



Effective Health Care Program

Comparative Effectiveness Review
Number 80

Strategies To Reduce Cesarean Birth in Low-Risk Women



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Strategies To Reduce Cesarean Birth in Low-Risk Women

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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

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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.

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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 email to epc@ahrq.hhs.gov.

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Ms. Kerry Harville served as project coordinator, shepherding innumerable planning, implementation, and writing tasks to completion. She guided and contributed to production of the plethora of forms, spreadsheets, and tables that are required to produce reliable evidence tables and summary data. Her attentiveness to the needs of the investigator team and to pacing the work was especially valued.

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Strategies To Reduce Cesarean Birth in Low-Risk Women

Structured Abstract

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

Data Sources. We searched MEDLINE® via PubMed and the Cumulative Index of Nursing and Allied Health Literature as well as the reference lists of included studies.

Review Methods. We included studies published in English from 1968 to February 2012. We excluded publications that did not address a Key Question, were not an eligible study design, or did not aim to reduce cesarean birth among low-risk women.

Results. Of the 97 studies included, 16 were good quality, 28 fair, and 53 poor. In this review, all studies compared the novel strategy to usual care or to variations in the same strategy. Few studies addressed prenatal strategies; the one such strategy that reduced cesarean was treatment of the cervix with hyaluronidase in the clinic at term to promote cervical softening. Strategies intended for use in labor included four trials that favored active management of labor, with 2.8- to 7.4-percent decreases in cesarean; one study showed a significant decrease. Doula support in labor was associated with significant reductions in cesarean (5.0 to 22.0%) in three studies. One of six trials of fetal assessment reported a significant reduction in total cesareans (20.6%). Three of eight trials of amnioinfusion reported a significant reduction in total cesareans (15 to 34.2%).

Virtually all studies within health care systems that changed policies or procedures 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, 7 included protocols for vaginal birth after prior cesarean, 6 included agreement on overarching labor and delivery guidelines, and 5 included active management of labor protocols. Overall, it is not possible to determine which components are definitively associated with reductions.

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

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Executive Summary

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 of concern for decades, with the last decline of 2 to 3 percent, occurring in the mid-1990s, being fully reversed by 1999, and the rate 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: “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 health care system, is associated with increased risk for both mother and infant, and has the potential to complicate subsequent pregnancies.^{4,5} Complications such as uterine rupture and abnormalities in placental attachment to the uterus (e.g., placenta accreta and percreta), which previously were extraordinarily rare, are becoming more common modern obstetric care challenges.^{6,7} Uterine rupture occurs along the scar line of a prior cesarean, and susceptibility is believed to result from relative weakness of the uterine wall at the point of scarring. Placenta accreta and percreta result when placental implantation occurs over or adjacent to scarring and the placenta invades the uterine muscle more deeply. This is believed to occur because the scarred tissue from prior cesarean has a less robust blood supply and abnormal architecture at the tissue and cellular level. 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 increased the use of “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 States, with the highest rates in the southeastern United 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 such as risk adjustment, that a large proportion of variation 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 preferences, and to a lesser extent patient preferences, are important drivers of variation.⁹⁻¹¹

Goals to reduce cesarean in the United States have become less ambitious. The Healthy People 2000 goal was to reduce cesarean to 15 percent of all births.¹² 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 a full-term singleton pregnancy and vertex presentation is 23.9 percent.^{13,14} The moving target reflects ambivalence in knowing the right rate for optimal maternal and infant outcomes and doubts about what strategies can safely reduce use of cesarean.^{15,16}

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

- Changes in reimbursement for births that favor interventions such as cesarean¹⁷
- Amplified perception of the risk of medicolegal liability claims for less than perfect infant outcomes or for failing to intervene¹⁸
- Shifts in consumer attitude that include less fear of or regret about cesarean¹⁹
- Lower psychosocial or emotional value placed on the experience of vaginal birth²⁰
- Concerns about pelvic floor damage and future continence^{21,22}
- Maternal desire for greater control over the timing and circumstances of birth,²³ such as maternal request for elective induction and cesarean²⁴

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.^{25,26}

Nonetheless, relatively little focus has been placed on research specifically designed to assess strategies to reduce use of cesarean. The notable exception is a study of approaches to promote trial of vaginal birth after 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.^{27,28} 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 strategies intended to reduce use of cesarean among low-risk women.

Objectives

The goal of this systematic evidence 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.

The PICOTS (population, intervention (“strategy” is used here), comparator, outcome, timing, and setting) are given below. Inclusion and exclusion criteria are given in Table A.

Population: The population consisted of low-risk pregnant women who have a singleton pregnancy and 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 those used during prenatal care, during labor, and as part of health systems strategies (quality assurance, audit and feedback, implementation of guidelines, etc.).

During prenatal care:

- Antenatal care models
- Exercise training
- Management of fear of childbirth
- Induction of labor for women at risk for cesarean
- Structured education for pushing
- Hyaluronidase injection in cervix

During labor:

- Early labor assessment

- Midwife-led care
- Measurement of labor progress
- Active management of labor
- Management of abnormal labor
- Amniotomy (surgical rupture of fetal membranes)
- Increased intravenous fluids
- Psychosocial support, including doulas
- Pain management
- Fetal assessment
- Amnioinfusion
- Unique strategies, including acupuncture and devices

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

Outcome Measures for Each Key Question: 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 a strategy, including adverse events (Figure A).²⁹

Timing: Strategies used during pregnancy and during labor were included.

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

Key Questions

We 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?

Table A. Inclusion/exclusion criteria

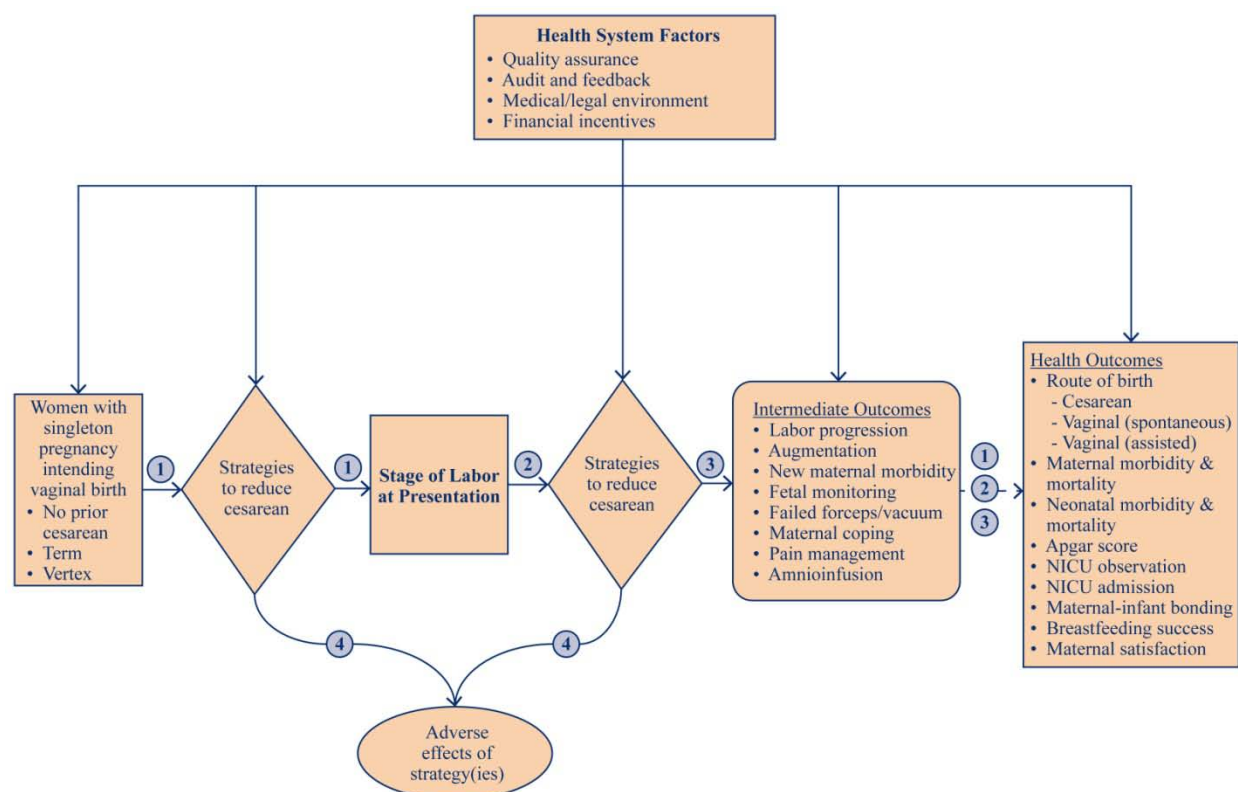
Category	Criteria
Study Population	Low-risk pregnant women who have a singleton pregnancy, a vertex presentation (as defined by the authors, where reported), term birth, and no previous cesarean birth
Time Period	All years
Publication Languages	English only
Admissible Evidence (Study Design and Other Criteria)	<p>Admissible designs Randomized controlled trials of interventions (KQs 1–4) Pre- and post-studies related to large-scale health systems changes (KQ2 only)</p> <p>Other criteria Original research studies must 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</p>

Note: KQ = Key Question. PICOTS = population, intervention (here, strategy), comparator, outcome, timing, and setting; they refer to the framework used by the Effective Health Care Program to summarize study characteristics.

