; Poor	Routine Care (196)	25.0	11.6 lower
	Doula Support (224)	13.4	
Kennell et al., 1991[58] US; Poor	Control group assigned after delivery (204)	18.0	10.0 lower
	Received support of a doula (212)	8.0	
	Observed by an inconspicuous observer (200)	13.0	5.0

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

The proportion of births by cesarean for the doula supported and usual care groups were two and 24 percent respectively (p<0.003). Labor duration did not differ significantly for the two groups (p-value not reported). Incidence of oxytocin administration for the doula supported and usual care groups were 42 percent and 96 percent respectively (p<0.001).

Table 13. Maternal outcomes for psychosocial/labor support strategies to reduce cesarean births

Strategy	Fever, % (n studies)	Infection, % (n studies)	Hemorrhage, % (n studies)	Mortality, % (n studies)
Control	10.3[56, 58] (2)	NR	2.6[56]	0[54]
Doula support[54, 58-59]	1.4[58a]	NR	NR	0[54]
Observation by inconspicuous observer[58]	7.0	NR	NR	NR
Nursing support[56-57]	0.7[56]	NR	2.7[56]	NR
Midwifery student support[60]	NR	NR	NR	NR
Trained friend or family member as labor support [55]	NR	NR	NR	NR

[a] One study[54] reported fever for the total study population ≥ 37.5º: 17.4%; ≥ 38º: 6.9%

In a U.S. trial,[54] 224 women were assigned to doula support and 196 to usual care. The study was conducted at a university hospital with an overall cesarean rate of 24 percent. All doulas completed training requirements that were equivalent to the Doulas of North America International doula certification. The doula met couples shortly after random assignment and stayed with them throughout labor and birth providing verbal encouragement, reassurance, teaching, and touch, to support the laboring woman and her partner. Women in the doula supported group had significantly fewer cesarean births (13.4 percent versus 25.0 percent, p=0.002) and fewer epidurals (64.7 percent versus 76.0 percent, p=0.008). Five-minute Apgar scores did not differ (p=0.30) (Table 14).

Another U.S. trial[58] randomized 412 women to doula support or monitoring by an inconspicuous observer. The authors also selected an additional 204 women for an additional "control" comparison group. The trial was conducted at a public hospital where companions were not routinely permitted to be with a woman during labor and birth. For study participants,

brief visits by family members were allowed if the labor area was not too busy. All doulas completed a three-week training period. They stayed at the patient bedside from admission through birth providing touch, encouragement and information about the labor and childbirth process. The observer stayed in the labor room, but at a distance from the mother, and did not interact with the laboring woman.

The proportions of cesarean births for the doula support, observed, and control groups were 8, 13 and 18 percent respectively (p<0.0001 for all three groups). When pair wise comparisons were made, significant differences remained (doula versus observed, p=0.009 and doula versus control, p=0.004). This study reported forceps births for 8.2 percent of women in the doula support group and 21.3 percent for women in the observed group (p=0.0006). Forceps-assisted births occurred in 26.3 percent of women in the control group (p=0.006, doula support group versus control group). Among participants who had spontaneous vaginal births, epidural use varied significantly for the doula, observed, and control groups (p<0.0001). The mean duration of labor was significantly shorter for the doula group compared to the observed (p<0.02) and control (p<0.02) groups. Labor augmentation occurred less frequently in the support group compared to the control group (p<0.0001). The percentages for oxytocin use for labor augmentation were 17, 23 and 43.6 percent, across groups (p<0.0001). Maternal fever was more common in the observed and control groups than in the supported groups, but there was no statistical analysis provided (Table 13). The authors noted that the proportion of newborns who remained in the hospital more than 48 hours because of medical problems was lower in the supported group (Table 14).

Table 14. Neonatal outcomes for psychosocial/labor support strategies to reduce cesarean births

Strategy	Apgar score <7 at 5-min, % (n studies)	NICU admission, % (n studies)	NICU days, mean ± SD (n studies)	Mortality, % (n studies)
Control	0.7-3.1[54-56] (3)[a, b, c]	4.9-7.3[56-57] (2)	NR	0-0.03[56, 58] (2)
Doula support[54, 58-59]	1.8[54a,b]	NR	NR	0[58]
Observation by inconspicuous observer[58]	NR	NR	NR	0
Nursing support[56-57]	0.9[56] 8.9 ± 0.9[b57]	7.1-7.2[56-57]	NR	0.06[56]
Midwifery student support[60]	9.12 ± 0.48[b]	NR	NR	NR
Trained friend or family member as labor support[55]	0.3[c]	NR	NR	NR

NICU, neonatal intensive care unit
[a] Percent with Apgar ≤ 7 at 5 min[54, 56]
[b] Reported mean Agpar ± SD at 5 minutes--Control 8.98 ± 0.45[60]; Control: 9.0 ± 0.8[57]
[c] Percent with Apgar ≤ 6 at 5 min[55]

Trained Female Friend or Family Member as Providers of Labor Support

In the RCT that used family or friend supports,[55] 291 women were assigned to the supported group and 295 women were assigned to usual care. The participant selected a female friend or family member who participated in two 2-hour learning sessions. A research assistant who was a doula certified by Doulas of North America conducted training that included: anatomy and physical changes during labor and childbirth, assessing labor progression, coping strategies, how to provide anticipatory guidance, comfort measures and reassurance to laboring women. There

were no restrictions on visitors or other support for laboring women at the hospital. The primary cesarean rate for the study facility during the enrollment period was 17.9 percent.

In this study, support from a trained friend or family member did not reduce cesarean births. The proportions of cesarean births for the intervention and usual care groups were 18.9 and 17.9 percent respectively (p=0.7). Women in the supported group had significantly shorter lengths of labor (p=0.004), greater cervical dilation at the time of epidural (p=0.007), and a higher five-minute Apgar scores above six (p=0.006).

Nurses and Midwifery Students as Providers of Labor Support

Two studies in the U.S. and Canada, investigated the effects of continuous labor support by nurses, and one in Finland examined the effects of labor support by midwifery students.[56-57, 133] The effectiveness of these strategies are presented in Table 15.

Table 15. Summary of effectiveness of cesarean reduction strategies: labor support by nurses and midwifery students

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Hemminki et al., 1990[60] Finland; Poor	Usual Care (118)	5.0	3.0 same
	Midwifery student support (122)	2.0	
Gagnon, 1997[57] Canada; Poor	Usual Nursing Care (204)	16.2	2.3 same
	One-to-one Nursing Care (209)	13.9	
Hodnett et al., 2002[56] US & Canada; Fair	Usual Care (3461)	12.6	0.1 same
	Nurse support (3454)	12.5	

[a] **Same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

One randomized controlled Canadian trial,[57] of poor quality, assigned 209 women to a one-to-one intrapartum support from a nurse and 204 women to usual care. Usual care consisted of two to three patients per nurse with variable labor support techniques provided. The intervention was almost continuous one-to-one nursing care from the time of randomization until one hour after the birth. In addition to usual intrapartum care, the support nurse provided physical comfort, emotional support, instruction on relaxation and coping with pain, and support for the father. The support nurses completed an initial 30-hour training period and quarterly refresher workshops.

Cesarean risk was not significantly different. The proportion of cesareans in the supported and usual care groups was 13.9 and 16.2 percent, respectively (RR=0.86, 95 percent CI: 0.54, 1.36). Use of oxytocin stimulation for women in the nurse supported group was 17 percent lower (RR=0.83; 95 percent CI: 0.67, 1.04). There were no significant differences in epidural analgesia (RR=0.96, 95 percent CI: 0.84, 1.09), instrumented vaginal births (RR=1.06, 95 percent CI: 0.74, 1.53), five-minute Apgar scores (RR=-0.1, 95 percent CI: 0.1, 1.05), and NICU admissions (RR=1.46, 95 percent CI: 0.64, 3.18).

A RCT [56] randomized 6290 participants to continuous labor support or usual care. Study sites included nine tertiary care and four community hospitals. The intervention was continuous labor support by a specially trained nurse from the time of randomization to birth. Nurses volunteered to participate and completed a two-day training program conducted by an expert labor nurse doula trainer. Usual care varied depending on a patient's stage of labor, condition, and nurse workload but did not include care by a nurse with special labor support training.

The proportion of cesarean births in the intervention and usual care groups was 12.5 and 12.6 percent, respectively (p=0.44). Labor augmentation for the continuous labor support and usual care groups was 30.1 and 27.2 percent, respectively (p=0.008). Assisted vaginal births, duration of labor, and use of epidural did not differ. There were no significant differences in neonatal outcomes including neonatal deaths (p value not provided), need for higher level of nursery care (p=0.70), five-minute Apgar scores (p=0.50) and length of hospital stay (p-value not provided).

A study conducted in Finland[60] included three trials: one small pilot using laywomen as labor support persons and two trials using midwifery students as labor support persons, one conducted in 1987 and one in 1988. The pilot study with laywoman support was stopped for economic and other reasons.

These studies were conducted at a university hospital. At this hospital, normal births are attended by midwives who do not stay with the patient constantly, and usually take care of more than one laboring woman at a time. Fathers are present for 60 to 70 percent of births. The hospital's cesarean birth rate was 9.8 percent. In 1987, 11 midwifery students volunteered to provide support in labor for study participants, and in 1988 all 16 midwifery students were required to participate.

The 1987 trial randomized 79 women to midwifery student labor support or usual care. The 1988 midwifery student trial randomized 161 women to either a midwifery student for labor support or usual care. The authors reported outcomes for each trial year and for both combined.[60] Cesarean births were equally common: none among supported and eight percent in the usual care in 1987, three and four percent in 1988, and five and five percent for both years combined. The supported group had significantly shorter labors from admission to birth ($p<0.05$). Among women giving birth for the first time, a smaller percentage of women in the supported group had labor durations of 11 hours or more ($p<0.01$). The percentage of women whose contractions stopped was significantly lower in the supported group (5 versus 15 percent, $p<0.01$). Postpartum complications (infections, discharge diagnoses and proportion of mothers not nursing at discharge) were rare and similar in both groups. Mean Apgar scores were higher for neonates in the supported group ($p<0.05$).

Pain Management

Methods of pharmacologic pain management include epidurals, spinal blocks, combined spinal-epidurals (CSE), and systemic and local analgesia. Epidural analgesia, in which local anesthetic, usually in conjunction with an opioid, is administered into the lower spinal area, is widely used in the United States. A recent report from 27 states showed more than 60 percent of women who gave birth vaginally in 2008 received epidural or spinal anesthesia.[134] Though the technique may be similar there are differences in the medications used and the method of administration (bolus, continuous infusion, patient controlled). A Cochrane review that evaluated epidural versus non-epidural or no analgesia in labor concluded that epidurals as compared to opiates were associated with an increased risk of instrumented birth but not an increased risk of cesarean.[135]

Overview of the Literature

Seven studies compared pain management strategies in labor with a goal of reducing the cesarean births. Two studies were conducted in the United States,[61-62] three in Europe,[63-65] and two in Asia.[66-67]Six of the studies were randomized clinical trials[62-67] and one was a quasi randomized trial.[61] All studies took place in the labor and delivery suites in single hospitals.

Inclusion criteria included term singleton pregnancy, without medical complications, vertex presentation, and intention of vaginal birth. One study[66] required previous childbirth, and one was restricted to women who had not previously had births.[65] Five of the studies included both nulliparous and parous women.[61-64, 67] Six studies used epidural analgesia although each of the studies was unique in their drug regimens and dosages. In four studies all women received epidurals and the intervention was focused on type,[61] medication dose,[64-65] or ability to ambulate.[63] Two trials compared epidural to analgesia given intravenously (IV) or by intramuscular (IM) injection[62, 66] and one evaluated paracervical block with tranquilizer to tranquilizer only.[67] One study was assessed as being of good quality,[64] two were considered fair,[62, 66] and the remaining four were poor quality.[61, 63, 65, 67]

Key Points

- Results across these studies are inconsistent. In total they provide low strength of evidence for lack of benefit of pain management strategies as an approach to reduce cesarean (Table 34).
- One study reported a significantly lower use of cesarean associated with intermittent epidural versus continuous epidural suggesting that lower cumulative doses of epidural analgesia may be associated with lower cesarean risk.[65]
- Cesarean risk among women receiving epidural analgesia as compared to IV or IM analgesia did not differ.[62, 66]

Detailed Synthesis

Seven studies evaluated the effect of various pain management strategies to reduce cesarean births.[61-67] The effectiveness of these strategies is presented in Table 16 below.

Table 16. Summary of effectiveness of cesarean reduction strategies of pain management

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Skrablin et al., 2011[65] Croatia; Poor	Continuous epidural (104)	14.4	9.4 lower
	Intermittent epidural (101)	5.0	
Karraz, 2003[63] France; Poor	Intermittent epidural bolus injections of 0.1% ropivacaine with 0.6 μg/ml sufentanil, non-ambulatory (74)	16.2	7.0 same
	Intermittent epidural bolus injections of 0.1% ropivacaine with 0.6 μg/ml sufentanil, ambulatory (141)	9.2	
Olofsson et al., 1998[64] Sweden; Poor	Epidural anesthesia with high dose local anesthetic (0.25% bupivacaine with adrenaline) (435)	14.7	4.5 same
	Epidural anesthesia with low dose (0.125% bupivacaine with sufentanil 10 μg (422)	10.2	
Mehrangiz et al., 2004[67] Iran; Poor	Promethazine only (50)	4.0	2.0 same
	Paracervical block with promethazine (50)	2.0	
Gambling et al., 1998[62] US; Fair	Intravenous meperidine analgesia (607)	5.6	-0.7 same
	Combined spinal-epidural anesthesia (616)	6.3	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Table 16. Summary of effectiveness of cesarean reduction strategies of pain management (continued)

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Norris et al., 2001[61] US; Poor	Epidural analgesia (1112)	13.4	-1.1
	Combined spinal-epidural anesthesia (1071)	14.5	same
Jalil et al., 2009[66] Malaysia;Fair	IM pethidine analgesia (98)	7.1	-4.6
	Epidural ropivacaine 0.2% with fentanyl 2μg/ml (94)	11.7	same

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Two studies examined whether the amount of epidural anesthesia received influences cesarean risk. The most recent study conducted in 205 women in Croatia [65] reported lower use of cesarean among nulliparous women who received an intermittent epidural (5 percent) compared to a continuous epidural (14.4 percent) (RR=2.9, 95 percent CI: 1.1, 7.7; p=0.03). The mean doses of levobupivacaine and fentanyl were significantly lower in the intermittent group. A good quality trial in Sweden with 1000 participants[64] demonstrated a significantly lower rate of combined instrumented births for women who received an epidural with low dose local anesthesia (bupivacaine 1.25 mg/ml with sufentanil 5μg/ml) (29.7 percent) as compared to epidural with high dose of local anesthesia (bupivacaine 2.5 mg/ml with adrenaline 5μg/ml) (48.9 percent) (p<0.0001). Cesarean births were 10.2 percent and 14.7 percent for the low and high dose respectively, but no statistical analysis was reported.