Analytic Framework

We developed the analytic framework (Figure A) 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, and neonatal morbidity and mortality. Adverse effects may occur at any point after the strategy has been implemented.

Figure A. Analytic framework for strategies to reduce cesarean birth in low-risk women



NICU = Neonatal intensive care unit

Note: Numbers in circles indicate the position of Key Questions in intervention process.

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 Web site. Working from the nomination, we drafted the initial KQs and analytic framework. The KQs and analytic framework were refined with input from Key Informants representing the fields of obstetrics and gynecology, midwifery, nursing, pediatric care, primary care, and patient advocacy. The Agency for Healthcare Research and Quality (AHRQ) reviewed the KQs and posted them to a public Web site for public comment. Using public input, we submitted final KQs, which AHRQ reviewed. 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 the 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[®]) from 1968 to February 2012. 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 that 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 KQs
- 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 health care 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 by one member, another member checked table entries for accuracy, completeness, and consistency. Abstracters 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, addressing of incomplete outcome data, and freedom from 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) 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 KQ. Within each KQ we have organized the sections to (1) summarize the number and crucial descriptors of studies, (2) note the quality of studies, (3) summarize the number of studies that identified benefits of the intervention out of the total, (4) describe interventions that were effective in more detail, and (5)

note the overall strength of evidence for an intervention. In the full report, we include evidence tables and summary tables for 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 can 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 using the approach to strength of evidence described in AHRQ’s Methods Guide for Effectiveness and Comparative Effectiveness Reviews^{30,31} and a standardized strength-of-evidence evaluation sheet with scoring algorithm (shown in the full report). The strength-of-evidence rating was based on:

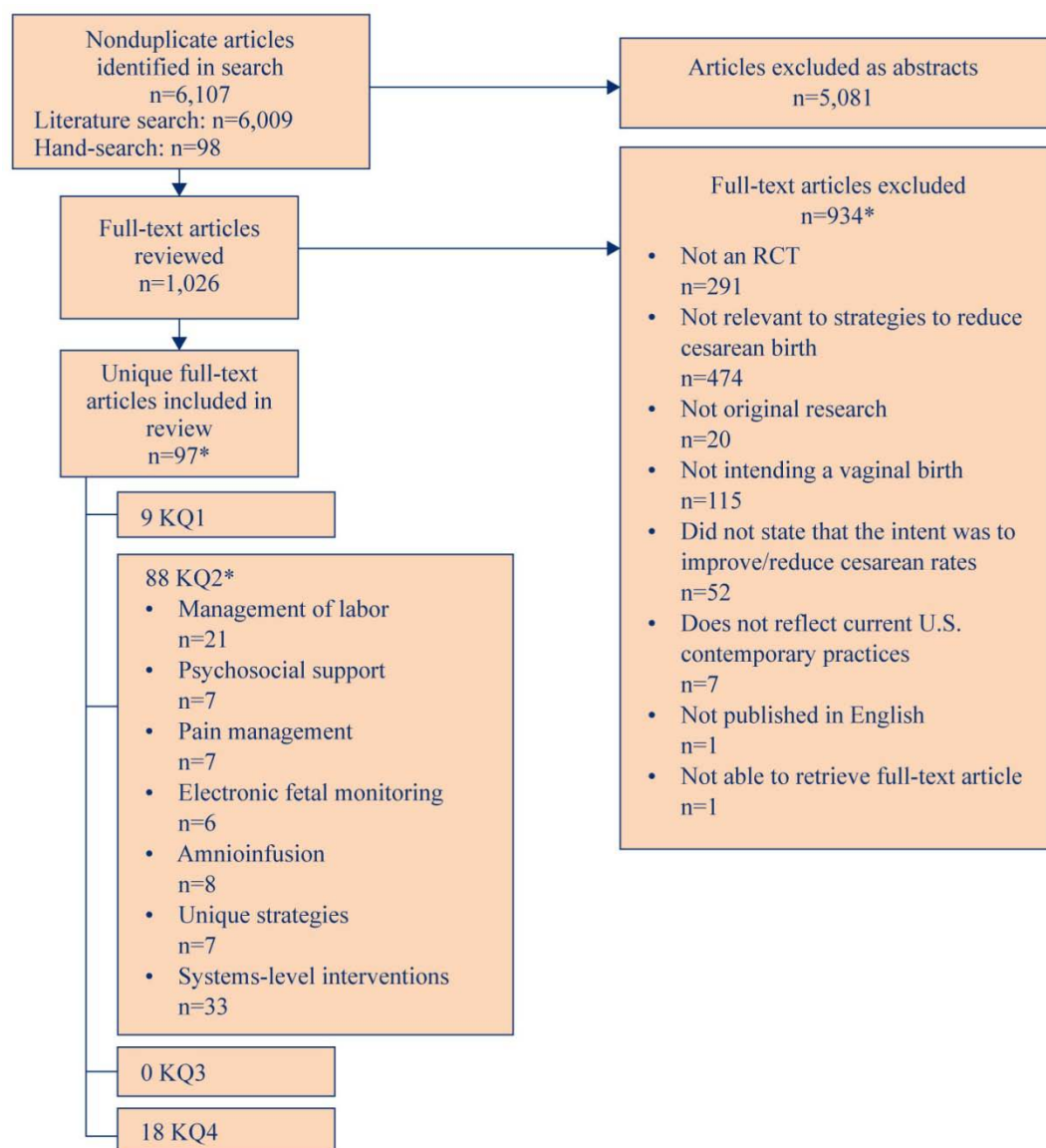
- Risk of bias (low, medium, or high)
- Consistency of findings (inconsistency not present, inconsistency present, or unknown or not applicable)
- Directness (direct comparison of influence on outcomes in RCT or indirect information from observational research)
- Precision (precise or imprecise based on outcome rates, size of individual studies, and total number of women in the studies for the strategy category)

Results

Literature Search Yield

We identified 6,107 nonduplicate publications. Ninety-seven were included in the review (Figure B). They represent 95 distinct study populations. Sixty-eight were RCTs and 29 were pre-post studies of health system changes. The most common reasons for exclusion were ineligible study design and irrelevance to the topic. Nine articles pertain to KQ1, 88 articles to KQ2, no articles to KQ3, and 18 articles to KQ4.

Figure B. Disposition of articles identified by the search strategy



KQ = Key Question

*The numbers of articles addressing KQs and excluded articles exceed the total number of articles in each category because some articles fit multiple exclusion categories or addressed more than one KQ.

KQ1. Effectiveness of Strategies Used During Pregnancy

Nine studies of strategies used during pregnancy were included in the review. Seven trials were rated as fair and two as poor. Three of the nine studies showed statistically significant benefit, but without replication, strength of evidence overall was insufficient. Care by members of a midwifery practice team who provided both prenatal and birth care demonstrated a modest 4.5-percent reduction in cesarean births in one study, with no difference reported in two similar studies. In another study, injection of hyaluronidase into the cervix in the outpatient clinic for patients at term with a low Bishop score promoted cervical softening. This strategy of cervical preparation, or “ripening,” reduced cesarean births by 31 percent. The study was small (n=168),

the vehicle use for the hyaluronidase injections is not allowed in the United States, and no other studies were found that investigated this strategy. Light exercise, strategies 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 strategies reported in individual studies.

The evidence about reducing cesarean through antenatal care models designed to enhance continuity is based on four RCTs with 4,337 participants (Table B). These fair-quality and poor-quality studies had inconsistent findings; two studies found a reduction in cesarean of 4.5 and 11.1 percent, while two found no benefit. This provides insufficient evidence. Each of the other approaches used during pregnancy is represented by a single trial with fewer than 300 participants that provides insufficient evidence to guide care.