A study of 2182 births in the U.S.[61] compared CSE to epidural only and reported no significant difference in cesarean use (14.5 percent for the CSE group and 13.4 percent for the epidural only). This poor quality study was unusual in that the anesthesia assignment was randomized by day of birth for a 10-month period. Additionally data sheets were missing for more than 600 women. A French study[63] investigated the impact of epidural dosing to allow ambulation in 215 women and reported 9.2 percent of women in the ambulatory group compared to 16.2 percent of women in the non-ambulatory group had cesareans (p=0.15). The ambulatory group also had a significantly shorter duration of labor.

A U.S. study with 1223 participants[62] compared CSE (sufentanil, bupivacaine and fentanyl) to IV meperidine but did not find differences in cesarean (6 percent and 5.5 percent respectively, p=ns). The use of forceps was higher in the subset of nulliparous women, but not different between the groups (10 percent for CSE and 9 percent for IV only, p=ns). A Malaysian study of 192 parous women [66] compared epidural (0.2 percent ropivacaine with fentanyl 2 μg/ml) to IM pethidine/meperidine with no statistically significant difference in cesarean (11.7 percent among women who received epidurals versus 7.1 percent in the IM arm, p=0.19). Women who received epidurals were more likely to have an instrumented birth and prolonged first and second stages of labor. A study of 100 women in Iran[67] compared paracervical block with tranquilizer to tranquilizer only and found no differences in cesarean (p=0.3). Women who received the block had faster pain relief and a shorter duration of the first stage of labor.

Data on maternal harms were reported in only three studies (Table 17).[61-62, 65] In the first, incidence of fever was similar in the intermittent (23 percent) and continuous (20 percent) epidural treatment groups and post partum hemorrhage was reported in three women.[65] Gambling and colleagues[62] reported fever in 22 percent of women in the CSE group and only

three percent in the IV group (p<0.005). Norris et al.[61] reported low rates of accidental dural puncture (1.3 percent in the CSE group compared to 1.2 percent in the epidural group).

Overall data on infant harms were not well reported. No significant differences in five-minute Apgar scores between groups were seen in any of the studies. Data on NICU admissions were not reported in any study. There were no infant deaths in the three studies that reported this information (Table 18).[62, 66-67]

Table 17. Maternal outcomes for pain management strategies to reduce cesarean births

Strategy	Fever, % (n studies)	Infection, % (n studies)	Hemorrhage, % (n studies)	Mortality, % (n studies)
Control	3.0[62]	NR	NR	0.0[66]
Intermittent epidural[65]	23.0	NR	1.0	NR
Continuous epidural[65]	20.0	NR	2.0	NR
Combined spinal-epidural[61-62]	22.0[62]	NR	NR	NR
Epidural with high dose local anesthetic[64]	NR	NR	NR	NR
Epidural;[66]; ambulatory[63]	NR	NR	NR	NR
Paracervical block with tranquilizer[67]	NR	NR	NR	NR

Table 18. Neonatal outcomes for labor management strategies to reduce cesarean births

Strategy	Apgar score <7 at 5-min, % (n studies)	NICU admission, % (n studies)	NICU days, mean ± SD (n studies)	Mortality, % (n studies)
Control	0-3.9[62, 64, 66-67] (4)	NR	NR	0[62, 66-67] (3)
Intermittent epidural[65]	3.0	NR	NR	NR
Continuous epidural[65]	1.9	NR	NR	NR
Combined spinal-epidural[61-62]	0[62a]	NR	NR	0[62]
Epidural with high dose local anesthetic[64]	4.5	NR	NR	NR
Epidural;[66]; ambulatory[63]	1.1[66]	NR	NR	0[66]
Paracervical block with tranquilizer[67]	0	NR	NR	0

NICU, neonatal intensive care unit
[a] Mean Apgar scores of 9 in both groups[61]

Fetal Assessments

Electronic fetal monitoring (EFM) uses special equipment to measure the fetal heart rate (FHR) in response to contractions of the uterus. It provides an ongoing record that can be followed by the health care provider. EFM has been the predominant tool used for fetal surveillance during labor. Methods for monitoring can be external, internal, or both. With external fetal monitoring a belt with an ultrasound transducer is strapped around the woman's

abdomen to detect the FHR. Another belt is placed on the abdomen to measure the strength, frequency, and duration of contractions. The FHR and uterine contraction information is recorded. For internal fetal monitoring, a wire or electrode is placed on the part of the fetus closest to the cervix, which is usually the scalp. This device records the heart rate. Uterine contractions and their strengths also may be monitored with a special intrauterine pressure catheter inserted through the cervix into the uterus. Internal monitoring can be used only after the membranes of the amniotic sac have ruptured. The normal FHR is between 110 and 160 beats per minute and typically changes in response to contractions. The heart rate may slow down as a contraction begins. Periodic increases in the heart rate also are normal. These changes form a pattern. Some patterns may suggest that the fetus is not getting enough oxygen.

Intermittent fetal scalp sampling is another way to evaluate fetal status during labor and often is used in conjunction with EFM.[68] Fetal scalp sampling helps determine recent fetal oxygenation status by testing the pH of fetal blood during periods of concerning heart rate patterns referred to as nonreassuring FHR patterns. This procedure requires a small blood sample to be taken from the scalp of the fetus. Normal pH documents adequate fetal oxygenation.

Fetal pulse oximetry was first tested in the late 1990's.[72] It is another way to continuously monitor the fetus during labor. It uses far red and near-infrared wavelengths in conjunction with a sensor placed near the fetal cheek to provide a continuous reading of fetal oxygenation during labor.[68] Human and animal studies have shown that in the fetus, which normally has an oxygen saturation in labor of 35 percent to 65 percent, an oxygen deficit does not develop until the saturation falls below 30 percent for at least 10 to 15 minutes.[136-138] Therefore fetal oxygen saturation 30 percent or greater tends to be considered reassuring, whereas values less than 30 percent for at least 10 minutes require further assessment or intervention.[136, 139-142]

Most recently, ST analysis of fetal electrocardiography (STAN) has emerged as an adjunct for fetal surveillance. STAN is another continuous monitoring device used for analyzing changes in the fetal electrocardiogram.[73] The device combines standard EFM technology with the addition of ST waveform analysis to provide a fetal electrocardiogram (ECG). The fetal ECG is obtained via a fetal scalp electrode. The STAN automatically identifies and analyses changes in the T wave and the ST segment of the fetal ECG to give clinicians more detailed information about fetal well-being.

Overview of the Literature

Six studies addressing the use of electronic fetal monitoring to reduce cesarean rates were included.[68-73]. Two RCTs were conducted in the U.S.;[69, 71] three are European studies conducted in Germany, France and Finland;[68, 72-73] and one was conducted in Australia.[70] Three studies compared the use of fetal pulse oximetry with fetal heart monitors to the use of fetal heart monitors either alone or with fetal pulse oximetry that did not display the readings.[69-71] One study compared the use of fetal pulse oximetry in additional to fetal heart monitoring and fetal scalp sampling to fetal heart monitoring and fetal scalp sampling alone.[68] Two studies compared the use of fetal ST-segment analysis of fetal cardiotocography to cardiotocography either alone or with an additional monitoring device.[72-73] Of six studies, one was good quality[71] with five being of fair quality.[68-70, 73]

Key Points:

- Across these categories of fetal assessment strategies there is low strength of evidence for lack of benefit, from six studies including more than 9,700 women (Table 34).
- Knowledge of intrapartum fetal oxygen saturation had no significant effect on 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.
- Fetal pulse oximetry did not slow or interfere with labor, nor did it result in an increase in adverse maternal, fetal, or neonatal outcomes.
- Use of ST analysis in conjunction with FHR monitoring did not reduce total cesareans or cesareans for nonreassuring fetal heart tracing when compared to routine FHR monitoring alone.

Detailed Synthesis

Fetal Pulse Oximetry

Three studies[68-70] evaluated whether the addition of fetal pulse oximetry to FHR monitoring, fetal scalp sampling or both, would improve fetal assessment and reduce operative birth rates without increasing adverse outcomes for the women, the fetus or the newborn. These trials enrolled women who were at least 36 weeks gestation, with a singleton fetus in vertex presentation, in labor, with ruptured membranes (or if not ruptured consented for artificial rupture), and nonreassuring FHR. The effectiveness of these strategies is presented in Table 19.

Table 19. Summary of effectiveness of cesarean reduction strategies: fetal pulse oximetry

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Kuhnert et al., 2004 [68] Germany; Fair	Fetal monitoring with CTG and fetal scalp blood sampling (73)	37.0	20.6 lower
	Fetal monitoring with CTG and fetal pulse oximetry and fetal scalp blood sampling (73)	16.4	
East et al., 2006[70] Australia; Fair	Fetal monitoring with CTG (295)	48.1	2.2 same
	Fetal monitoring without CTG and fetal pulse oximetry (306)	45.9	
Bloom et al., 2006[71] US; Good	Fetal pulse oximetry with oxygen saturation not displayed to clinician (2712)	27.5	1.2 same
	Fetal pulse oximetry with oxygen saturation displayed to clinician (2629)	26.3	
Garite et al., 2000[69] US; Fair	Fetal monitoring with CTG (502)	26.0	-3.0 same
	Fetal monitoring with CTG and fetal pulse oximetry (508)	29.0	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.
CTG, cardiotocography

The first study was a U.S. multicenter trial at nine centers.[69] Patients gave consent for possible study inclusion but were only randomized once one of the pre-determined concerning FHR patterns developed while in labor. Included women also needed to be at least two centimeters dilated and at minus two station or lower in the pelvis. All randomized participants (n = 1010) underwent FHR monitoring with either Doppler or scalp electrode, or both. For

patients in the intervention group a fetal oxygen sensor was placed against the fetal check and connected to a monitor. For women in the control group, only an electronic FHR monitoring was used. For both groups the FHR was defined as reassuring, nonreassuring, or ominous. An ominous FHR pattern, defined as FHR persistently less than 70 beats per minute for at least seven minutes, required immediate birth in either group. The difference in management between the two groups occurred among the patients with nonreassuring FHR patterns. In the intervention group a fetus with a nonreassuring FHR tracing was considered to be normally oxygenated if the fetal oxygen saturation was greater than 30 percent at any time between two contractions. However, if the fetal oxygen saturation remained less than 30 percent for the entire interval between two contractions, the clinician reverted back to the FHR and used the same criteria as that used for the standard control group as follows. If the FHR was persistently nonreassuring the clinician could rule out acidosis by examining spontaneous or induced FHR accelerations or scalp pH to rule out fetal acidosis. If reassurance could not be established, cesarean or operative vaginal birth was undertaken.

Despite randomization, the intervention arm included more women with induced labors and use of prostaglandins for cervical ripening. There was a 50 percent relative reduction, in the number of cesareans performed for nonreassuring fetal status (intervention group 4.5 percent versus 10.2 percent for controls) with no significant difference in overall cesarean use between the two groups (29 percent in the intervention group and 26 percent in the control group). An independent reviewer evaluated all electronic FHR tracings. The reviewer identified three cesarean births in each group done for nonreassuring fetal status in which there were protocol violations. There were no differences between the two groups in adverse maternal (including placental abruption, postpartum hemorrhage, wound infection, intrapartum fever, and endometritis). Neonatal outcomes were similar with five neonatal deaths, three in the intervention group and two in the control group. Four of the five deaths were caused by complex congenital heart anomalies. The fifth occurred in an infant from the intervention group whose five-minute Apgar score and umbilical cord pH were normal, yet postnatally developed bilateral tension pneumothoraces (Table 21).

In a German trial, [68] 146 patients were recruited with nonreassuring FHR patterns (defined by International Federation of Gynaecology and Obstetrics [FIGO] score less than 8).[143] Women in this study also needed to be at least two centimeters dilated and at minus two station or lower in the pelvis. They were randomized to two groups: 1) triple fetal surveillance with a FHR monitoring, fetal scalp sampling, and fetal pulse oximetry (n = 73) or 2) control group in which women received only FHR monitoring and fetal scalp sampling (n = 73). After randomization, management of labor was as follows: In the intervention group if cardiotocography (CTG) was nonreassuring, fetal blood sample (FBS) pH was greater than 7.25, and fetal pulse oximetry was greater than 30 percent, they continued CTG and fetal pulse oximetry and attempted vaginal birth. If the CTG was nonreassuring and the fetal blood sample pH was greater than 7.25, but the fetal pulse oximetry was less than 30 percent, they still continued CTG and fetal pulse oximetry; however, a followup fetal scalp sampling was performed. If that repeat scalp sampling pH was less than or equal to 7.25, clinical intervention was necessary (either tocolysis for intrauterine resuscitation, cesarean, or assisted vaginal birth). In the control group if CTG was non-reassuring and fetal scalp blood sample pH was greater than 7.25, they continued CTG and attempted vaginal birth. If the fetal blood sample pH was less than or equal to 7.25 clinical intervention was necessary. In either group if CTG was ever found to be pathologic, patients were delivered immediately.

There was no difference between the two groups in incidence of nonreassuring FHR patterns in the first and second stages of labor. The first scalp pH sampling for baseline assessment in the two groups was also similar. The proportion of cesareans was significantly lower in the intervention group than in the control group (16.4 percent versus 37 percent, respectively), and the proportion of operative vaginal births for nonreassuring fetal status was also significantly lower in the intervention versus control group (17.8 percent versus 30.1 percent) demonstrating almost a 50 percent reduction in the risk of operative births for nonreassuring fetal status. There were no adverse maternal or neonatal events in either group (Tables 20 and 21).