KQ2. Effectiveness of Strategies Used During Labor

Management of Labor

Twenty-one studies on labor management strategies were included. Three labor management strategies that significantly reduced the use of cesarean in individual studies, all of good quality, each conducted in a different country (United States, South Africa, and United Kingdom) were: (1) use of a partogram, a graphic representation of the progress of labor, to plot labor progress over a 4-hour versus a 3-hour window (5.8%, odds ratio [OR]=1.8, 95% confidence interval [CI], 1.1 to 3.2; (2) a combined strategy of using a partogram to graph labor progress along with active management to augment labor (7.4%, relative risk [RR]=0.68, 95% CI, 0.50 to 0.93); 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% CI, 0.35 to 0.93, $p=0.02$). Two of these studies addressed carefully documenting the progress of labor in women having their first birth, with structured responses for intervening for slowly progressing labors. The third addressed the management of abnormal progress in a group of women approximately half of whom had a prior birth.

Home-based triage of when a woman in labor should leave for the hospital did not reduce use of cesarean when compared with telephone triage. Early labor assessment done to delay hospital admission until active labor did not reduce use of cesarean when compared with direct admission of women in labor. A midwife-led unit for birth did not reduce use of cesarean when compared with a normal unit and special unit. Cesarean rates were identical in women who did and did not have amniotomy, artificial rupture of the membranes, at the time of hospital admission. Increased intravenous fluids during labor did not reduce use of cesarean. An oral carbohydrate solution increased use of cesarean. Each of these strategies was assessed to have provided insufficient evidence (Table B).

Evidence about measurement of labor progress is conflicting in two studies of good quality, one study of fair quality, and one of poor quality. In contrast to the two trials, mentioned above, that noted benefit for specific uses of partograms, adding a partogram with a 2-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, and the proportion of births by cesarean among women randomized to a 2-hour versus a 4-hour partogram were equivalent. Providing a computerized reference range for assessing labor progress also did not reduce the use of cesarean.

Active management of labor did not reduce the use of cesarean in five studies, and a second study of propranolol administered simultaneously with oxytocin for arrested first stage of labor

did not find a significant reduction in cesarean. The six RCTs of active management have conflicting findings, but as fair- and good-quality studies of more than 5,300 women, they provide low strength of evidence for lack of benefit. Single studies of strategies used during labor provide insufficient evidence to inform care.

Psychosocial Support

We identified seven studies that examined the effect of psychosocial support strategies on cesarean births. One trial was of fair quality and six of poor quality. The three doula-support studies showed a reduction in cesarean births for women in the doula-support groups ranging from 5 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. The specific mechanism by which doula support influences outcomes is unknown. A study using female family members or friends, who received 4 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 with women who received usual labor care. There is low strength of evidence favoring benefit for traditional trained doula support. 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 (Table B).

Pain Management

We identified seven trials that aimed to reduce cesarean by optimizing the pain management approach, predominantly through varied dosing strategies. These included ambulatory versus nonambulatory epidural, epidural with high-dose anesthetic versus epidural with low-dose anesthetic, continuous versus intermittent epidural, promethazine only versus promethazine with paracervical block, intravenous meperidine or epidural versus combined spinal-epidural anesthesia (two studies), and intramuscular pethidine versus epidural with ropivacaine and fentanyl. A single study, judged to be poor quality due to lack of description of the randomization allocation and concealment procedures, reported a threefold reduction in cesareans among women who received intermittent epidural (5%) compared with continuous epidural (15%, $p=0.03$). 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% compared with 49%, $p<0.00001$). The proportion of cesareans was 10.2 percent for the low-dose group and 14.7 percent for the high-dose group, 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. All examined different strategies. 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 B).

Fetal Assessments

Six studies of approaches to assessing fetal well-being in labor were included in this review. Of these, one was good quality and five were fair. Three of the four studies investigating use of fetal pulse oximetry to measure oxygen levels and blood pH demonstrated a significant reduction

in cesarean performed for fetal distress. Reduction in cesareans performed for fetal distress ranged from 5.7 to 24.6 percent; however, knowledge of intrapartum fetal oxygen saturation did not have a significant effect on overall use of cesarean. 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 with 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 9,300 women (Table B).

Amnioinfusion

Eight studies of fetal strategies during labor were included. Three were rated as fair quality and five as poor quality. Amnioinfusion, instilling sterile fluid into the uterus to surround the fetus, is performed for fetal heart tracings indicating potential distress. Four of eight studies found that its use led to 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.

Amnioinfusion to dilute 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, 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 decreased cesarean, although the strength of evidence is insufficient to support its use to prevent cesarean (Table B).

Unique Strategies

Seven studies not amenable to grouping focused on unique strategies to reduce cesarean births. These studies varied in quality, with two good-quality, two fair-quality, and three poor-quality studies. Large single studies, comprising approximately 500 to 2,400 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 compared with usual care. Small studies of other strategies, such as acupuncture, a molded dental device for use during pushing, or a single intravenous dose of propranolol given after admission, did not show reduced risk of cesarean when compared with standard care approaches. As unique studies, these provide insufficient evidence to guide care (Table B).

Systems-Level Strategies

Thirty-three publications in 31 study settings described the findings of systems-level strategies, which included changes in policies, procedures, or protocols intended to reduce cesarean births. From baseline to followup, 18 of 31 studies achieved statistically significant reductions in cesarean, with decreases ranging from 1.6 to 17.0 percent. None of the four systems-level RCTs demonstrated effectiveness. Three of these trials were poor quality and one was fair (Table B).

More than 16 different types of strategy components were 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 exactly the 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 5 percent or more. Ten of these pre-post studies documented reductions in cesarean with strategies 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 were most often provided at both the unit and individual level. The next most common components of successful strategies, with a 5-percent or greater reduction, were tracking of progress of labor using a 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 with unsuccessful systems-level strategies, the overall number of components used in any one study is modestly lower among unsuccessful interventions. Successful and unsuccessful strategies had many components in common. In general, 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 these data mean that the evidence is insufficient to determine if systems-level strategies reduce cesarean.

KQ3. Head-to-Head Comparisons of Strategies

All studies compared the novel strategy with usual care or with a variation on the same strategy.

We did not identify comparisons of distinctive strategies—for instance, doula support versus active management of labor or pain management strategies versus fetal monitoring strategies. Several comparisons evaluated different approaches to the same strategy such as different approaches to epidural dosing or to monitoring progress of labor. These comparisons of variations on like strategies are noted in the sections that discuss those interventions. For now, there is no evidence to inform prioritization of one type of intervention to another.

KQ4. Adverse Effects of Strategies To Reduce Cesarean Birth

Eighteen studies included in the review reported on adverse effects in the populations participating in these studies of strategies to reduce cesarean. Few of the adverse effects presented in the reports had a plausible direct correlation to the strategy used to prevent cesarean birth. Most studies 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 strategy 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 KQs ranged from insufficient to low (Table B). 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 strategy had entirely consistent evidence supporting effectiveness), and variation in reporting of indications for cesarean. At times there was low strength of evidence for lack of benefit. This means that studies with some deficiencies did not demonstrate reduced use of cesarean, but future research could change that assessment.

Table B. 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
<i>KQ1. Strategies During Pregnancy (n=9)</i>					
Antenatal care model 4 (4,337)	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 3 fair-quality studies, 1 poor-quality study
Exercise training 1 (160)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
Management of fear of childbirth 1 (176)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 poor-quality study
Induction of labor for women at-risk for cesarean 1 (270)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
Education on pushing 1 (100)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
Hyaluronidase 1 (168)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
<i>KQ2. Strategies During Labor Management of Labor (n=21)</i>					
Early labor assessment 2 (1,668)	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 2 fair-quality studies with conflicting findings
Midwife-led unit 1 (1,111)	High	N/A	Direct	Imprecise	Insufficient; 1 poor-quality study
Measurement of labor progress 4 (10,823)	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 good-quality studies, 1 fair-quality and 1 poor-quality study
Active management of labor 6 (5,330)	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 good-quality studies, 2 fair-quality studies
Management of abnormal labor 5 (2,764)	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 2 good-quality studies, 2-fair quality studies, 1 poor-quality study
Amniotomy 1 (128)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
Increased intravenous fluids 1 (195)	Low	N/A	Direct	Imprecise	Insufficient; 1 good-quality study
Oral carbohydrate solution 1 (201)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study

Table B. 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
<i>KQ2. Strategies During Labor (continued)</i>					
<i>Psychosocial Support (n=7)</i>					
Doula support 3 (1,136)	High	Consistent	Direct	Precise	Low strength of evidence for benefit; 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-quality studies and 1 fair-quality study
<i>Pain Management (n=7)</i>					
Pain management 7 (5,525)	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 4 poor-quality studies, 2 fair-quality studies, 1 good-quality study
<i>Fetal Assessment (n=6)</i>					
Fetal pulse oximetry 4 (7,098)	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 1 good-quality, 3 fair-quality studies
Fetal assessment by STAN 2 (2,271)	Moderate	Consistent	Direct	Imprecise	Low or moderate evidence for lack of benefit; 2 fair-quality studies
<i>Amnioinfusion (n=8)</i>					
Amnioinfusion for fetal distress 2 (588)	High	Inconsistent	Direct	Imprecise	Insufficient; 1 fair-quality and 1 poor-quality study
Amnioinfusion for meconium 5 (1,565)	High	Inconsistent	Direct	Imprecise	Insufficient; 3 poor-quality and 2 fair-quality studies
Amnioinfusion for oligohydramnios 1 (60)	High	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study