The third trial, called the FOREMOST trial, was conducted in four Australian academic hospitals.[70]. Six-hundred and one women with nonreassuring fetal monitoring were randomly assigned to a group with fetal pulse oximetry with CTG or a control group monitored using conventional CTG alone. Monitoring continued from time sensor was placed until as close to birth as possible. In either group, if the CTG became reassuring, labor was continued unless otherwise indicated. In both groups, ominous FHR patterns prompted birth. In the control group, a nonreassuring CTG prompted evaluation and management of the FHR pattern. In the intervention group, if oxygen saturation levels were less than 30 percent for 10 minutes or not recording, evaluation and management of FHR pattern was recommended. Evaluation and management could include maternal position change, supplemental oxygen, hydration, correction of hypotension, discontinuation of oxytocin infusion, or birth. Fetal blood scalp sampling was available to all without restriction and the study did not regulate management based on fetal scalp pH or lactate values.

The primary outcome measured was operative birth (cesarean, forceps, vacuum) for nonreassuring fetal status. This study reported a significant reduction in operative births for nonreassuring fetal status in the intervention group compared to those in the control group (24.9 percent versus 32.2 percent; RR=0.77, 95 percent CI: 0.599, 0.999; p=0.048). Cesareans for nonreassuring fetal status, represented 13.8 percent of intervention group and 20 percent of control group births (RR=0.69, 95 percent CI: 0.48, 0.99; p=0.042). However, the overall rate of operative births between the two groups did not differ (intervention group 73 percent versus control group 71 percent [RR=0.77, 95 percent CI: 0.599, 0.999; p=0.48]). Women in the intervention group were more likely to have an operative birth secondary to dystocia than those in the control group. This difference in indication was significant for assisted vaginal birth, not for cesareans. Fetal scalp blood sampling was performed more often in the control group. There were four cases of endometritis in the intervention group and one in the control group (p=0.192). Postpartum maternal fever was similar between the groups (p=0.792) (Table 20). There was also no difference in neonatal outcomes (Apgar score, cord pH/fetal acidosis, NICU admission), nor serious adverse events (Table 21).

The fourth study was conducted by the National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network.[71] This RCT enrolled women at 14 academic centers to test whether fetal oximetry in addition to conventional EFM would reduce the overall use of cesarean. The study was launched after a rigorous training phase with the oximetry equipment. During the study, all women recruited underwent placement of fetal pulse oximeter after placement of a standard internal electronic FHR monitor and intrauterine pressure catheter. If the oximeter was not placed within three attempts, it was considered unsuccessful or if a signal registration was not accomplished by 15 minutes the attempt was also considered unsuccessful, and the patient was not randomization. One hundred seventy women had failed attempts at sensor placement and 42 other attempts were abandoned secondary to prolonged

FHR decelerations during placement. Ultimately, 5341 women were randomly assigned to open fetal oximetry in addition to conventional electronic fetal monitoring or to masked fetal oximetry with conventional electronic fetal monitoring.

Nonreassuring FHR patterns were defined according to the criteria used by Garite.[69] Intrapartum management in both groups was otherwise left to the discretion of the attending physician. Fetal pulse oximeter sensors were removed before study completion in 238 women in the intervention group and 267 women in the masked group (reasons: patient request, n=244; physician request, n = 196; technical problems, n = 65). Discomfort accounted for 92 percent of patient requests for sensor removal and interference with cervical examination or management of labor for 67 percent of physician requests.

Cesarean births did not differ between the oximetry and masked groups (26.3 and 27.5 percent, p=0.31). Cesarean births for nonreassuring FHR (7.1 and 7.9 percent, p=0.30) and dystocia (18.6 and 19.2 percent, p=0.76) were also similar. Results were similar in the subgroup (n = 2168) of women in whom a nonreassuring FHR was detected prior to randomization as well as those with normal baseline FHR. Maternal and neonatal outcomes did not differ significantly between groups (Tables 20 and 21). One neonatal death occurred due to sepsis in the masked group.

Table 20. Maternal outcomes for fetal assessment strategies to reduce cesarean births

Strategy	Fever, % (n studies)	Infection, % (n studies)	Hemorrhage, % (n studies)	Mortality, % (n studies)
Control	8.0-29.8[69-70] (2)	10.7[71a]	3.2[69]	NR
Fetal monitoring with CTG, fetal pulse oximetry and fetal blood sampling[68]	NR	NR	NR	NR
Fetal monitoring with CTG and fetal pulse oximetry[69-70]	9.0-30.8[69-70]	NR	3.0[69]	NR
Fetal pulse oximetry with oxygen saturation displayed to clinician[71]	NR	10.7[a]	NR	NR
Fetal monitoring with CTG and STAN[72]	NR	NR	NR	NR
Fetal monitoring with STAN[73]	NR	NR	NR	NR

CTG, cardiotocography; STAN, ST analysis
[a] Reported chorioamnionitis

Table 21. Neonatal outcomes for fetal assessment strategies to reduce cesarean births

Strategy	Apgar score <7 at 5-min, % (n studies)	NICU admission, % (n studies)	NICU days, mean ± SD (n studies)	Mortality, % (n studies)
Control	0.1-3.8[69-73a] (5)	1.5-14.7[69-73] (5)	NR	0-0.4[69, 71-73] (4)
Fetal monitoring with CTG, fetal pulse oximetry and fetal blood sampling[68]	NR	NR	NR	NR
Fetal monitoring with CTG and fetal pulse oximetry[69-70]	1.6 (2)	3.0-18.1 (2)	NR	0.6[69]
Fetal pulse oximetry with oxygen saturation displayed to clinician[71]	0.2[a]	4.8	NR	0
Fetal monitoring with CTG and STAN[72]	1.5	1.3	NR	0
Fetal monitoring with STAN[73]	1.3	3.6	NR	0

NICU, neonatal intensive care unit; CTG, cardiotocography; STAN, ST analysis
[a] Percent with Apgar < 4 at 5 min

Fetal ST-Segment Analysis Studies

Two RCTs assessed ST-segment analysis (STAN) to provide additional information.[72-73] The effectiveness of these strategies is presented in Table 22 below.

Table 22. Summary of effectiveness of fetal assessment cesarean reduction strategies: fetal STAN

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Vayssiere et al., 2007[72] France; Fair	Fetal monitoring with CTG (400)	16.3	2.8 same
	Fetal monitoring with CTG and STAN (399)	13.5	
Ojala et al., 2006[73] Finland; Fair	Fetal monitoring with CTG (739)	4.7	-1.7 same
	Fetal monitoring with STAN (733)	6.4	
	Fetal monitoring with STAN (733)	6.4	

[a] **Same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.
CTG, cardiotocography; STAN, ST analysis

A study at an academic institution in Finland examined whether intrapartum monitoring with STAN could reduce the rate of neonatal acidemia and operative intervention during labor. [73] A total of 1483 were randomly assigned to the intervention group and were monitored by STAN through a scalp electrode, and in the control group women were monitored by a conventional FHR monitor either via an internal intrauterine scalp electrode or an external ultrasound signal sensor. Fetal blood sampling was optional in both groups, based on clinician's judgment. If scalp pH was less than 7.20, immediate birth was recommended. Primary outcome measures were neonatal acidemia (defined as umbilical artery pH less than 7.10), operative interventions (cesarean and vacuum birth), and need for fetal blood sampling.

An umbilical artery blood gas was available for 714 neonates in the intervention group and 722 in the control group. There were 83 cases of inadequate monitoring, five in the control group (secondary to technical difficulties) and 78 in the intervention group. Failure in the intervention group was attributed to: monitoring stopped more than 20 minutes before birth (n = 25), poor signal quality (n = 21), technical difficulties with scalp electrode (n = 19), total recording time less than 20 minutes (n = 7) and one case of unsuccessful recording. In the control group, 83 percent used an internal scalp electrode for monitoring, and 17 percent used an external ultrasound sensor. Overall cesarean rate did not differ between the two groups (6.4 percent intervention versus 4.7 percent control, p=0.24). Fetal blood sampling was used less in the intervention group compared to the control group (7 percent versus 15.6 percent, p<0.001). When evaluating fetal pH using values less than 7.10 as a criterion of neonatal acidemia, there were no differences between the groups. There were no maternal complications related to the STAN, electronic fetal monitor or fetal blood sampling (Table 20). Neonatal outcomes did not differ between groups with no difference in neonatal acidemia, Apgar scores, need for intubation, or admission to the NICU (Table 21). There were no neonatal deaths.

In the second study,[72] a multicenter trial in France, the authors sought to assess whether STAN reduced operative births for nonreassuring fetal status or reduced need for at least one scalp pH during labor. The study population included participants who either had an abnormal FHR pattern (by FIGO classification) or thick meconium stained amniotic fluid during labor. After rupture of membranes, 799 women were randomized to intervention with both STAN and an electronic fetal monitor for CTG to monitor fetal status in labor or to the control group with only an electronic fetal monitor for CTG to monitor fetal status. In the STAN group, fetuses were monitored continuously through a scalp electrode and recommendations were based on STAN

guidelines. Scalp pH testing was optional in both groups. If scalp blood pH was less than 7.20, immediate birth was recommended. As soon as possible after birth, umbilical cord artery and vein gases were obtained and analyzed.

The proportion of operative births for nonreassuring fetal status did not differ between the two groups (33.6 percent for the study group versus 37 percent for the control group [RR=0.91, 95 percent CI: 0.75, 1.10]). Use of operative interventions for dystocia also did not differ between groups. The percentage of women whose fetus had at least one blood scalp pH measurement during labor was substantially lower in the intervention group (27 percent compared to 62 percent in the control group [RR=0.44, 95 percent CI: 0.36, 0.52]). Neonatal outcomes did not differ between groups (acidosis, Apgar score, and NICU admission), with one fetal death in the CTG only group (Table 21).

Amnioinfusion

Amnioinfusion (AI) refers to instilling fluid (lactated ringers solution or normal saline) into the amniotic cavity. This procedure is typically performed during labor through a catheter introduced transcervically after rupture of fetal membranes. A nasogastric feeding tube can also used if an intrauterine pressure catheter is not available.[80]

Severe reduction of amniotic fluid (oligohydramnios) can increase the risk of a number of pregnancy complications, including FHR deceleration, cord compression during labor, fetal hypoxia and acidosis. Variable decelerations are the most common type of FHR decelerations, seen in 50 to 80 percent of labors.[75] Recurrent variable decelerations have been shown to be due to cord compression in labor in women with oligohydramnios.[144] Oligohydramnios can be present before rupture of membranes or more commonly occurs in labor after rupture of membranes. Variable decelerations in general are harmless; however, when severe or if they remain persistent, they may be associated with fetal compromise as a result of hypoxia and acidemia.[145] As a result severe variable decelerations when recurrent are often non-reassuring and can lead to increased risk of instrumented and cesarean births. Amnioinfusion has been shown to be a simple, inexpensive, effective, and safe method for the relief of significant heart rate abnormalities during prolonged labor with oligohydramnios and/or in the presence of meconium stained amniotic fluid and has been associated with decreased use of cesarean but debate continues.[80, 146]

Overview of the Literature

We identified eight RCTs addressing use of amnioinfusion to reduce cesarean birth rates.[74-81] Three were conducted in India,[74-76] two were conducted in South Africa,[77-78] one in Zimbabwe,[78] one in Egypt,[80] and one in the United States.[81] Four were found to be of fair quality[76, 78, 80]{Strong, 1990 #5931} with the remaining four being of poor quality.{, #336;, #407;, #3390;, #3369}

All eight studies compared the use of transcervical amnioinfusion to the use of standard obstetric care without amnioinfusion. Five studies evaluated amnioinfusion in the context of moderate to heavy meconium stained amniotic fluid,[74, 76-79] two studies evaluated use of amnioinfusion in the context of nonreassuring FHR tracings,[75, 80] and one evaluated use of prophylactic amnioinfusion in the context of oligohydramnios.[81]

Although all studies used either warmed or room temperature normal saline, the amnioinfusion protocols varied. In five studies[74-76, 78, 80] 500 ml of normal saline was initially infused over 30 minutes, followed by slow infusions up to either 1 liter total volume[76, 78, 80] or

until birth.[74-75] Three studies infused normal saline at 15 ml per minute either to a volume of 1 liter,[77] 800 ml followed by a slower infusion until birth,[79] or 250 ml to attain an amniotic fluid index greater than or equal to 8 centimeters.[81]

Key Points:

- Studies of amnioinfusion did not find consistent overall decrease in use of cesarean. The strength of evidence is insufficient to support use to prevent cesarean (Table 34).
- Amnioinfusion did not consistently lead to a reduction in overall cesarean rates. When performed for concerning fetal heart tracings, four of eight studies reported a significant reduction in cesareans performed for fetal distress.[74-76, 80]
- Amnioinfusion for moderate or heavy meconium when performed in under-resourced hospital settings where electronic monitoring was limited or absent, improved neonatal outcomes.
- Prophylactic amnioinfusion for oligohydramnios did not reduce use of cesarean.

Detailed Synthesis

Five RCTs[74, 76-79] evaluated the effect of transcervical amnioinfusion during labor complicated by the presence of moderate or heavy meconium. The effectiveness of these strategies is presented in Table 23.

Table 23. Summary of effectiveness of cesarean reduction strategies: amnioinfusion for meconium

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Choudhary et al., 2010[74] India; Poor	Standard obstetric care without amnioinfusion (146)	63.7	34.2 lower
	Transcervical amnioinfusion (146)	29.5	
Rathor et al., 2002[76] India; Fair	Standard obstetric care without amnioinfusion (100)	36.0	15.0 lower
	Transcervical amnioinfusion (100)	21.0	
Moodley et al., 1998[77] South Africa; Poor	Standard obstetric care without amnioinfusion (30)	47.0	7.0 same
	Transcervical amnioinfusion (30)	40.0	
Mahomed et al., 1998[78] Zimbabwe; Fair	Standard obstetric care w/o amnioinfusion (336)	11.3[b]	1.8 same
	Transcervical amnioinfusion (325)	9.5	
Hofmeyr et al.,1998[79] South Africa; Poor	Standard obstetric care without amnioinfusion (176)	43.0	1.0 same
	Transcervical amnioinfusion (176)	42.0	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.
[b] Reported as 12.3 in text, but should be 11.3 based on data presented in paper.