Table B. 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. Strategies During Labor (continued)					
Unique Strategies (n=7)					
Acupuncture 2 (145)	High	Inconsistent	Direct	Imprecise	Insufficient; 2 fair-quality studies
Dental device 1 (64)	High	N/A	Direct	Imprecise	Insufficient; 1 poor-quality study
Allowing eating 1 (2,426)	Low	N/A	Direct	Precise	Insufficient; 1 good-quality study
Inflatable obstetric belt 1 (500)	Low	N/A	Direct	Imprecise	Insufficient; 1 good-quality study
Propranolol 1 (57)	High	N/A	Direct	Imprecise	Insufficient; 1 poor-quality study
Allowing walking 1 (916)	High	N/A	Direct	Precise	Insufficient; 1 poor-quality study
Systems-Level Strategies (n=33)					
Systems-level strategies 33	High	Inconsistent	Indirect	Precise	Insufficient
KQ4. Adverse Effects of Strategies					
Adverse effects 18 (14,075)	Moderate	Inconsistent	Indirect	Imprecise	Insufficient; fair- to poor-quality studies with inconsistent reporting of multiple adverse effects

KQ = Key Question; N/A = not applicable; STAN = ST segment analysis of fetal electrocardiography

Note: See the Methods section 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.

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 that 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 used in more than one setting. For all of the studies included in this review, the comparators were standard obstetric care or 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 whether reductions in cesarean were achieved at the expense of an increase in assisted or complicated vaginal births. The studies reflected the base population of women seeking care in the setting in which the study was done and intending vaginal births. We did not include studies focused only on high-risk populations.

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 to the United States. We have taken care to indicate when this is the case in the detailed tables of the full report. Differences in the health systems, homogeneity of the population, and prevailing rates of cesarean are important to note. While we attempted to restrict the review to trials conducted in settings with clinical care settings similar to those in the United States, this was likely not the case in all instances. Even developed westernized countries may deploy medical resources and have patterns of care that dramatically differ from those in the United States. It is important to note that applicability for guiding care for women in the United States is best served by relatively contemporary U.S. data because cultural norms and health systems factors mitigate against international studies' fully capturing the context of care and populations in the United States.

Conclusions

No particular intervention strategy was uniformly successful in reducing cesareans in all trials of the strategy. Strength of evidence was low to insufficient across all strategies. The only strategy to achieve evidence of benefit was involvement of doulas for personalized support in labor, and that evidence was rated low because of the poor quality of trials.

Several strategies are not supported by the current literature. These include measurement of progress in labor as the primary component of intervention, active management of labor, nursing and midwifery students as support in labor, modifications of pain management approaches, fetal pulse oximetry, and fetal assessment by ST segment analysis of fetal electrocardiography. This does not mean the strategy has no merit and should not be investigated in the future. It does mean that, based on the current literature, there is not evidence of effectiveness for the purpose of reducing cesarean use among low-risk women. For the majority of strategies, the evidence is insufficient, including many instances in which a single study is the only evidence about the approach. While certain components of systems-level interventions were common among successful interventions, none was supported by a randomized trial, and for each instance of inclusion in a successful pre-post intervention, there were instances of unsuccessful use of similar components.

This literature contains intriguing examples of single studies that deserve further exploration. Use of hyaluronidase to hasten cervical changes favorable to labor at term was studied using a vehicle for the injection that is not allowed in the United States. Modifications and safety evaluation would be a prerequisite to future trials. Further exploration of the elements of doula support that were common across successful trials would be informative in order to conduct larger scale replications in U.S. populations. Similarly, use of amnioinfusion to reduce fetal distress appears to reduce cesareans for this indication. More information is needed about why it did not reduce overall use of cesarean. Potential explanatory factors include trials that were underpowered or use of outcome measurements that allow cesareans undertaken for varied reasons to be grouped in uninformative ways. We also need 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. Detailed research in the context of multisite trials is warranted to more carefully parse which tools, individually and combined, have effect. Indeed, the need for future research in this area is clear. Better definition of research needs is the focus of a companion piece to this evidence review: Future Research Needs for Strategies To Reduce

Cesarean Birth in Low-Risk Women. In producing the companion report (Future Research Needs Paper No. 22), information was gathered from multiple stakeholders, including obstetricians, family physicians, midwives, insurers, advocacy groups, and individual women, and a system of information gathering and surveys was used to prioritize the research most urgently needed.

In conclusion, no approach dominated as a strategy appropriate to reduce use of cesarean in low-risk women in the United States. The literature spans the globe and may not have the level of applicability we would desire to contemporary U.S. populations. This is a concern, as cesarean rates among low-risk women continue to rise, and the individual and public benefits of avoiding unnecessary cesarean may be substantial.

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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 2 to 3 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 health care system, is associated with increased risk for both mother and infant, and has the 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 Uterine rupture occurs along the scar line of a prior cesarean and susceptibility is believed to result from relative weakness of the uterine wall at the point of scarring. Placenta accreta and percreta result when placental implantation occurs over or adjacent to scarring and the placenta invades the uterine muscle more deeply. This is believed to occur because the scarred tissue from prior cesarean has a less robust blood supply and abnormal architecture at the tissue and cellular level. 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 increased the use “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 United 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 preferences, and to a lesser extent patient preferences are important drivers of variation.⁹⁻¹²

Goals for reducing cesarean in the United States have become less ambitious over time. The Healthy People 2000 goal was to reduce cesarean to 15 percent of all births.¹³ 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.¹⁴⁻¹⁵ 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.¹⁶⁻¹⁷

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

- Changes in reimbursement for births that favor interventions like cesarean¹⁸
- Amplified perception of risk of medico-legal liability claims for less than perfect infant outcomes or for failing to intervene¹⁹
- Shifts in consumer attitude that include less fear of or regret about cesarean²⁰
- Lower psychosocial or emotional value placed on the experience of vaginal birth²¹
- Concerns about pelvic floor damage and future continence²²⁻²³
- Maternal desire for greater control over the timing and circumstances of birth²⁴ such as maternal request for elective induction and cesarean.²⁵

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.²⁶⁻²⁷

Nonetheless relatively little focus has been placed on research specifically designed to assess strategies to reduce use of cesarean. The notable exception is a 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.²⁸⁻²⁹ 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 systematic evidence 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.

Strategies

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

During prenatal care

- Antenatal care models
- Exercise training
- Management of fear of childbirth
- Induction of labor for women at risk for cesarean
- Structured education for pushing
- Hyaluronidase injection in cervix

During labor

- Early labor assessment
- Midwifery-led care
- Measurement of labor progress
- Active management of labor
- Management of abnormal labor
- Amniotomy (surgical rupture of fetal membranes)
- Increased intravenous fluids
- Psychosocial support, including doulas
- Pain management
- Fetal assessment
- Amnioinfusion
- Unique strategies, including acupuncture and devices

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 adverse effects of strategies employed by pregnant women or their health care providers as reported in the literature. “Adverse effects” are defined by the Evidence Based Practice Center program as the totality of all possible adverse consequences of an intervention.³⁰ We also sought not to duplicate efforts of other recent AHRQ reviews including vaginal birth after cesarean, maternal request for cesarean, and elective induction.³¹⁻³³

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 section 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 section presents the findings of the literature search and the review of the evidence by KQ, synthesizing the findings across strategies. We have organized the sections to (1) summarize the number and crucial descriptors of studies; (2) note the quality of studies; (3) summarize the number of studies that identified benefits of the intervention out of the total; (4) describe interventions that were effective in more detail; and note (5) the overall strength of evidence for an intervention.

The final section of the report discusses the results and enlarges on the methodologic considerations relevant to each KQ. We also outline the current state of the literature and challenges for future research on the strategies to reduce cesarean birth. In addition, we have produced a companion piece to this evidence review: Future Research Needs for Strategies To Reduce Cesarean Birth in Low-Risk Women (Future Research Needs Paper No. 22). Information was gathered from multiple stakeholders, including obstetricians, family physicians, midwives, insurers, advocacy groups, and individual women, and a system of information gathering and surveys was used to prioritize the research most urgently needed.

The report includes a number of appendixes to provide further detail on our methods and the studies assessed. The appendixes 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
- Appendix G: Strength of the Evidence Calculator
- Appendix H: Summary PICOTS table

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 health care 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 Nurses; 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. In conjunction with existing reviews on related topics such as vaginal birth after cesarean, maternal request for cesarean, and elective induction, 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 effectiveness of strategies to reduce cesarean birth.³¹⁻

³³ 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, as well as childbirth education organizations and professionals.

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 low-risk 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 Web site. Working from the nomination we drafted the initial Key Questions (KQs) and analytic framework. The KQ and analytic framework were refined 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.

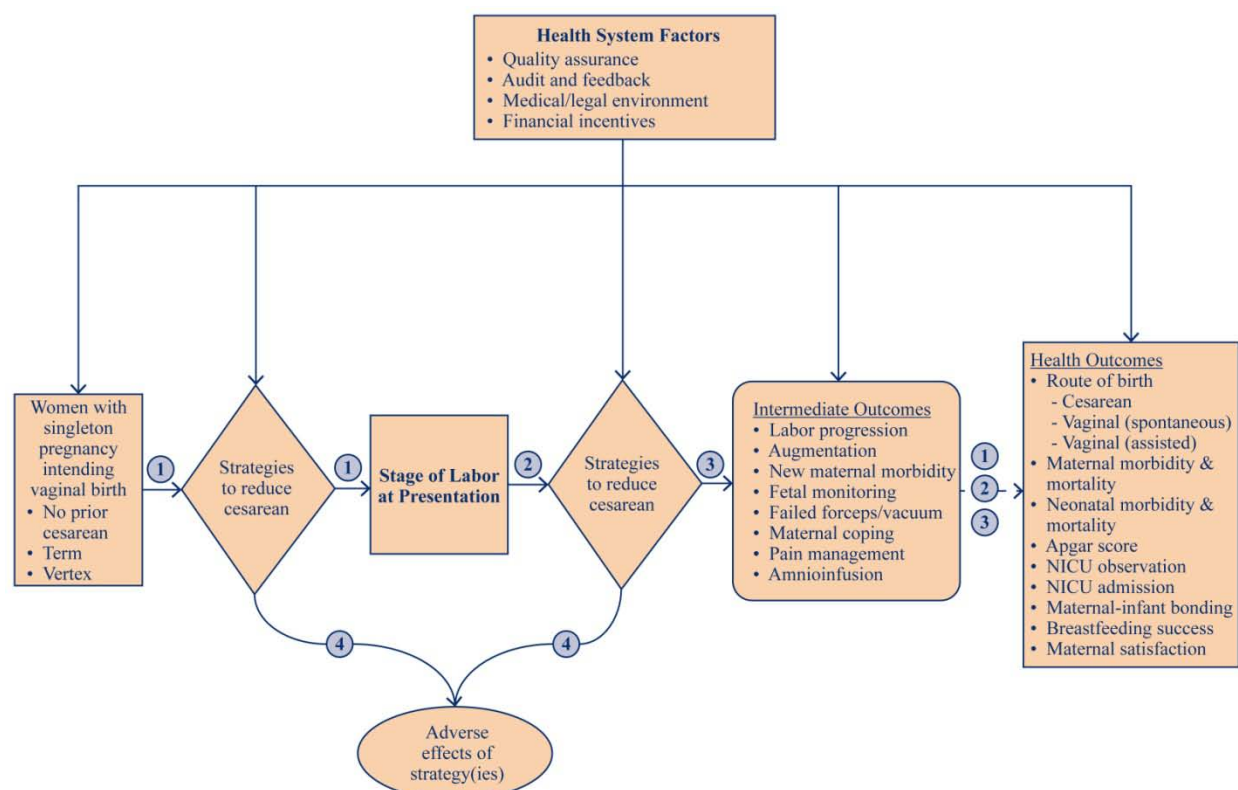
After reviewing the public commentary, we prepared final KQ and submitted them to AHRQ for review. The primary change in response to public comments was to broaden the terminology from “interventions” to “strategies” to more clearly indicate interest in all approaches to reduce cesarean. We identified 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 email 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 for strategies to reduce cesarean birth



NICU = neonatal intensive care unit

Note: 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 strategies, we employed an adapted version of the Cochrane highly sensitive search strategy.³⁴ 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 February 2012. Appendix A provides our search terms and yield for each database.

Process for Study Selection

For this review, the relevant population for all KQs 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)	<u>Admissible designs</u> Randomized controlled trials of strategies (KQ1–4) Pre- and post-studies related to large-scale health systems changes (KQ2 only) <u>Other criteria</u> 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

KQ=Key Question; PICOTS=population, intervention, comparator, outcome, timing, and setting—refers to the framework used by the Effective Health Care Program to summarize study characteristics.

Study Population

For this review, the relevant population for all KQs 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.³⁵ 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. Searches were from the earliest literature currently available, 1968.

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 strategy under study.
- The stated primary or secondary aims indicate intention to examine influence of the strategy on cesarean risk/rate or route of birth.
- The analytic models indicate the authors conducted data analysis of the effect of the strategy as it relates to cesarean risk/rate or route of birth.
- The results 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 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 adverse effects resulting from the use of strategies to reduce cesarean birth. Adverse effects 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 Reviews³⁶ and the Cochrane Handbook for Systematic Reviews of Interventions³⁷ 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.³⁷ 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 KQ

We evaluated the overall strength of the evidence for the primary outcome of reduction of cesarean use for each category of strategy. We used the approach to strength of evidence as described in the EPCs’ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.^{36, 38}

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

- 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 individual studies and the total number of women in the studies for the category of strategy).

The key outcome for each category of strategy 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 strategy 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 strategy could be scored as low evidence of lack of benefit. Two reviewers independently graded the body of evidence and calculated 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 strategy category (Appendix F).

Peer Review and Public Commentary

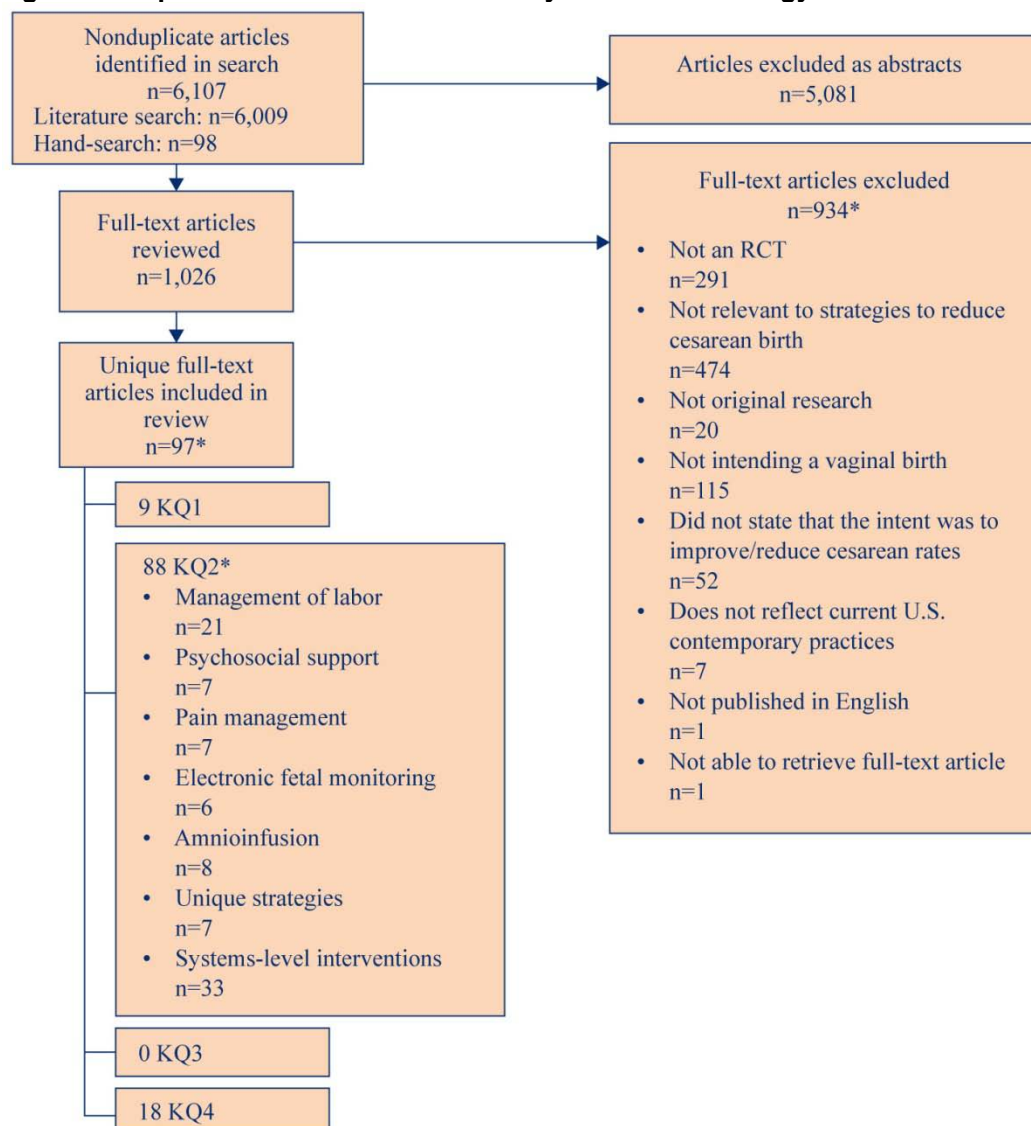
Experts were invited to provide external peer review. The draft report was posted for four weeks to elicit public comment. We addressed all reviewer comments by revising the text as appropriate. We responded to each comment submitted from peer and public review in a disposition of comments report. This report will be available on the AHRQ Web site 3 months after the posting of this final CER.