The first two[74, 76] were conducted in teaching hospitals in India with women at term who had moderate or thick meconium during labor. In both of these studies in under-resourced areas labors were not monitored continuously by electronic fetal monitors, but instead intermittently (approximately every 15 minutes) via auscultation for FHR, and contractions were assessed every 30 minutes by palpation, evaluating the uterine tone, intensity, frequency, and duration of contractions. Choudhary et al.[74] enrolled 292 participants who were randomly assigned to the intervention group who received transcervical amnioinfusion or the control group who received

standard labor management. Cesareans were performed if there were FHR abnormalities defined as bradycardia or severe irregularity for 10 to 20 minutes, or if there was a slow progression of labor.

This study reported a significant reduction in the incidence of cesarean birth rates in the amnioinfusion group compared to the control group (29.5 percent versus 63.7 percent cesarean births) with a significantly higher rate of normal vaginal birth in the intervention group compared to the control group (70.5 percent versus 31.5 percent). Maternal fever was lower in the intervention group than in the control group, but the difference was not significant (p=0.238) (Table 24). Amnioinfusion during labor was not associated with any significant maternal complications.

Table 24. Maternal outcomes for amnioinfusion strategies to reduce cesarean births

Strategy	Fever, % (n studies)	Infection, % (n studies)	Hemorrhage, % (n studies)	Mortality, % (n studies)
Control	0-12[74-76, 78-81] (7)	0[75]	NR	NR
Transcervical amnioinfusion[74-81]	0.9-20[74-76, 78-81] (7)	0[75]	NR	NR

Table 25. Neonatal outcomes for amnioinfusion to reduce cesarean births

Strategy	Apgar score <7 at 5-min, % (n studies)	NICU admission, % (n studies)	NICU days, mean ± SD (n studies)	Mortality, % (n studies)
Control	0-13.2[74-76, 78-81] (7)[a]	2.5-22.9[76, 78-80] (4)	3.0%[78b]	0-11[74, 76-80] (6)
Transcervical amnioinfusion[74-81]	0-4.1 [74-76, 78-81] (7)[a]	1.8-12.8[76, 78-80] (4)	1.6%[78b]	0-2[74, 76-80] (6)

NICU, neonatal intensive care unit
[a] Reported mean Apgar at 5 minutes ± SD--Intervention: 9.57 ± 0.67; Control: 9.33 ± 1.03[77]
[b] Reported percent in NICU more than 4 days

Amnioinfusion was associated with improved neonatal outcomes as evidenced by the incidence of respiratory distress in the newborn infants which was greatly reduced by amnioinfusion in the study versus control group (2.7 percent versus 23.3 percent, p=0.000). Meconium aspiration syndrome was also markedly reduced by amnioinfusion with 0.68 percent incidence in the intervention group compared to 15.8 percent in the control group (p=0.000). Neonatal mortality was much higher at 10.9 percent in the control group compared to 1.4 percent in the intervention group (p=0.010). Amnioinfusion improved the Apgar score at both one and five minutes in newborns in the study group versus the control group (10.3 percent versus 30.8 percent and 0.7 percent versus 8.2 percent, p=0.000 respectively). Amnioinfusion was not associated with increasing any significant neonatal complications (Table 25).

In the second study, Rathor and colleagues[76] enrolled 200 women in labor, who were randomized to either an amnioinfusion or control group. The authors reported cesarean was significantly less frequent in the amnioinfusion group compared to the control group (21 percent versus 36 percent) with cesarean for fetal distress also reduced to 12 percent in the amnioinfusion group compared to 26 percent in the control group. Five percent of infants were born by forceps in the amnioinfusion group versus 14 percent in the control group. The incidence of maternal fever was lower in the amnioinfusion group compared to the control group, but the

difference was not significant (Table 24). Seven neonatal deaths occurred: two (2 percent) in the amnioinfusion group and five (5 percent) in the control group. Amnioinfusion was associated with a significant improvement in the one-minute Apgar score and fewer admissions to the NICU compared to the control group (Table 25).

The last two RCTs[79] were from different sites of the same trial, the Collaborative Randomized Amnioinfusion for Meconium Project (CRAMP) in South Africa and Zimbabwe. The sample size calculation for the multicenter study was based on an expected incidence of meconium aspiration of 10 percent of the control group. After initiation of the study it became clear that the South African centers had lower incidence of MAS than that used to estimate sample size versus those in Zimbabwe. Therefore the two sites, South Africa (CRAMP 1) and Zimbabwe (CRAMP 2) reported findings separately.[78-79]

The South African site (CRAMP 1)[79] evaluated 176 women randomized to the amnioinfusion group and a control group of 176 who received standard obstetric care. All women allocated to receive amnioinfusion did. One woman in the control group also received an amnioinfusion but was retained in the control group for intention-to-treat analysis. The care differed in this portion of the study (compared to Zimbabwe) in that electronic fetal monitoring and intrauterine pressure monitoring were available and used in most cases. Cesarean risk was similar with 42 percent in the amnioinfusion group and 43 percent in the control group having cesarean births (RR=0.98, 95 percent CI: 0.76, 1.26). There was no significant difference in assisted vaginal births (RR=0.72, 95 percent CI: 0.31, 1.67), nor was there significant difference in the incidence of maternal fever (RR=1.23, 95 percent CI: 0.65, 2.33). The study did not report maternal deaths. Overall incidence of meconium aspiration syndrome was much lower than expected, with no significant difference between the two groups (0.02 percent in the amnioinfusion group versus 0.03 percent in the control [RR=0.67, 95 percent CI: 0.19, 2.33]). There were no perinatal deaths and no significant differences in five-minute Apgar scores less than 7 (RR=1.49, 95 percent CI: 0.43, 5.18) or NICU admissions (RR=0.75, 95 percent CI: 0.17, 3.28) (Table 25).

Of 661 women enrolled in the Zimbabwe study (CRAMP 2), 325 were randomly assigned to amnioinfusion and 336 were assigned to standard obstetric care.[78] No electronic FHR monitors were used in this study, instead patients were auscultated and occasionally a handheld ultrasound detector was used to assess FHR. In this setting the midwives were aware of the need for suctioning of the airway of infants born with meconium but were usually unable to do so because of lack of equipment. Also, the pediatrician was never present at the birth, only being called after birth when there was a problem. The primary outcomes were cesarean, meconium aspiration syndrome, and perinatal death. Use of cesarean did not differ between groups (9.5 percent in the intervention group compared to 12.3 percent in the controls [RR=0.84, 95 percent CI: 0.53, 1.32]). Nor were there significant differences in the rate of cesarean births secondary to fetal distress (RR=0.61, 95 percent CI: 0.24, 1.52). MAS was significantly less frequent in the amnioinfusion group (3.1 percent versus 12.8 percent in the control [RR=0.24, 95 percent CI: 0.12, 0.48]). Perinatal morbidity was reduced in the amnioinfusion group in regards to the need for neonatal ventilation (RR=0.31, 95 percent CI: 0.15, 0.61). There were four neonatal deaths in the amnioinfusion group (1.2 percent) and twelve in the control group (3.6 percent), which was not significant (RR=0.34, 95 percent CI: 0.11, 1.06). There were significant reductions in five-minute Apgar scores less than seven (RR=0.35, 95 percent CI: 0.17, 0.73) as well as NICU admissions (RR=0.56, 95 percent CI: 0.39, 0.79). No complications of amnioinfusion were detected (Table 25).

In the fifth study, a separate study from South Africa, 60 patients were randomized into two groups, either the amnioinfusion or standard obstetric care.[77] Only those in the active phase of labor, with meconium stained amniotic fluid, and a normal electronic fetal monitor recording were allowed to participate. Sixty-five percent of the participants were primigravidas. A total of 12 patients (40 percent) in the amnioinfusion group gave birth by cesarean, compared to 14 (47 percent) in the control group. Of these, three (10 percent) in the study group and seven patients (23 percent) in the control group had cesareans for fetal distress; the remainder in both groups had a cesarean for dystocia. These differences were not statistically significant. There were no maternal complications related to the amnioinfusion. Fewer infants in the study group developed HIE (zero versus two controls) or MAS (one versus four controls), neither statistically significant. There were no neonatal deaths (Table 25).

Two additional RCTs[75, 80] conducted in academic hospitals evaluated the use of amnioinfusion in cases of intrapartum fetal distress as noted by moderate or severely abnormal FHR patterns, to reduce need for cesarean (Table 26).

Table 26. Summary of effectiveness of cesarean reduction strategies: amnioinfusion for fetal distress

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Abdel-Aleem et al., 2005[80] Egypt; Fair	Standard obstetric care without amnioinfusion (219)	68.0	20.1 lower
	Transcervical amnioinfusion (219)	47.9	
Regi et al., 2009[75] India; Poor	Standard obstetric care without amnioinfusion (75)	37.3	-1.1 same
	Transcervical amnioinfusion (75)	38.4	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

In a study in Egypt at a university hospital,[80] women with nonreassuring or ominous FHR tracings were approached for enrollment as long as immediate birth was not contemplated. Four hundred thirty-eight were randomized. The intervention group received amnioinfusion in addition to conventional treatment, and the control group received standard obstetrical care without amnioinfusion. If the FHR pattern did not become reassuring after the first 200 ml of amnioinfusion, a cesarean was performed. However, if the FHR pattern corrected, the infusion was completed and the FHR monitoring continued until birth of infant. Women in the amnioinfusion group also received 1 g of amoxicillin IV for infection prophylaxis prior to the procedure. Amnioinfusion was completed in all but five women. These women were included in the amnioinfusion group for the intent-to-treat analysis.

The amnioinfusion group had a significant reduction in use of cesarean for fetal distress compared to the control group (47.9 percent versus 68 percent, respectively, RR=0.7, 95 percent CI: 0.60, 0.83). This study also reported a reduction in nonreassuring and ominous FHR patterns in the amnioinfusion group compared to the control group (47.9 percent versus 68 percent, respectively, RR=0.7, 95 percent CI: 0.60, 0.83). Incidence of uterine hypertonicity and maternal pyrexia did not differ by group. Significantly fewer newborns had Apgar scores less than seven at one (RR=0.38, 95 percent CI: 0.26, 0.55) and five (RR=0.31, 95 percent CI: 0.15, 0.64) minutes in the amnioinfusion group compared to the control group (Table 25). Also, 14 newborns in the amnioinfusion group were admitted to the NICU, compared to 31 newborns in the control group (RR=0.45, 95 percent CI: 0.25, 0.83). All newborns in the amnioinfusion group

were discharged alive without complication, whereas three newborns in the control group had meconium aspiration syndrome and one died (Table 25).

An Indian study enrolled 150 women in active labor with repetitive moderate or severe decelerations.[75] Women were randomized to amnioinfusion or standard obstetrical care with no amnioinfusion. Cesarean or operative vaginal birth was performed if there was evidence of nonreassuring fetal status. Two women from the amnioinfusion group were excluded, one because the catheter could not be placed, and the other woman gave birth before the amnioinfusion could be started. Most participants (70.9 percent) were nulliparous. Cesarean risk did not differ between the intervention and control groups (38 percent versus 37.3 percent respectively). Cesareans for fetal distress were less common in the amnioinfusion group (20 percent) compared to the control group (32 percent, p=0.009). Variable decelerations fully resolved in 79.5 percent of the amnioinfusion group (p=0.001). There were two cases of maternal fever in the amnioinfusion group; however, this was not significant (Table 24). No other adverse maternal outcomes were reported. Birth asphyxia, Apgar scores at one or five minutes, and NICU admission did not differ between the two groups (Table 25).

In the final study by Strong and colleagues, prophylactic amnioinfusion was performed in the setting of oligohydramnios (amniotic fluid index less than or equal to five) to assess impact on cesarean.[81] Women were randomized into two groups: prophylactic amnioinfusion (n = 30) and a control group (n = 30) who received standard obstetric care without amnioinfusion. Overall risk of cesarean was lower in the amnioinfusion group at 13.3 percent compared to 20 percent in the control group, but not significantly. Cesareans performed for fetal distress were similar. There was no difference in rate of forceps births between groups. Maternal fever occurred in 20 percent of the amnioinfusion group compared to seven percent of the control group, but was not statistically significant (Table 24). There were no differences in Apgar scores at one or five minutes between the two groups (Table 25).

Unique Strategies

Overview of the Literature

We identified seven RCTs that explored the effects of various other unique interventions on the incidence of cesarean birth, including two studies examining traditional Chinese medicine acupuncture,[82-83] two assessing devices,[84-85] one assessing the effect of propranolol administration every four hours during labor,[86] and two on the role of activities such as walking[87] or eating[88] during labor. Four of these studies were conducted in the United States,[82-83, 85, 87] two in the United Kingdom,[84, 88] and one in Puerto Rico.[86] Five studies were completed in academic health sciences centers[82-83, 85-87] and two were conducted in the nonacademic hospital setting.[84, 88] All studies employed a usual care comparison group; one study[83] also included a sham procedure comparison. Two were good quality,[84, 88] two were fair quality,[82-83] and the remaining three were poor quality.[85-87]

Key Points

- As single studies of unique strategies this literature provides insufficient evidence to guide care (Table 34).
- Large single studies of walking, eating, or using an inflatable obstetric belt during labor showed no effect on the incidence of cesarean birth as compared with usual care.

- Small studies of other interventions such as acupuncture, a molded dental device, or propranolol showed no effect of intervention on rates of cesarean birth when compared with standard care approaches.

Detailed Synthesis

We identified seven studies evaluating the effect of unique interventions strategies to reduce cesarean births.[82-88] The effectiveness of these strategies is presented in Table 27 below.

Table 27. Summary of effectiveness of cesarean reduction strategies: unique strategies

Author, Year Country; Quality	Intervention (n)	Cesarean birth, %	Change in cesarean, %[a]
Harper et al., 2006[82] US; Fair	Usual care (26)	39.0	22.0 same
	Acupuncture sessions (30)	17.0	
Matsuo et al., 2009[85] US; Poor	Usual care (32)	25.0	12.5 same
	Dental support device during active pushing (32)	12.5	
Adamsons et al., 1999[86] Puerto Rico; Poor	Usual care (23)	17.4	5.7 same
	Propranolol during labor (34)	11.7	
Bloom et al., 1998[87] US; Poor	Usual care (531)	6.0	2.0 same
	Walking during 1st stage of labor (536)	4.0	
O'Sullivan et al., 2009[88] UK; Good	Usual care (1216)	30.0	0 same
	Allowed to eat during labor (1227)	30.0	
Cox et al., 1999[84] UK; Good	Usual care (240)	3.8	-2.0 same
	Inflatable obstetric belt (260)	5.8	
Asher et al., 2009[83] US; Fair	Acupuncture (30)	20.0	-10.0
	Usual care (no acupuncture) (30)	10.0	3.0
	Sham acupuncture (29)	7.0	same

[a] **Same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.

Acupuncture

Two RCTs from the same institution evaluated the use of traditional Chinese medicine acupuncture to initiate labor, with secondary objectives including reducing the rate of cesarean.[82-83] In the first trial,[82] 30 women were randomized to receive acupuncture on three of four consecutive days for initiation of labor, with 26 women randomized to usual care. The incidence of cesarean was 17 percent in the intervention group and 39 percent among control patients (p=0.07). In the second trial,[83] participants were randomized to up to five acupuncture treatments over two weeks (n = 20), sham acupuncture (n = 29), or usual care (n = 30). The cesarean rate was 20 percent in the acupuncture group as compared with 57 percent in the usual care group; however, the sham treatment had the lowest incidence of cesarean, at 7 percent (p=0.37 for comparison across the three groups). Both studies found similar maternal and neonatal outcomes for intervention as compared with control participants (Tables 28 and 29).

Devices

Two trials evaluated the utility of devices for reducing use of cesarean. The larger of these studies[84] randomized women to use of an inflatable obstetric belt to provide fundal pressure during contractions (n = 260) or to usual care (n = 240), finding a similar incidence of cesarean

between the groups (5.8 and 3.8 percent respectively, p=0.29). There were fewer malpositions at birth in the belt group as compared with usual care (15 percent versus 20.8 percent) but these were not statistically distinct differences. Other neonatal and maternal outcomes were similar between the two groups (Tables 28 and 29).

Matsuo and colleagues assessed whether the use of a molded dental device during active pushing (n = 32) had an effect on cesarean as compared with usual care (n=32).[85] The device was designed to optimize dental occlusion, based on evidence indicating this may improve isometric muscle strength.[147]The observed incidence of cesarean was 12.5 percent in the intervention group as compared with 25.0 percent in patients treated per usual care (no test of statistical significance reported).

Table 28. Maternal outcomes for unique strategies to reduce cesarean births

Strategy	Fever, % (n studies)	Infection, % (n studies)	Hemorrhage, % (n studies)	Mortality, % (n studies)
Control	NR	7-8[83, 87] (2)	0-3.3[83-84, 86] (3)	0.08[88]
Acupuncture[82-83]	NR	23[83]	10[83]	NR
Sham acupuncture[83]	NR	21	7	NR
Propranolol[86]	NR	NR	0	NR
Inflatable obstetrical belt[84]	NR	NR	1.2	NR
Dental support device during pushing[85]	NR	NR	NR	NR
Walking during first stage labor[87]	NR	8	NR	NR
Allowed to eat during labor[88]	NR	NR	NR	0

Table 29. Neonatal outcomes for unique strategies to reduce cesarean births

Strategy	Apgar score <7 at 5-min, % (n studies)	NICU admission, % (n studies)	NICU days, mean ± SD (n studies)	Mortality, % (n studies)
Control	0-1.8[87-88] 9.0 ± 0.2[83a] 9.0[88b] (4)	3.3-9.4[83, 85, 88] (3)	NR	0[84, 87] (2)
Acupuncture[82-83]	8.8 ± 0.8[83a]	0[83]		NR
Sham acupuncture[83]	8.9 ± 0.4[a]	0		NR
Propranolol[86]	NR	NR	NR	NR
Inflatable obstetrical belt[84]	NR	NR	NR	0
Dental support device during pushing[85]	9[b]	9.4	NR	NR
Walking during first stage labor[87]	0	NR	NR	0
Allowed to eat during labor[88]	1.3[c]	5.0	NR	NR

NICU, neonatal intensive care unit
[a] Reported mean Apgar at 5 minutes ± SD
[b] Reported median Apgar at 5 minutes
c Reported Apgar ≤ 7 at 5 minutes

Medical Interventions

One small RCT [86] found a modest, insignificant effect of a single intravenous two mg dose of propranolol at admission for beta-adrenergic blockage and prevention of dysfunctional labor (n = 34), with 11 percent of intervention participants having a cesarean compared with 17.6 percent those receiving usual care (p=0.367). Duration of the first stage of labor was similar between the two groups, while second stage duration was significantly longer in the medication group as compared with usual care (median 31 versus 19 minutes, p<0.001). Neonatal and other outcomes were similar between the two groups (Tables 28 and 29).

Activities

Two RCTs assessed whether simple changes in activities during labor may influence risk of cesarean. A large RCT of walking during the first stage of labor (n = 536) found similar use of cesarean as compared with patients who were restricted to bed (n = 531), four percent and six percent respectively (p=0.25).[87] Investigators noted that 22 percent of women randomized to walk did not elect to walk. Duration of labor and other maternal and infant outcomes were similar between the walking and usual care groups (Tables 28 and 29).

Another large RCT assessed the incidence of cesarean among women encouraged to eat a light diet during labor (n = 1227) as compared with those limited to water and ice consumption (n = 1216). This trial also found similar incidence of cesarean in both groups (30 percent in each).[88] In terms of adherence to the intervention, 29 percent of those randomized to the eating group chose not to eat, while 20 percent of those randomized to usual care with restricted intake elected to eat during labor. The overall incidence of vomiting was similar between those randomized to eating as compared with those limited to water consumption; no cases of pulmonary aspiration were observed in either group (Tables 28 and 29).

Systems Level Interventions

Overview of the Literature

We classified research as system-level interventions when an entire administrative unit within a health system was responsible for implementing policies or procedures that were aimed at reducing cesarean birth rates. The level from which interventions were launched ranged from a national health ministry and multi-hospital quality improvement teams, to individual departments' decisions about labor and delivery routines. Interventions included varied scopes of influence from a national media focus on publically released cesarean birth rates for all hospitals in South Korea, to introduction of a new computerized system to analyze progress of labor in a single facility. Common strategies included audit and feedback of hospital and physician data about cesarean trends, and implementation of guidelines or standardized protocols for particular procedures such as management of vaginal breech births.

We identified a total of 31 studies with 33 publications that were designed to investigate the effectiveness of one or more system-level interventions for reducing use of cesarean birth.[41, 89-120] Multiple publications from the same study were instances in which authors extended the length of followup. Because system-level randomized trials are rare, we elected during design of this review that system-level interventions would be the only portion of the systematic review to include studies that are not randomized. Twenty-seven studies compared a baseline period with subsequent trends in cesarean after implementation of the intervention(s) intended to decrease rates of cesarean.[89-92, 95-97, 99-102, 104-106, 108-120] For brevity in tables and text we have called these

pre-post assessments. There was seven unique pre-post studies of good quality,[92, 97, 100-102, 108, 115] and 22 of poor quality.[104-107, 109-114, 116-120]

Four studies provide outcomes from randomized trials. Three of the trials were conducted outside the United States.[93-94, 98] One was done within a consortium of US and Canadian hospitals.[41] Of the pre-post assessment studies, 16 were conducted in the United States,[91, 95-96, 99-100, 102, 104-106, 108-110, 112-113, 116, 118] four in Europe[89-90, 114-115], three in Asia,[92, 111, 119] one in Australia,[120] one in Canada,[101]one in South America,[117] and one spanned multiple continents.[97] There was one trial of fair quality,[98] and three of poor quality.[41, 93-94]

Key Points

- No system-level interventions are supported by clinical trials. The content of interventions examined in observational studies is varied. Overall the evidence is insufficient to determine if systems based interventions reduce cesarean.
- Seventeen of 31 studies reported statistically significant reductions in cesarean with a range of 1.6 to 17.0 percent decreases.
- No randomized trials documented the effectiveness of interventions.
- Twelve observational studies reported achieving a reduction of five percent or more.
- More than16 categories of components have been used in various combinations in these systems interventions. The most common component was audit and feedback of data.
- Ten pre-post studies, documented reductions in cesarean from implementing varied forms of auditing of trends with regular feedback of data to either the organizational unit (hospital, department, labor and delivery staff) or the individual care providers or both.
- The next most common components of successful interventions, with a five percent or greater reduction, were tracking of progress in labor and protocols for active management of labor.
- However it is important to note that these components were also common in systems-level interventions that failed to reduce cesarean use; thus it is not possible to say which components are superior.

Detailed Synthesis

Overview

The outcomes of systems levels interventions are summarized in Table 30 (below). Both randomized trials and pre-post study types are included. The indication that cesarean risk was the "same" in a study is based on small effect size with lack of statistical significance. Indication of higher risk means the risk was statistically higher in the intervention portion of trials or at the end of the intervention period than at baseline.

Table 30. Summary of systems level strategies to reduce cesarean births

Author, Year Country Study Type; Quality	Health Systems Interventions (n)	Cesarean birth, %	Change in cesarean, %[a]
Sanchez-Ramos et al., 1990[110] US Pre-post; Poor	Baseline: (4350)	27.5	17.0 lower
	Intervention: New guidelines for managing women with prior CS; Also guidelines for evaluation and management of dystocia and fetal distress to reduce primary CS (5163)	10.5	
Langrew et al.,1996[116] US Pre-post; Poor	Baseline: (NR)	31.1	15.7 lower
	Intervention: Confidential provider feedback, more aggressive labor techniques (12,118)	15.4	
Berglund et al., 2010[89] Ukraine Pre-post; Poor	Baseline: (1,696)	29.9	14.5 lower
	Intervention: WHO Effective Perinatal Care training & implementation (2,439)	15.4	
Rust et al., 1993[112] US Pre-post; Poor	Baseline: (467)	21.2	11.0 lower
	Intervention: Vaginal birth after CS, external cephalic version, adequate labor documentation and peer review of all CS for fetal distress (430)	10.2	
Socol et al., 1993[100] US Pre-post; Good	Baseline: (4,240)	27.3	10.4 lower
	Intervention: Vaginal birth after CS encouraged, provider data circulated, active management of labor introduced as routine (4,669)	16.9	
Iglesias et al., 1991[101] Canada; Good	Baseline: (237)	23.0	10.0 lower
	Intervention: Vaginal birth after CS encourage, breech protocol introduced; guidelines for dystocia indication implemented (242)	13.0	
Maher et al.,1994[120] Australia Pre-post; Poor	Baseline: (1,112)	20.6	9.6 lower
	Intervention: Vaginal birth after CS encouraged, active management of labor and regular peer review (1,167)	11.0	
Poma, 1998[104] US Pre-post; Poor	Baseline: (2,234)	23.2	7.2 lower
	Intervention: Case review of cesareans using ACOG guidelines with feedback to individual providers (1,783)	16.0	
Calvo et al., 2009[90b] Spain (Menorca) Pre-post; Poor	Baseline: (NR)	29.0	7.0 lower[c]
	Intervention: Multifaceted feedback with rating of appropriateness of all CS (NR)	22.0	
Liang et al., 2004[119] Taiwan Pre-post; Poor	Baseline: (9,864)	36.7	6.5 lower
	Intervention: Peer review included pre CS consultation (required second opinion for all CS) and post CS surveillance. Weekly CS conferences; physicians CS rates presented at conference. Also protocol for selective trial of labor for women with prior CS. (7,937)	30.2	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.
[b] Two entries in table to reflect sites with data that could not be combined and had different outcomes

[c] Statistical evidence not provided

Table 30. Summary of systems level strategies to reduce cesarean births (continued)

Author, Year Country Study Type; Quality	Health Systems Interventions (n)	Cesarean birth, %	Change in cesarean, %[a]
Meyers and Gleicher, 1988, 1993[99, 103] US Pre-post; Poor	Baseline: (1,697)	17.5	5.6 lower
	Intervention: Implementation of 6 key guidelines with data feedback to individual providers (3,218)	11.9	
Boylan et al., 1991[102] US Pre-post; Good	Baseline: (1,843)	24.3	5.5 lower
	Intervention: Active management of labor introduced as routine (2,057)	18.8	
Main et al., 1999[96] US Pre-post; Poor	Baseline: (3,200 to 3,600)	24.0	5.5 lower
	Intervention: Intensive outcomes feedback initially with provider identity coded then public within departments (NR)	18.5	
Sloan et al., 2000[117] Ecuador Pre-post; Poor	Baseline: (14,743)	26.6	4.5 lower
	Intervention: Policy to provide co-management for CS candidates, including required second opinion (7,381)	22.1	
Kim et al., 2005 [92] South Korea Pre-post; Good	Baseline: (161,360)	43.0	3.4 lower
	Intervention: Public media release of hospital cesarean data (NR)	39.6	
Bickell et al., 1996[108] and Dillon et al, 1992[107] US Pre-post; Good; Poor	Baseline: (1,430 mean for 45 hospitals))	29.1	3.3 same[c]
	Intervention: External peer review (1,503 mean for 45 hospitals)	25.8	
Kiwanuka and Moore, 1993[114] UK Pre-post; Poor	Baseline: (1,895)	15.9	3.2 lower
	Intervention: Audit and feedback (2,216)	12.7	
Kazandjian and Lied, 1998[97] US, Canada, UK, Japan Pre-post; Good	Baseline: (NR)	22.5	3.1 lower
	Intervention: Reporting of cesarean rates within a quality improvement program (NR)	19.4	
Robson et al., 1996[115] UK Pre-post; Good	Baseline: (12,628)	12.0	2.5 lower
	Intervention: Medical audit(8,497)	9.5	
Smith et al., 2000[91] US Pre-post; Poor	Baseline: (NR)	27.0	2.5 lower[c]
	Intervention: Reporting of cesarean rates within a quality improvement program (NR)	24.5	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.
[b] Two entries in table to reflect sites with data that could not be combined and had different outcomes
[c] Statistical evidence not provided