Results

Article Selection

We identified 6,107 nonduplicate publications through the search process, with 1,026 proceeding to full-text review (Figure 2). Sixty-eight RCTs were included in the review, representing 68 distinct study populations. Sixty-four RCTs were conventional strategy trials and four were RCTs of systems-level strategies. Twenty-nine pre-post studies of large scale health systems changes were also identified.

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.

The most common reasons for exclusion were irrelevance to the topic and ineligible study design (66%). Nine articles pertain to Key Question (KQ) 1, 88 articles to KQ2, zero articles to KQ3, and 18 articles to KQ4. Tables 2 and 30 provide a summary of the strategies to reduce cesarean represented in this review in order from greatest to least observed reduction in cesarean.

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

Author, Year Country	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Choudhary et al., 2010 ³⁹ India	Standard obstetric care without amnioinfusion (146)	63.7	34.2 lower
	Transcervical amnioinfusion (146)	29.5	
Spallicci et al., 2007 ⁴⁰ Brazil	Placebo cervical injection (85)	49.0	31.0 lower
	Hyaluronidase injection in cervix (83)	18.0	
Sanchez-Ramos et al., 1996 ⁴¹ US	Oxytocin plus placebo (47)	51.1	24.6 lower
	Oxytocin plus propranolol (49)	26.5	
Trueba et al., 2000 ⁴² Mexico	Standard care (50)	24.0	22.0 lower
	Childbirth educator trained as doula (50)	2.0	
Kuhnert et al., 2004 ⁴³ 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 ⁴⁴ Egypt	Standard obstetric care without amnioinfusion (219)	68.0	20.1 lower
	Transcervical amnioinfusion (219)	47.9	
Rathor et al., 2002 ⁴⁵ India	Standard obstetric care without amnioinfusion (100)	36.0	15.0 lower
	Transcervical amnioinfusion (100)	21.0	
McGrath and Kennell, 2008 ⁴⁶ US	Routine care (196)	25.0	11.6 lower
	Doula support (224)	13.4	
Harvey et al., 1996 ⁴⁷ Canada	Physician care (93)	15.1	11.1 lower
	Nurse-midwife care (101)	4.0	
Kennell et al., 1991 ⁴⁸ US	Control group assigned after birth (204)	18.0	10.0 (control vs. doula) 5.0 (control vs. observer) lower
	Received support of a doula (212)	8.0	
	Observed by an inconspicuous observer (200)	13.0	
Skrablin et al., 2011 ⁴⁹ Croatia	Continuous epidural (104)	14.4	9.4 lower
	Intermittent epidural (101)	5.0	
Pattinson et al., 2003 ⁵⁰ South Africa	Expectant management (350)	23.4	7.4 lower
	Aggressive management (344)	16.0	
Lavender et al., 1998 ⁵¹ 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 ⁵² Australia	Standard hospital-based care(539)	17.8	4.5 lower
	Community-based model care (550)	13.3	
Harper et al., 2006 ⁵³ US	Usual care (26)	39.0	22.0 same
	Acupuncture sessions (30)	17.0	

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

Author, Year Country	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Bidgood et al., 1987 ⁵⁴ 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 ⁵⁵ US	Usual care (32)	25.0	12.5 same
	Dental support device during active pushing (32)	12.5	
Garite et al., 2000 ⁵⁶ US	Standard intravenous fluids of 125 ml/hr (94)	17.0	7.1 same
	Increased intravenous fluids (101)	9.9	
Moodley et al., 1998 ⁵⁷ South Africa	Standard obstetric care without amnioinfusion (30)	47.0	7.0 same
	Transcervical amnioinfusion (30)	40.0	
Karraz, 2003 ⁵⁸ 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 ⁵⁹ US	Standard care (30)	20.0	7.0 same
	Amnioinfusion (30)	13.0	
Adamsons et al., 1999 ⁶⁰ Puerto Rico	Usual care (23)	17.4	5.7 same
	Propranolol during labor (34)	11.7	
Saisto et al., 2001 ⁶¹ Finland	Conventional therapy (91)	48.4	4.9 same
	Intensive therapy (85)	43.5	
Nicholson et al., 2008 ⁶² US	Standard care (134)	14.9	4.6 same
	Induction of labor (136)	10.3	
Olofsson et al., 1998 ⁶³ 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 ⁶⁴ US	Usual care (205)	11.7	4.2 same
	Active management (200)	7.5	
Phipps et al., 2009 ⁶⁵ Australia	Standard care (50)	26.0	4.0 same
	Structured education for pushing (50)	22.0	
Lopez-Zeno et al., 1992 ⁶⁶ US	Traditional management (354)	14.1	3.6 same
	Active management (351)	10.5	
Hemminki et al., 1990 ⁶⁷ Finland	Usual care (118)	5.0	3.0 same
	Midwifery student support (122)	2.0	
McNiven et al., 1998 ⁶⁸ Canada	Direct admission (104)	10.6	3.0 same
	Early labor assessment (105)	7.6	

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

Author, Year Country	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Vayssiere et al., 2007 ⁷⁰ France	Fetal monitoring with cardiotocography only (400)	16.3	2.8 same
	Fetal monitoring with cardiotocography and STAN (399)	13.5	
Mahomed et al., 1998 ⁶⁹ Zimbabwe	Standard obstetric care without amnioinfusion (336)	11.3 ^b	1.8 same
	Transcervical amnioinfusion (325)	9.5	
Somprasit et al., 2005 ⁷¹ Thailand	Conventional management (640)	14.7	2.8 same
	Active management (320)	11.9	
Bernitz et al., 2011 ⁷² Norway	Special unit (282)	18.8	2.8 same
	Normal unit (417)	18.0	
	Midwife-led unit (412)	16.0	
Gagnon et al., 1997 ⁷³ Canada	Usual nursing care (204)	16.2	2.3 same
	One-to-one nursing care (209)	13.9	
East et al., 2006 ⁷⁴ 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 ⁷⁵ US	Usual care (531)	6.0	2.0 same
	Walking during 1 st stage of labor (536)	4.0	
Mehrangiz et al., 2004 ⁷⁶ Iran	Promethazine only (50)	4.0	2.0 same
	Paracervical block with promethazine (50)	2.0	
Waldenstrom et al., 1997 ⁷⁷ Sweden	Standard maternity care (932)	8.9	1.8 same
	Birth center care (928)	7.1	
World Health Organization, 1994 ⁷⁸ Indonesia, Thailand, Malaysia	Baseline (10,049)	6.2	1.7 same
	Use of WHO partogram to guide active management of labor and decisions about cesarean (9,130)	4.5	
Cohen et al., 1987 ⁷⁹ US	Control (75)	14.6	1.3 same
	Early aggressive management (75)	13.3	
Bloom et al., 2006 ⁸⁰ US	Fetal pulse oximetry with oxygen saturation not displayed to clinician (2,712)	27.5	1.2 same
	Fetal pulse oximetry with oxygen saturation displayed to clinician (2,629)	26.3	
Hofmeyr et al., 1998 ⁸¹ South Africa	Standard obstetric care without amnioinfusion (176)	43.0	1.0 same
	Transcervical amnioinfusion (176)	42.0	
Windrim et al., 2007 ⁸² 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	
Sadler et al., 2000 ⁸³ New Zealand	Routine management (331)	9.7	0.3 same
	Active management (320)	9.4	