Table 30. Summary of systems level strategies to reduce cesarean births (continued)

Author, Year Country Study Type; Quality	Health Systems Interventions (n)	Cesarean birth, %	Change in cesarean, %[a]
Calvo et al., 2009[90b] Spain (Llatzer) Pre-post; Poor	Baseline: (NR)	17.5	1.7 same
	Intervention: Multifaceted feedback with rating of appropriateness of all CS (NR)	15.8	
World Health Organization, 1994[98] Indonesia, Thailand, Malaysia **RCT**; Fair	Baseline: (10,049)	6.2	1.7 same
	Intervention: Use of WHO partogram with action line at 4hrs to guide active management of labor and decisions about cesarean (9,130)	4.5	
Gilstrap et al., 1984[109] US Pre-post; Poor	Baseline: (6,693)	16.8	1.6 lower
	Intervention: Informal criteria and policies established to assure adequate trial of labor, monitoring fetal distress, and criteria for management of breech (6,162)	15.2	
Studnicki et al., 1997[118] US Pre-post; Poor	Baseline: (NR)	24.5	1.5 same[c]
	Intervention State legislation requiring practice guidelines to staff credentialed for CS deliveries and establishment of, peer review boards to review CS deliveries (183,921)	23.5	
Tay et al., 1992[111] Singapore Pre-post; Poor	Baseline: (3,156)	12.3	0.6 same
	Intervention: Critical review of indications for CS and departmental audit (5,238)	11.7	
Althabe et al.,[93] South America **RCT**; Poor	Control Group: Usual care (39,175)	24.9	0.2 same
	Intervention: Mandatory second opinion driven by evidence-based guidelines for indications (n=34,735)	24.7	
Elferink-Stinkens et al., 2004[94] Netherlands **RCT**; Poor	Control Group: Usual care (>130,000)	NR	0.0 same
	Intervention: Report of departmental data in table and graph form with follow-up (>130,000)	NR	
Gregory et al., 1999[95] US Pre-post; Poor	Baseline: (5,134)	29.6	-0.5 same
	Intervention: 17 sequentially introduced quality improvement interventions (> 30,000 births)	30.1	
Hamilton et al., 2004[41] US and Canada **RCT**; Poor	Control Group: (2,515)	16.9	-0.7 same
	Intervention: Computer assisted evaluation of labor progress with visual display of labor curves and reference ranges (2,478)	17.6	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.
[b] Two entries in table to reflect sites with data that could not be combined and had different outcomes
[c] Statistical evidence not provided

Table 30. Summary of systems level strategies to reduce cesarean births (continued)

Author, Year Country Study Type; Quality	Health Systems Interventions (n)	Cesarean birth, %	Change in cesarean, %[a]
Oleske et al., 1992[106] US Pre-post; Poor	Baseline: (130,249)	21.2	-1.2 same
	Intervention: Informational brochures on average cost, length of stay and CS birth rate distributed to patients and providers. Press release of statewide cesarean birth patterns (167,654)	22.4	
Porreco, 1990[105] US Trend; Poor	Baseline: (22,624)	17.3	2.0 higher
	Intervention: Educational strategy focused on management of six key drivers of CS rate (23,462)	19.3	
Pridjian et al., 1991[113] US Pre-post; Poor	Baseline (2,827)	12.5	3.4 higher
	Intervention: Systematically incorporating VBAC into patient management (3,049)	15.9	

[a] **Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the intervention and comparison arms of the trial.
[b] Two entries in table to reflect sites with data that could not be combined and had different outcomes
[c] Statistical evidence not provided

Randomized Clinical Trials

Each of the four trials grouped hospitals in pairs matched for key characteristics. The researchers randomly assigned a member of the pair to implement the intervention while the other member of the pair continued usual practice.[41, 93-94, 98] Each trial evaluated a different type of strategy and none demonstrated effectiveness for reducing use of cesarean.

- **Nationwide trial of annual audit and feedback in the Netherlands**. The intervention consisted of annual reports summarizing each department's cesarean profile in the context of anonymized data from other departments. Several analyses were provided that included graphs and figures to make clear the status of a particular department. The departmental leadership was contacted after receipt of the report to followup and to answer questions. This ensured the reports were reviewed. Over the course of three years during which the reports evolved from only departmental data to include individual provider data in context, the variation in cesarean use within hospital in the intervention decreased but there was no overall difference at the end of the trial between those randomized to receive or not receive reports and followup.[94]
- **Implementation of the World Health Organization partogram** with four hour action line to guide active management of labor. The trial was conducted in Indonesia, Thailand, and Malaysia. They do not report an intention to treat analysis of the hospitals as randomized but do reveal the overall change from baseline at intervention hospitals was a 1.7 percent reduction that was not statistically meaningful.[98]
- **Requirement for a second opinion** of a higher or equal rank physician with application of evidence-based guidelines for each category of indications for cesarean (e.g. elective, breech, failure to progress, emergent, etc.). In the intervention group cesarean was the route for 24.9 percent of births, compared to 24.7 in the hospitals that did not implement the requirements.[93]

- **Use of a novel computer system** for evaluation of labor progress in a consortium of Canadian and U.S. hospitals. The computerized system featured visual display of labor curves with addition of references ranges (5th, 50th, and 95th percentile norms); 16.9 percent of women who gave birth in hospitals that continued their usual care patterns had cesareans compared to 17.6 in the hospitals using the computerized system.[41]

Observational Data

The 27 non-randomized studies used prospective observational designs in which baseline data about route of birth were collected for an extended period of time prior to implementation of a policy, protocol, or procedure change. Then followup data were collected over time after implementation. Across these studies numerous types of strategies were implemented and evaluated. In order to describe content, we grouped strategies into 16 broad categories: 1) active management of labor, 2) group agreement on guidelines 3) audit and feedback of site specific data about cesarean trends at regular intervals, 4) evaluation of labor progression 5) evidence-based practice education and tools, 6) feedback of data to individual providers, 7) goals for increasing vaginal births after prior cesarean, 8) maternal support in labor (partner, doula, etc.), 9) protocols for breech vaginal birth, 10) protocols for induction, 11) protocols for pain management in labor, 12) protocols for twin vaginal birth, 13) quality improvement teams or tools used, 14) required second opinions, 15) World Health Organization initiatives, and 16) miscellaneous unique components. Rarely a study evaluated a single component; most often researchers studied the influence of a combination of approaches. None of the studies demonstrating decreased use of cesarean used only a single component (Table 31).

Five international studies also achieved reductions in cesarean of five or more percent from baseline. One focused on implementation of the World Health Organization Effective Perinatal Care Program in the Ukraine and resulted in a 14.5 percent lower proportion of cesarean at the end of the two-year evaluation period.[89] A six-component study in Australia that included protocols for vaginal birth after cesarean and audit and feedback through peer review achieved a reduction to an 11.0 percent annual cesarean rate from 20.6 percent, a decrease of 9.6 percent.[120] Of the international pre-post intervention studies, this 1994 study bears the most similarities to a U.S. practice setting. A Canadian study in a small hospital with fewer than 300 births a year reduced their annual cesarean rate by ten percent through implementing protocols for vaginal birth after cesarean, management of breech, and diagnosis of dystocia.[101] Another small study in two Spanish hospitals used audit and feedback of data to providers along with appropriateness ratings of all cesareans. The authors reported a seven percent decline in cesarean at one site, and a 1.7 percent decrease at a second site.[90] Data were not combined in a single estimate, and the publication did not include statistical testing of the precision of either estimate. Of note, the site with the higher baseline rate (29.0 compared to 17.5 percent) was the site with the greater reduction in cesarean. The final international study to meet the criteria of important reduction was conducted in Taiwan and included audit and feedback at the departmental and individual level as well as regular cesarean review meetings and protocols for trial of labor among women with prior cesarean.[119]

Table 31. Components of interventions in the United States with at least five percent reduction of cesarean

Author, Year	Evaluation of labor progress	Audit and feedback to units	Feedback to individual provider	Goals for increasing VBAC	Active management of labor	Agreed on guidelines	Protocols for vaginal breech	Protocols for induction of labor	Other unique components	Maternal support in labor (partner/doula)	Protocols for vaginal twins	Protocols for labor pain management	Required second opinion	**Total components of 16 possible**	**Percent Reduction**
Sanchez-Ramos et al., 1990[110]	●	●		●		●	●	●	●		●			**8**	**17.0**
Langrew et al., 1996[116]	●	●	●		●			●	●					**6**	**15.7**
Rust et al.,1993[112]	●			●	●	●	●	●						**6**	**10.9**
Socol et al., 1993[100]	●	●	●	●	●					●		●		**7**	**9.4**
Poma, 1998[104]		●	●			●								**3**	**7.2**
Meyers and Gleicher, 1998, 1993[99, 103]	●	●	●	●			●		●				●	**7**	**5.6**
Boylan et al., 1991[102]	●				●									**2**	**5.5**
Main et al., 1999[96]		●	●											**2**	**5.6**
Total studies (n)	**6**	**6**	**5**	**4**	**4**	**4**	**3**	**3**	**3**	**1**	**1**	**1**	**1**		

In order to examine the total number and type of components used in less successful systems-level interventions in the U.S. we grouped those studies in Table 32 below. While the overall number of components used in any one study is modestly lower than more successful interventions, and there is a shift in the components used, commonality with those studies that reported decreased rates is also apparent. This implies that it is not possible to determine from components alone which interventions are destined to succeed.

Table 32. Components of interventions in the United States with least success in reduction of cesarean

Author, Year	Evaluation of labor progress	Audit and feedback to units	Feedback to individual provider	Goals for increasing VBAC	Active management of labor	Agreed on guidelines	Protocols for vaginal breech	Protocols for induction of labor	Other unique components	Maternal support in labor (partner/doula)	Protocols for vaginal twins	Protocols for labor pain management	Required second opinion	**Total components of 16 possible**	**Percent Reduction**
Gilstrap et al., 1984[109]	●					●	●							**3**	**1.6**
Studnicki et al., 1997[118]		●				●								**2**	**1.5**
Gregory et al., 1999[95]	●	●	●	●	●	●		●	●	●		●		**10**	**-0.5**
Hamilton et al., 2004,[41]	●													**1**	**-0.7**
Oleske et al., 1992[106]				●					●					**2**	**-1.2**
Porreco, 1990[105]	●			●			●	●	●		●			**6**	**-2.0**
Pridjian et al., 1991[113]				●										**1**	**-3.4**
Total studies, n	**4**	**2**	**1**	**4**	**1**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**0**		

In summary, no system-level interventions are supported by clinical trials. The content of interventions examined in observational studies is varied. Overall the evidence is insufficient to determine if systems based interventions reduce cesarean.

Key Question 3. Where head-to-head comparisons are available, what strategies are shown to be superior in reducing the use of cesarean birth among women, with a singleton pregnancy, who are intending for a vaginal birth?

No studies addressed KQ3. It is discussed as a part of Future Research. All studies compared the novel strategy to usual care or to variations in the same intervention. For example, some studies evaluated variations in the timing of the action line in partograms or dosing of epidurals. These studies are reviewed within KQ2 in the section for the related type of intervention. None examined direct comparisons of distinct strategies.

Key Question 4. What are the nature and frequency of adverse effects resulting from strategies used to reduce cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

Overview of the Literature

We have included summaries of standard maternal outcomes of labor for each strategy (Tables 4, 10, 13, 17, 20, 24, and 28) in the context of results for KQ1-2. These include events such as fever, infection, and hemorrhage. We have not considered these to be direct harms, instead we have summarized the harms that are plausibly caused by the strategy, for example dural puncture for epidural and perineal tears for education on pushing. Of the studies reporting outcomes of strategies employed to reduce cesarean, 15[32, 35-36, 47, 51, 61-62, 71, 74-75, 80, 83-84, 86, 88] reported data about outcomes that could be classified as adverse events or harms related to the strategy implemented to reduce cesarean. We summarized the harms data from these studies in this overview section (Table 33).

Key Points

- Few of the harms presented have a direct relationship to the strategy being used to prevent cesarean birth.
- Harms most commonly reported include maternal fever, nausea/vomiting, and anesthesia-related side effects.

Detailed Synthesis

The most common side effects reported were maternal fever, nausea/vomiting, and anesthesia-related morbidities (Table 33). There were no reports of harms that were directly causally linked to the strategy used to prevent cesarean.

Table 33. Overview of harms reported in studies of strategies to reduce cesarean birth

Author, Year Country	Intervention (n)	Key harms
Abdel-Aleem et al., 2005 [80] Egypt	G1: Transcervical amnioinfusion (219) G2: Standard obstetric care without amnioinfusion (219)	• Maternal fever >38°C in 16 of amnioinfusion group, compared to 13 in the standard care group (RR: 1.23; 95% CI: 0.61, 2.50) • Uterine hypertonicity in 16 in amnioinfusion group compared to 14 in standard care group (RR: 1.14; 95% CI: 0.57, 2.28)
Asher et al., 2009[83] US	G1: Acupuncture (30) G2: Sham acupuncture (29) G3: Usual care (no acupuncture) (30)	• Chorioamnionitis was reported in 23% of the acupuncture group, 21% of the sham acupuncture group, and 7% of the usual care group (p=0.20) • No significant difference in postpartum hemorrhage and/or uterine atony among the groups (p=0.70).
Adamsons et al., 1999 [86] Puerto Rico	G1: Propranolol during labor (34) G2: Usual care (23)	• No anesthesia-related morbidity in either group
Barakat et al., 2009[32] Spain	G1: Exercise training (80) (72) G2: No exercise training (80) (70)	• No exercise-related injuries in either group

Table 33. Overview of harms reported in studies of strategies to reduce cesarean birth

Author, Year Country	Intervention (n)	Key harms
Bidgood et al., 1987 [51] UK	G1: High-dose oxytocin (19) G2: Low-dose oxytocin (21) G3: Observation (20)	• Hyperstimulation, defined as >7 contractions in 15 min and/or rise in baseline tone >1.33 kPa pressure, in 7 women in the high-dose oxytocin group
Bloom et al., 2006 [71] US	G1: Fetal pulse oximetry with oxygen saturation displayed to clinician (2629) G2: Fetal pulse oximetry with oxygen saturation not displayed to clinician (2712)	• Chorioamnionitis was reported in 10.7% of each group • No significant difference in postpartum endometritis (p=0.87) or wound complications (p=0.72) • Reported facial marks from the sensor (5.8% vs. 3.4%; p=0.74)
Choudhary et al., 2010[74] India	G1: Transcervical amnioinfusion (146) G2: Standard obstetric care without amnioinfusion (146)	• No significant difference in maternal fever--3% of the amnioinfusion group compared to 5% of standard care (p=0.238)
Cox et al., 1999[84] UK	G1: Inflatable obstetric belt (260) G2: Usual care (240)	• Significantly more women in the control group experienced a 3rd degree perineal tear (6.5 % vs. 0.4%; OR: 16.72; 95% CI: 2.81, >2.81) • Six women in the obstetrical belt group needed catheter insertion for urinary retention compared to 2 in the standard care group
Gambling et al., 1998[62] US	G1: Combined spinal-epidural anesthesia (616) G2: Intravenous meperidine analgesia (607)	• Maternal fever (>38°C was more common in CSE group (22% vs. 3%; p<0.005) • 8 infants delivered by emergency cesarean due to profound fetal bradycardia within 1 hr of analgesia • Pruritus reported in 48% of participants • Nausea reported in 2.4% of participants
Hinshaw et al., 2008 [47] UK	G1: Early oxytocin (208) G2: Delayed oxytocin (204)	• No significant differences in maternal fever (p=0.48) postpartum hemorrhage (> 500 ml; (p=0.87) and blood transfusion rates reported (4.8% vs. 4.9%) • Reported major depression within 48 hours of labor by EPDS (20% vs. 15%; p=0.22)
Norris et al., 2001[61] US	G1: Combined spinal-epidural anesthesia (1071) G2: Epidural analgesia (1112)	• Accidental dural puncture in 1.3% of CSE group and 1.2% of epidural group • Intravascular catheter in 6.4% of CSE group and 4.4 of epidural group • Failed epidural in 0.8% of CSE group and 0.7% of epidural group • Positional headache in 1.7% of CSE group and 1.6% of epidural group • Blood patch in 0.4% of CSE group and 0.6% of epidural group
O'Sullivan et al., 2009[88] UK	G1: Allowed to eat during labor (1227) G2: Usual care (1216)	• 35% of those allowed to eat during labor vomited compared to 34% of those only allowed ice chips and water (RR: 1.05; 95% CI: 0.94, 1.17; p=0.41)
Phipps et al.,2009[35] Australia	G1: Structured education for pushing (50) G2: Standard care (50)	• Reported episiotomy and perineal tear rates • No significant difference in 3rd degree tear rates (p=0.142)

Table 33. Overview of harms reported in studies of strategies to reduce cesarean birth

Author, Year Country	Intervention (n)	Key harms
Regi et al., 2009[75] India	G1: Transcervical amnioinfusion (75) G2: Standard obstetric care without amnioinfusion (75)	• Intrapartum temperature ≥ 38.3°C in 2.7% of the amnioinfusion group, 0% in standard care group.
Spallicci et al., 2007[36] Brazil	G1: Hyaluronidase injection in cervix (83) G2: Placebo cervical injection (85)	• No significant difference in those reporting cramps between the two groups (p=0.2709).

EPDS, Edinburgh Postnatal Depression Scale

Summary and Discussion

State of the Literature

We identified 6106 non-duplicate publications through the search process, with 1,025 proceeding to full text review (Figure 2). Ninety-two publications were included, 63 RCTs and 29 pre- post-studies of large scale health systems changes, representing 90 distinct study populations. Using uniform criteria for assessment we found 16 of these studies to be good quality; 26 fair; and 50 poor. The most common reasons for exclusion were irrelevance to the topic and ineligible study design. Eight articles pertain to KQ1, 85 articles to KQ2, no articles to KQ3, and 17 articles to KQ4. Few interventions have been studied in more than three trials. Most included trials were the only randomized study of the intervention.

Summary of Outcomes by Key Question

KQ1. Strategies during pregnancy

Collaborative consistent midwifery care during pregnancy and in labor, compared to conventional care, reduced cesarean births by 4.5 percent in one RCT. No difference was reported in two similar studies. Outpatient injection of hyaluronidase into the cervix, in patients at term with a low Bishop score, decreased cesarean births by 31 percent (from 49 percent to 18 percent) in a single Brazilian study. No other studies were found that repeated evaluation of this or other agents for cervical ripening as a means to prevent cesarean. Light exercise, intervention to reduce fear of labor, education about how to push in labor, and pre-emptive management of specific risks detected during antenatal care were among the ineffective outpatient interventions. Each of these interventions was represented by only one study.

KQ2. Strategies during labor

Management of labor.

The only labor management strategies found to significantly reduce use of cesarean were seen in individual trials of 1) administration of propranolol concurrent with oxytocin for dysfunctional labor treatment, 2) use of a partogram with an active management protocol, and 3) use of a 4-hour partogram compared with a 3-hour partogram, meaning more time was taken to assess/restore labor progress (see Table 2). However, these findings were often not replicated in similar interventions. A second study did not find a significant reduction in the use of cesarean when propranolol and oxytocin were used for similar indications. Adding a partogram to standard written labor progress notes was not effective. Cesarean rates with two-hour and four-hour partograms were equivalent. Providing an individualized, computer-generated reference range for assessing labor progress did not reduce the use of cesarean. Active management of labor did not reduce the use of cesarean and was evaluated in four studies.

Other strategies included home-based triage, which when compared with telephone triage, did not reduce the use of cesarean. Early labor assessment to delay hospital admission until active labor, compared with direct admission of women in labor, did not reduce the use of cesarean. Cesarean rates were identical in women who did and did not have amniotomy at the time of hospital admission. Increased intravenous fluids did not reduce the use of cesarean.

Psychosocial Support.

Seven studies investigated potential benefits of psychosocial support in labor. One study was assessed as being fair quality and the remaining six studies were poor quality. Three doula support interventions reduced cesarean births. Women who had doula support had five to 22 percent fewer cesareans. In contrast to trained doulas, there were no significant differences in cesarean use for women who received labor support from trained female friends or family members, nurses, or midwifery students compared to women who received usual labor care.

Pain Management.

We identified seven trials of pain management that aimed to reduce cesarean. One study was assessed as being good quality; two were fair quality; and four were poor quality. A single study, judged to be of poor quality due to the lack of description of the randomization allocation and concealment procedures, reported almost a three-fold reduction in cesarean rates for women who received intermittent epidural (5 percent) as compared to continuous epidural (15 percent, $p=0.03$).[65] A larger good quality study that compared high versus low dose epidural reported significantly fewer instrumental births (vacuum extraction and cesarean) in women who received the lower dose of analgesia (30 percent compared to 49 percent in the high dose group, $p<0.00001$).[64] The cesarean rates for the two groups were 10.2 percent and 14.7 percent for the low and high dose respectively, but no statistical analysis was reported. None of the remaining five studies reported a significant difference in use of cesarean. These studies varied in quality, sample size, comparison of anesthetics used, parity of the study population, and overall rate of cesarean birth. None examined the same intervention.

Fetal Assessments.

Of six studies investigating means to improve assessment of fetal status, one was good quality with five being of fair quality. Knowledge of intrapartum fetal oxygen saturation had no significant effect on the overall use of cesarean, but three of the four studies investigating use of fetal pulse oximetry reported a statistically significant reduction in cesareans performed for fetal distress that ranged from 5.7 to 24.6 percent. Fetal pulse oximetry did not slow or interfere with labor, nor did it result in an increase in adverse maternal, fetal, or neonatal outcomes. Use of ST analysis in conjunction with FHR monitoring did not reduce cesarean rates overall, nor cesarean rates for non-reassuring fetal heart tracing when compared to routine FHR monitoring alone.

Amnioinfusion.

Eight studies investigated amnioinfusion as an intervention for fetal benefit that could prevent cesarean. Four studies were assessed to be of fair quality with the remaining four being poor quality. Three of eight studies found a significant reduction in cesarean use. While amnioinfusion did not consistently lead to a reduction in overall cesarean rates when performed for concerning fetal heart tracings, four of eight studies did show a significant reduction in cesareans performed for suspected fetal distress. Amnioinfusion for moderate or heavy meconium when performed in under-resourced hospital settings where electronic monitoring was limited or absent, improved neonatal outcomes. Prophylactic amnioinfusion for oligohydramnios without fetal distress did not reduce use of cesarean. Amnioinfusion did not increase maternal or neonatal morbidity, mortality, or complications. It appears to be simple, safe, and relatively easy to perform and can be done even in under-resourced or underfunded hospital settings. However,

in developed countries there was no evidence to support use of amnioinfusion for the specific purpose of reducing cesarean.

Unique Interventions.

Seven studies explored the influence of various other unique interventions on the incidence of cesarean birth. Two studies were assessed to be of good quality, two were fair quality, and the remaining three were poor quality. Large single studies of walking, eating, or using an inflatable obstetric belt during labor showed no effect on the incidence of cesarean as compared with usual care. Small studies of other interventions such as acupuncture, a molded dental device, or propranolol had no effect of intervention on rates of cesarean birth when compared with standard care approaches.

Systems Level Interventions.

From baseline to followup, 18 of 31 studies achieved statistically significant reductions in cesarean with a range of 1.6 to 17.0 percent decreases. None of the four systems-level RCTs demonstrated effectiveness. Three were poor quality and one fair. Twelve observational studies reported achieving a reduction of five percent or more. More than16 broad categories of components have been used in various combinations in these systems interventions.

Ten pre-post studies documented reductions in cesarean from implementing varied forms of auditing of trends with regular feedback of data to either the organizational unit (hospital, department, labor and delivery staff) or the individual care providers or both. Overall audit and feedback was most often provided at both the unit and individual level. These components individually or combined were the most common component of studies that reported a decrease in cesarean of five percent or more. The next most common components of successful interventions, with a five percent or greater reduction, were tracking of progress in labor combined with active management. Care must be taken in interpretation because similar components were used in strategies that were associated with decreased rates of cesarean and with unchanged or worse rates.

Caution must be used in interpretation of this literature. Both the trials and the observational studies are subject to limitations in causal inference that can be draw. In other words, it is not necessarily correct to attribute the observed effects to the intervention package alone, or the lack of effect to failure of the intervention as compared to other factors at work in the comparison groups that also tended to decrease use of cesarean. Consider in the case of randomized trials that, at minimum, leadership of the units involved were invested in the importance of research on reducing cesarean and willing to participate in research about how best to accomplish that goal. In these randomized studies, trial assignment could not feasibly be masked at all levels – sites would have been able to infer their status. Sites not assigned to implement the study protocol, or to delay, may nonetheless have galvanized inclinations to reduce cesarean and have informally, even unwittingly, initiated changes over multi-year followup periods that reduced cesarean to a degree. If this effect were at work the trials would be biased towards the null meaning they were less likely to detect an effect of intervention.

Especially in pre-post studies, determining with confidence what components are crucial in decreasing cesarean is challenging. As an illustration of the difficulty of determining the importance of specific components, consider the table that follows as an example. This table presents the same analysis of components of intervention as that in Table 31 which features successful interventions in the United States. This table compiles the data for the seven studies in

the United States that showed either no benefit or that the intervention was worse than control or baseline. Overall, these less successful interventions included fewer components with the exception of the study that had 10 of the 16 categories we examined. The components used however, overlap with those incorporated into systems level interventions that had greater effects. In short, there does not appear to be a guaranteed "active component" or threshold number of components that is consistently associated with the desired result of fewer cesareans.

It is possible that the ability to change rates is related to the novelty of the concept that it is possible to exert influence at a systems level. Some have suggested that the window may be closing in which jaded healthcare systems are willing to focus efforts on decreasing annual cesarean rate or on improving trends in specific categories of indication for cesarean. In this instance earlier studies would be expected to have greater effect. Including all 33 publications, so that followup data are reflected in the proper timeframe, no clear secular trend is apparent in the outcomes of grouped by calendar time:

- The two interventions published before 1990, significantly reduced cesarean by almost two and six percent.[103, 109]
- From 1990 up to 1995, there were 14 reports of which seven reported a significant decrease in cesarean.[100-102, 110, 112, 114, 120]
- From 1995 up to 2000, there were eight studies of which four reported a significant decrease. [116 115 104 97]
- In 2000 and after, four of nine reported a significant decrease.[41, 89, 117, 119]

Neither year of publication nor year of intervention initiation was correlated with effect size.

Similarly, it has been proposed that sites with higher rates of cesarean will experience a greater urgency to reduce that rate or simply that a higher baseline allows greater potential to accomplish decreases in cesarean. We did not find this to be a strong effect. When the baseline cesarean rate for all included studies is plotted against the achieved reduction in cesarean, baseline is modestly correlated ($r=0.44$, with $r^2=0.19$) with the absolute magnitude of reduction in cesarean. However, this contribution is far from suggesting there are sites with rates that make them destined to succeed or doomed to failure.

Seventeen of 31 (55 percent) of these studies achieved reduction in cesarean that was statistically distinct from their baseline rate. Eleven reduced the rate of cesarean by an absolute amount of five percent or more. Since the trend in almost all of these study settings has been for cesarean rates to rise, this suggests that systems level interventions can contribute to "bending the curve" and reducing or perhaps holding steady the proportion of women who give birth by cesarean. Which components are effective at doing this is unclear.

KQ3. Head-to-head comparisons

All studies compared the novel strategy to usual care with no direct comparisons of new strategies. Though not novel interventions, we did include comparisons of partograms that stipulated different lengths of time before action was indicated. The papers about partograms are reviewed in strategies for management of labor.

KQ4. Harms of strategies

Few of the harms presented have a direct relationship to the strategy used to prevent cesarean birth. Harms most commonly systematically collected by authors included maternal fever, nausea/vomiting, and anesthesia-related side effects. Where devices were used that were introduced into the uterus there was not compelling evidence of increased risk for infection.

Some interventions like amnioinfusion were associated in some studies with significant improvements in neonatal outcomes.