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

Author, Year Country	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Barakat et al., 2009 ⁸⁴ Spain	No exercise training (80)	15.7	0.4 same
	Exercise training (80)	15.3	
Althabe et al., 2004 ⁸⁵ South America	Usual care (39,175)	24.9	0.2 same
	Mandatory second opinion driven by evidence-based guidelines for indications (34,735)	24.7	
Hodnett et al., 2002 ⁸⁶ US & Canada	Usual care (3,461)	12.6	0.1 same
	Nurse support (3,454)	12.5	
Frigoletto et al., 1995 ⁸⁷ US	Active management (1,009)	19.5	0.1 same
	Usual care (906)	19.4	
Ajadi et al., 2006 ⁸⁸ Nigeria	No amniotomy on admission (64)	1.6	0.0 same
	Amniotomy on admission (64)	1.6	
Elferink-Stinkens et al., 2004 ⁸⁹ Netherlands	Usual care (>130,000)	NR	0.0 same
	Report of departmental data in table and graph form with follow-up (>130,000)	NR	
Hinshaw et al., 2008 ⁹⁰ UK	Delayed oxytocin (204)	13.7	0.0 same
	Early oxytocin (208)	13.7	
Lavender et al., 2006 ⁹¹ UK	4-hour partogram (1,485)	9.1	0.0 same
	2-hour partogram (1,490)	9.1	
O'Sullivan et al., 2009 ⁹² UK	Usual care (1,216)	30.0	0.0 same
	Allowed to eat during labor (1,227)	30.0	
Waldenstrom et al., 2001 ⁹³ Sweden	Standard care (505)	11.9	0.0 same
	Team midwife care (495)	11.9	
Hamilton et al., 2004 ⁹⁴ US & Canada	Labor progress evaluated by plotting cervical dilatation against time (2,514)	16.9	-0.7 same
	Computerized reference range used to evaluate labor progress (2,474)	17.6	
Gambling et al., 1998 ⁹⁵ US	Intravenous meperidine analgesia (607)	5.6	-0.7 same
	Combined spinal-epidural anesthesia (616)	6.3	
Campbell et al., 2006 ⁹⁶ US	Standard care (300)	17.9	-1.0 same
	Lay doula support (298)	18.9	
Norris et al., 2001 ⁹⁷ US	Epidural analgesia (1,112)	13.4	-1.1 same
	Combined spinal-epidural anesthesia (1,071)	14.5	
Regi et al., 2009 ⁹⁸ India	Standard obstetric care without amnioinfusion (75)	37.3	-1.1 same
	Transcervical amnioinfusion (75)	38.4	
Ojala et al., 2006 ⁹⁹ Finland	Fetal monitoring with cardiotocography only (739)	4.7	-1.7 same
	Fetal monitoring with STAN (733)	6.4	

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

Author, Year Country	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Cox et al., 1999 ¹⁰⁰ UK	Usual care (240)	3.8	-2.0 same
	Inflatable obstetric belt (260)	5.8	
Garite et al., 2000 ¹⁰¹ 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 ¹⁰² Canada	Telephone triage (731)	25.4	-3.2 same
	Home-based triage (728)	28.6	
Jalil et al., 2009 ¹⁰³ Malaysia	IM pethidine analgesia (98)	7.1	-4.6 same
	Epidural ropivacaine 0.2% with fentanyl 2 µg/ml (94)	11.7	
Palomäki et al., 2006 ¹⁰⁴ Finland	Oxytocin plus placebo (55)	4.0	-7.0 same
	Oxytocin plus propranolol (55)	11.0	
Asher et al., 2009 ¹⁰⁵ US	Acupuncture (30)	20.0	-10.0 3.0 same
	Usual care (no acupuncture) (30)	10.0	
	Sham acupuncture (29)	7.0	
Scheepers et al., 2002 ¹⁰⁶ Netherlands	Placebo (99)	7.1	-13.5 higher
	Oral carbohydrate solution (102)	20.6	

^a**Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the strategy and comparison arms of the trial, **higher** indicates a higher rate supported by statistical significance

^bReported in text as 12.3, but based on data presented should be 11.3

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?

Overview of the Literature

Nine studies of strategies used during pregnancy were included in the review (Table 3).^{40, 47, 52, 61-62, 65, 77, 84, 93} 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,⁶² one study of cervical ripening with injection of hyaluronidase in clinic was conducted in Brazil,⁴⁰ and the balance were conducted in Europe and Australia. Seven trials were rated as fair,^{40, 47, 62, 65, 77, 84, 93} and two as poor (Appendices E and H).^{52, 61}

Key Points

- Evidence about reducing cesarean through antenatal care models designed to enhance continuity is based on four RCTs with 4,337 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 strategy.

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

Author, Year Country; Quality	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Spallicci et al., 2007 ⁴⁰ Brazil; Fair	Placebo cervical injection (85)	49.0	31.0 lower
	Hyaluronidase injection in cervix (83)	18.0	
Harvey et al., 1996 ⁴⁷ Canada; Fair	Physician care (93)	15.1	11.1 lower
	Nurse-midwife care (101)	4.0	
Homer et al., 2001 ⁵² Australia; Poor	Standard hospital-based care (539)	17.8	4.5 lower
	Community-based model care (550)	13.3	
Saisto et al., 2001 ⁶¹ Finland; Poor	Conventional therapy (91)	48.4	4.9 same
	Intensive therapy (85)	43.5	
Nicholson et al., 2009 ⁶² US; Fair	Standard care (134)	14.9	4.6 same
	Induction of labor (136)	10.3	
Phipps et al., 2009 ⁶⁵ Australia; Fair	Standard care (50)	26.0	4.0 same
	Structured education for pushing (50)	22.0	
Waldenstrom et al., 1997 ⁷⁷ Sweden; Fair	Standard maternity care (932)	8.9	1.8 same
	Birth center care (928)	7.1	
Barakat et al., 2009 ⁸⁴ Spain; Fair	No exercise training (80)	15.7	0.4 same
	Exercise training (80)	15.3	
Waldenstrom et al., 2001 ⁹³ 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 strategy 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 strategies 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 1,283 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.⁵² 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% confidence interval (CI): 0.4, 0.9; p=0.02).⁵²

Another RCT conducted in Australia randomized 1,000 pregnant women with uncomplicated pregnancies prior to 25 weeks gestation to either team midwifery care or standard obstetric care.⁹³ 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%) had a cesarean, compared to 56 of 471 (11.9%) receiving standard care (OR=1.00, 95% CI: 0.66, 1.15). There was no difference between the reported neonatal outcomes for the intervention and control groups (mortality 1.1% vs. 1.5%, 5-minute Apgar <7 1.9% vs. 1.5%, NICU admission 10.3% vs. 7.6% [OR=1.4, 95% CI: 0.87, 2.26]) (Tables 4 and 5).⁹³

A pilot study of nurse-midwifery care compared to physician care in Canada randomized 194 women from the community.⁴⁷ Women in the control group chose their physician, any obstetrician or family physician in the city, using a standard referral process. Women assigned to nurse-midwife care received care from a team of seven nurse-midwives. The scheduling for the midwifery clinic was designed so that women saw as many of the midwives as possible during their antenatal clinic visits. Women who received care from the nurse-midwives were significantly less likely to have a cesarean. Of the women receiving midwifery care 4 of 101 (4.0%) had a cesarean compared to 14 of 93 (15.1%) of those who received physician care (95% CI: 2.89, 19.3%; p=0.01). More infants in the physician care group had Apgar scores less than seven at one minute (13.9% vs. 29.0, 95% CI: 3.75, 26.6%; p=0.013) and were admitted to the NICU (7.9% vs. 19.4, 95% CI: 1.8, 2.1%; p=0.02). There were no neonatal deaths in either group.⁴⁷

A Swedish RCT randomized 1,860 women at their first or second antenatal visit to either a birth center care model or a standard care model.⁷⁷ The birth center care model was comprehensive and integrated antenatal, intrapartum and postpartum care with the same team of midwives. Their practice, which is in a hospital-based birth center, 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. While midwives were the primary caregivers in this model, as well, there were separate antenatal and intrapartum midwife teams.⁷⁷

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% CI: -4.3, 0.7; p=0.18).⁷⁷ Neonatal outcomes for the intervention and control groups did not differ (mortality 0.9% vs. 0.2 percent, five-minute Apgar less than seven 1.3% vs. 1.1 percent, and special care nursery admission 11.1% vs. 9.0%).⁷⁷

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	2.2-3.0 ^{47, 62}	NR	2.6-12.7 ^{47, 52, 77, 93} (4)	0 ^{47, 77}
Antenatal care, community model ⁵² , birth center ⁷⁷ , team midwife care ^{47, 93}	1.0 ⁴⁷	NR	1.6-12.5 ^{47, 52, 77, 93} (4)	0 ^{47, 77}
Exercise training ⁸⁴	NR	NR	NR	NR
Education on pushing ⁶⁵	NR	NR	NR	NR
Hyaluronidase injection in cervix ⁴⁰	NR	NR	NR	NR
Induction ⁶²	4.4	NR	NR	NR
Intensive therapy for fear of childbirth ⁶¹	NR	NR	NR	NR