Strength of the Evidence for Effectiveness of Strategies

Overview

Overall the strength of evidence to answer the key questions was insufficient to low (Table 34 and Appendix G). Deficiencies in the strength of evidence most often related to:

- High proportion of strategies that were represented by only one study which prevents determination of consistency of findings across studies and populations.
- Preponderance of study designs with high risk of bias in part because means to mask participants and providers to status is challenging.
- Underpowered studies that did not enroll sufficient participants to properly evaluate cesarean as an outcome though reducing cesarean was a stated aim.
- Inconsistent findings across studies; for all strategies in which there was more than one RCT, there was not consistent demonstration of effectiveness.
- Inconsistent selection and definition of outcomes; studies did not consistently report total cesarean, primary cesarean, and repeat cesarean (when applicable).
- Operational definitions of indications for cesarean are incompatible across studies so that these outcomes cannot be aggregated across studies.

In the table that follows we provide strength of evidence ratings grouped by strategies (where applicable) within key question (Appendix G).

Strength of the Evidence by Key Question

Table 34. Strength of evidence for various strategies to reduce cesarean birth

Strategy n total studies (n total participants)	Risk of Bias	Consistency	Directness	Precision	**Strength of Evidence**
KQ1. Effectiveness of strategies during pregnancy to reduce cesarean birth					
Antenatal Care Model **3 (4143)**	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 2 studies of fair quality, 1 poor quality
Exercise training **1 (160)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality
Management of fear of childbirth **1 (176)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of poor quality
Induction of labor for at-risk **1 (270)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality
Education on pushing **1 (100)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality
Hyaluronidase **1 (168)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality

Table 34. Strength of evidence for various strategies to reduce cesarean birth*

Strategy n total studies (n total participants)	Risk of Bias	Consistency	Directness	Precision	**Strength of Evidence**
KQ2: Effectiveness of strategies during labor to reduce cesarean birth					
Early labor assessment **2 (1,668)**	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 2 studies of fair quality with conflicting findings
Measurement of labor progress **4 (10,823)**	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 studies of good quality, 1 fair and 1 poor quality
Active management of labor **4 (2,764)**	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 studies of good quality, 2 of fair quality
Management of abnormal labor **5 (2,764)**	Moderate	Inconsistent	Direct	Imprecise	Insufficient; two studies of good quality, two of fair quality, one of poor quality
Amniotomy **1 (128)**	Moderate	N/A	Direct	Imprecise	Insufficient; 1 study of fair quality
Increased IV fluids **1 (195)**	Low	N/A	Direct	Imprecise	Insufficient; 1 study of good quality
Doula support **3 (1,136)**	High	Consistent	Direct	Precise	Low strength of evidence; 3 poor quality studies
Trained friend or family as labor support **1 (598)**	High	N/A	Direct	Imprecise	Insufficient; 1 poor quality study
Nursing and midwifery student support **3 (7,568)**	High	Consistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 poor and 1 fair studies
Pain management **7 (5,525)**	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 4 poor, 2 fair, 1 good study
Fetal pulse oximetry **4 (7,098)**	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 1 good, 3 fair studies
Fetal assessment by STAN **2 (2,271)**	Moderate	Consistent	Direct	Imprecise	Low or moderate evidence for lack of benefit; 2 fair quality studies

* See Chapter 2: Methods for more detail about grading strength of evidence. Assessment of insufficient evidence often resulted from single trials or small numbers of studies with combinations of high risk of bias, inconsistent results, and poor precision. The latter often resulted from relatively limited power of individual or aggregated studies to accurately estimate the effect. Low strength of evidence for lack of benefit was most commonly assigned in the setting of moderate to low risk of bias and larger studies in which the predominance of the literature found no benefit but a single study reported reduction in cesarean..

Table 34. Strength of evidence for various strategies to reduce cesarean birth

Strategy n total studies (n total participants)	Risk of Bias	Consistency	Directness	Precision	**Strength of Evidence**
KQ2: Effectiveness of strategies during labor to reduce cesarean birth					
Amnioinfusion for fetal distress **2 (588)**	High	Inconsistent	Direct	Imprecise	Insufficient; 1 fair and 1 poor study
Amnioinfusion for meconium **5 (1565)**	High	Inconsistent	Direct	Imprecise	Insufficient; 3 poor and 2 fair studies
Amnioinfusion for oligohydramnios **1 (60)**	High	NA	Direct	Imprecise	Insufficient; 1 fair quality study
Other strategies (acupuncture) **2 (145)**	High	Inconsistent	Direct	Imprecise	Insufficient; two fair studies
Dental device **1 (64)**	High	N/A	Direct	Imprecise	Insufficient; one poor study
Allowing eating **1 (2426)**	Low	N/A	Direct	Precise	Insufficient; one good study
Inflatable obstetric belt **1 (500)**	Low	N/A	Direct	Imprecise	Insufficient; one good study
Propranolol **1 (57)**	High	N/A	Direct	Imprecise	Insufficient; one poor study
Allowing walking **1 (916)**	High	N/A	Direct	Precise	Insufficient; one poor study
Systems level strategies **33**	High	Inconsistent	Indirect	Precise	Insufficient
Adverse effects of strategies to reduce cesarean birth					
Harms **17 (14,403)**	Moderate	Inconsistent	Indirect	Imprecise	Insufficient; fair to poor quality studies with inconsistent reporting of multiple adverse events

Applicability

Studies included in the review were selected to provide data that is relevant to the care of low risk, term pregnant women. Applicability describes the extent to which study population, interventions, and outcomes in this literature apply to that target group. In this report, the study populations were predominantly low risk pregnant women at term with a singleton pregnancy, a vertex presentation, and no previous cesarean birth. However, eligibility criteria and participant characteristics were not always clearly described in detail. Some studies that recruited from among laboring women included a proportion of women with multiple gestations, complications of pregnancy, and prior pelvic surgery or cesarean, not meeting the criteria of low risk.

In these instances the studies reflected the base population of women seeking care in the setting in which the study was done and who were intending vaginal births. We did not include

studies focused only on high risk populations. More than half of the studies were conducted outside the United States and differences in the health systems, homogeneity of the population, and prevailing rates of cesarean are important to note.

Interventions varied widely with most not being replicated in more than one study. All of the strategies evaluated were of potential utility to the target population for the report. Likewise the comparison group for the RCTs was standard care, which with the exception of international settings with limited resources, is becoming increasingly similar around the globe. Where distinct differences such as midwifery based care or lack of use of electronic monitoring are the norm, we have called attention to this in order to alert the reader to limitations in applicability. Fortunately the outcome of interest—cesarean—is readily measured with accuracy and would not be expected to differ in ways that would affect applicability with the exception of classification of reasons for cesarean which has high variability even among individual providers within the same facilities.

In summary, constraints for applicability are easily identified in this literature and the reader will generally be able to understand any differences in the study setting and their setting. The primary hindrance is the lack of clear evidence to apply. No clearly effective means of decreasing cesarean in the target population emerged from the synthesis of the evidence.

Future Research

State of the Science

Recent reports by the Consortium on Safe Labor, a group of 19 U. S. hospitals conducting an observational study on labor progression and the use and timing of cesareans among women with labor protraction and arrest, show that cesarean birth among women having their first birth has risen to almost one in three.[148] Much of this increase occurred with the past decade .[1] Since the 1980s researchers and policymakers have sought to implement strategies both in the context of trials and systems level changes to reduce the number of cesarean births in low risk women. No approaches to prevent cesarean have proven to be effective with moderate or high strength of evidence. Means to forestall a continued rise in cesarean are needed which will require continued research. Some cross-cutting methodologic challenges should be noted in future research.

Methodologic Issues

- Randomized trials will be needed and they must be powered for plausible changes in the proportion of women having cesareans.
- Prior power calculations have often been based on reductions in risk of cesarean that have not previously been achieved. This review provides a range of plausible estimates for ability to influence cesarean use.
- Secondary outcomes and desire to stratify on patient characteristics such as nulliparity and multiparity should be pre-specified and the study designed to have adequate power for these.
- Tracking and reporting of total, primary, and repeat cesareans should be undertaken if the study is not restricted to nulliparous women.
- Consensus definitions of indications for cesarean that can be validated from medical records and case-report forms in trials should be developed. It is essential to be able to

track whether decreasing use of cesarean for one indication results in shifts in use of cesarean for other indications.

- Maternal outcomes need to be expanded to uniformly include collection of complications of labor, vaginal birth, and cesarean birth.
- More robust measures of maternal coping, satisfaction, and perceived quality of the birth experience are needed.
- Infant outcomes need to be expanded to include a uniform panel of measures that capture infant status better than Apgar scores and NICU admission. Length of stay and incidence of specific complications are needed.
- Longterm followup of infants into childhood will be needed to assure any reduction in cesarean is not achieved at the risk of future neurodevelopmental impairments.
- Interventions need placebo, sham, or attention control comparison groups, and innovative means of masking patients and providers should be explored.
- Replication of individual but promising studies is warranted.
- Likewise as effective individual strategies emerge, the opportunity for direct comparisons should be considered including studies explicitly designed to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.
- Many gaps in knowledge about the determinants of cesarean use remain. While there has been some focus on individual patient characteristics that predispose to cesarean, many of these factors such as age, BMI and prior cesarean are not directly amenable to intervention. Attention would be well spent on identifying malleable contributors to the rising cesarean rate as well as to understanding socio-cultural attitudes about birth including cesarean.

Gaps in Areas of Research

- Randomized trials are needed at the systems level to ascertain whether promising intervention components are indeed effective in promoting decreased use of cesarean.
- Most strategies to reduce cesarean will require multisite research to improve applicability and to assure power to detect the outcomes with precision.
- Mechanism by which interventions exert an effect must be explored. For instance, does the doula's presence affect the decisions of medical staff? Does her interaction with the laboring woman reduce anxiety?
- Knowledge of mechanisms will multiply the options for new interventions and to use multiple interventions that act at different points in the pathway leading to cesarean.
- Interventions shown to be effective will need to be explored across the different racial/ethnic and socioeconomic groups representative of the U.S. population.
- Interventions aimed at disrupting staffing phenomena – like the increase in cesarean near change of shifts and differential rates through the week – could have promise.
- Likewise investigation of staffing models like use of hospitalists and integration of midwifes is of interest.
- Active management of labor trials, in U.S. settings, powered not to intermediate outcomes like length of labor, but to see differences in route of birth are needed.
- Continued exploration is warranted to determine if additional technologies to enhance fetal surveillance can improve infant outcomes while reducing cesarean.

- Qualitative and quantitative research is needed to help determine what factors are contributing to decisions to have elective cesarean.
- Trials that examine the role of informed medical decision making approaches as a tool to aid patients and providers in communication about choices and in resolving decisional uncertainty are warranted.
- Sociologic and economic models could be informative for understanding the factors that determined whether cesarean rates are perceived as concerning or not among members of the public, women of childbearing age, obstetrical care providers, payors, and policy makers.
- Natural experiments in tort reform should be accompanied by sophisticated analyses of subsequent litigation cesarean trends.

Conclusions

No particular intervention strategy was uniformly successful in reducing cesareans. Strength of evidence was low to insufficient across all interventions. While certain components of systems-level interventions were common among successful interventions, none were supported by a randomized trial.

This literature contains intriguing examples of strategies that deserve continued research. They include further exploration of outpatient use of agents to promote cervical softening, determination of what elements of doula support were common across successful trials in order to conduct larger scale replications, use of amnioinfusion to reduce fetal distress and thereby reduce total cesareans, and evaluations of whether components of systems interventions succeed because of the components themselves or because the interventions selected reflect the will of the health system and care providers to promote decreased use of cesarean.

In conclusion, no approach dominated as a strategy appropriate to reduce use of cesarean in low risk women in the United States.

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List of Acronyms/Abbreviations/Symbols

±	plus or minus
≤	less than or equal to
≥	greater than or equal to
%	percent
AE	adverse events
AHRQ	Agency for Healthcare Research and Quality
AROM	Artificial rupture of membranes
BMI	body mass index
BP	blood pressure
bpm	beats per minute
CDC	Center for Disease Control and Prevention
CER	comparative effectiveness review
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
cm	centimeter
cm/min	centimeter per minute
CS	cesarean
ºC	degree Celsius
CSE	combined spinal epidural
CTG	cardiotocography
ECG	electrocardiogram
EFM	electronic fetal monitoring
EPC	Evidence-based Practice Centers
EPDS	Edinburgh Postnatal Depression Scale
et al.	and others
etc.	et cetera
FBS	Fetal blood sampling
FHR	fetal heart rate
fl	fluid liter
$FSPO_2$	Fetal oxygenation
ºF	degree Fahrenheit
g	gram(s)
HIE	hypoxic-ischemic encephalopathy
HIV	human immunodeficiency virus
hr(s)	hour(s)
IM	intramuscular
In	inch
IQR	interquartile range
IUPC	Intrauterine pressure catheter
IV	intravenous
kg	kilogram

kPa(s)/min	kilopascal per minute(s)
KQ	key question
L, l	liter
MAS	meconium aspiration syndrome
max	maximum
mg	milligram
mg/ml	milligram per milliliter
min	minute(s)
mL, ml	milliliter
mm Hg	millimeters of mercury
mU/min	milliunit per minute
n	number
NHS	National Health Services
NICU	neonatal intensive care unit
NOQAS	Newcastle-Ottawa Quality Assessment Scale
NR	Not reported
NRFS	nonreassuring fetal status
NS	not significant
OR	odds ratio
O_2	oxygen
P, p	p value
PCO2	partial pressure of carbon dioxide
pH	power of hydrogen
PICOTS	Population(s), Intervention(s), Outcome(s), Timing, and Setting
PO2	partial pressure of oxygen
PROM	premature rupture of membrane
pt	patient
RCT	randomized controlled trial
RN	registered nurse(s)
ROB	Cochrane Risk of Bias
RR	relative risk
SD	standard deviation
SE	standard error
SEM	standard error of mean
STAN	ST segment analysis
TEP	technical expert panel
U.K., UK	United Kingdom
U.S., US	United States
VBAC	vaginal birth after cesarean
vs., v	versus
w/	with
wk(s)	week(s)
yr(s)	year(s)
µg/l	micrograms per liter