NR=not reported

Exercise Training

Physical activity has been associated with reduced maternal complications in pregnancy and may have potential to reduce cesarean risk.¹⁰⁸⁻¹⁰⁹ 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.⁸⁴ 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% vs. 15.7%).⁸⁴

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.⁶¹ 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.⁶¹

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 \pm SD (n Studies)	Mortality,% (n Studies)
Control	0.8-8.2 ^{40, 47, 52, 62, 77, 93} (6) ^a	6.7-19.4 ^{47, 52, 62, 77, 93} (5)	10.2-17.2 ^{77, 93} (2)	0-1.5 ^{47, 52, 77, 93} (4)
Antenatal care, community model ⁵² , birth center ⁷⁷ , team midwife care ^{47, 93}	1.3-4.0 ^{47, 52, 77, 93} (4)	7.9-14.5 ^{47, 52, 77, 93} (4)	9.6-11.1 ^{77, 93} (2)	0-1.1 ^{47, 52, 77, 93} (4)
Exercise training ⁸⁴	9.9 \pm 0.2 ^b	NR	NR	NR
Education on pushing ⁶⁵	NR	NR	NR	NR
Hyaluronidase injection ⁴⁰	2.4 ^b	NR	NR	NR
Induction ⁶²	0	1.5	NR	0
Intensive therapy for fear of childbirth ⁶¹	NR	NR	NR	NR

NICU=neonatal intensive care unit^a Not specified if 1, 5, or 10 minute Apgar score; ^b Mean \pm SD; Control group: 9.9 \pm 0.3⁸⁴
NR=not reported

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.⁶² 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 \geq 30 kg/m², (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 8 lbs 8 oz. 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 statistically the same across groups: 10.3 percent among the intervention group and 14.9 percent among those who received standard care, in this study powered to detect a 66 percent relative difference.⁶² There was no difference between these reported neonatal outcomes for the intervention and control groups: (mortality 0.0% vs. 0.8%, 5-minute mean Apgar score 8.9 vs. 8.9, 5-minute Apgar score less than 7 0.0% vs. 0.8%). NICU admission rates for the intervention were lower for the intervention group (1.5% vs. 6.7%: RR=0.22, 95% CI: 0.05, 0.99; p=0.03).⁶²

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.⁶⁵ The strategy 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 percent among those receiving standard care. The study had inadequate sample size to detect differences in cesarean risk.⁶⁵ Use of episiotomy and incidence of perineal tears did not differ between the groups.⁶⁵

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.⁴⁰ The strategy consisted of 5 ml of 20,000 IU 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 strategies: 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 2,684 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% CI: 18, 44; $p < 0.0001$).⁴⁰ 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.⁴⁰

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?

Management of Labor

Overview of the Literature

This section presents results of 21 studies meeting our review criteria and addressing strategies for management of labor. These strategies 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 (two trials);^{68, 102} a midwife-led unit;⁷² measurement of labor progress with a partogram, a graphic representation of the progress of labor, or computerized reference curve (four trials);^{51, 82, 91, 94} active management of labor (six trials);^{50, 64, 66, 71, 83, 87} management of abnormal labor (five trials);^{41, 54, 79, 90, 104} amniotomy (one trial);⁸⁸ intravenous (IV) fluids (one trial);⁵⁶ and an oral carbohydrate solution (one trial).¹⁰⁶ Of the 17 trials, six were conducted in the United States,^{41, 56, 64, 66, 79, 87} four in the UK,^{51, 54, 90-91} three in Canada,^{68, 82, 102} one in the Netherlands,¹⁰⁶ one in Norway,⁷² one in Finland,¹⁰⁴ one in New Zealand,⁸³ one in Thailand,⁷¹ one in Nigeria,⁸⁸ one in South Africa,⁵⁰ and one was multinational

(US and Canada)⁹⁴. All but three of the trials^{41, 72, 104} included only nulliparous women. Two studies were published in the 1980s,^{54, 79} six studies in the 1990s,^{41, 51, 64, 66, 68, 87}; and 13 studies in 2000 or later.^{50, 56, 71-72, 82-83, 88, 90-91, 94, 102, 104, 106} There were five trials of good quality,^{41, 50-51, 56, 91} seven of fair quality,^{54, 68, 82, 88, 102, 104, 106} and nine of poor quality (Appendices E and H).^{64, 66, 71-72, 79, 83, 87, 90, 94}

Key Points

- 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.
- 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.
- Each of the early labor assessment strategies was found to provide insufficient evidence (Table 34). The four studies of measurement of labor progress, which enrolled 10,832 women, provide low strength of evidence for lack of benefit of partograms for reducing cesarean. The six RCTs of active management have conflicting findings but as good and poor quality studies of more than 5,300 women, they provide low strength of evidence for lack of evidence of benefit. Single studies provide insufficient evidence to inform care.
- 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.
- A midwife-led unit, compare to a normal unit and special unit, did not reduce the use of cesarean.
- Active management of labor, as defined by the authors, did not reduce the use of cesarean.
- 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 4-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.
- 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.
- An oral carbohydrate solution increased 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.¹¹⁰⁻¹¹¹ Two Canadian trials of fair quality assessed the effect of early labor assessment strategies (see Table 6 below).^{68, 102} A trial of 1,459 nulliparous women compared home-based triage (n=728) with telephone triage (n=731).¹⁰² 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%) than the telephone triage group (25.4%), but this difference was not statistically significant (RR=1.12, 95% CI: 0.94, 1.32). Five-minute Apgar scores (RR=1.52, 95% CI 0.54-4.23), admission to a Level II nursery (RR=0.93, 95% CI: 0.63, 1.37), and admission to a Level III nursery (RR=2.35, 95% 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	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
McNiven et al., 1998 ⁶⁸ Canada; Fair	Direct admission (104)	10.6	3.0 same
	Early labor assessment (105)	7.6	
Janssen et al., 2006 ¹⁰² Canada; Fair	Telephone triage (731)	25.4	-3.2 same
	Home-based triage (728)	28.6	

^aSame indicates the use of cesarean was not statistically different across the strategy 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.⁶⁸ Women in the early labor assessment group were evaluated and only admitted to the labor and delivery unit if they were in active labor, defined as the presence of regular, painful contractions and cervical dilation greater than 3 cm. 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%) than the direct admission group (10.6%), but this difference was not statistically significant (OR=0.70, 95% CI: 0.27, 1.81).⁶⁸ As shown in Table 11, the percentage of infants with Apgar scores lower than seven at five minutes was comparable (p=0.318).⁶⁸

Midwifery-Led Care

According to the U.K.'s National Institute for Health and Clinical Excellence, low-risk women who give birth in a midwife-led unit are more likely to have a normal birth with less intervention.¹¹² A poor quality trial from Norway compared outcomes for nulliparous and multiparous women who gave birth in 1) a midwife-led unit for low-risk women who wanted as little intervention as possible where epidural and augmentation outside of the second phase of second stage of labor were not available (n=412); 2) a normal unit for women with expected normal births where extended surveillance, epidural, operative vaginal birth, cesareans, and induction of labor were offered (n=417); and 3) a special unit for women requiring extended surveillance in the antepartum period, during labor, or after birth (n=282).⁷² Women expecting normal births can give birth at any of the three units; however, the midwife-led unit only accepts low-risk women. Eligible women who desired to participate were randomized to one of the three

units at the onset of spontaneous labor. The percentage of women who had a cesarean birth was lower in the midwife-led unit (16.0%) than the normal unit (18.0%) or special unit (18.8%), but these differences were not statistically significant (midwife-led unit vs. normal unit RR=0.90, 95% CI: 0.67, 1.22; midwife-led unit vs. special unit RR=0.87, 95% CI: 0.62, 1.20).⁷² The percentage of women with postpartum hemorrhage, neonates with Apgar score less than seven at five minutes, and NICU admissions did not differ significantly across groups (Tables 10 and 11).⁷²

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.¹¹³ 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.¹¹⁴ Four trials investigated strategies to measure labor progress. Three involved partograms,^{51, 82, 91} and the fourth used a computerized reference range (Table 7).⁹⁴

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

Author, Year Country; Quality	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Lavender et al., 1998 ⁵¹ 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 ⁸² 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 ⁹¹ UK; Good	4-hour partogram (1,485)	9.1	0 same
	2-hour partogram (1,490)	9.1	
Hamilton et al., 2004 ⁹⁴ US & Canada; Poor	Labor progress evaluated by plotting cervical dilatation against time (2,514)	16.9	-0.7 same
	Computerized reference range used to evaluate labor progress (2,474)	17.6	

^a**Lower** indicates a lower rate supported by statistical significance; **same** indicates the use of cesarean was not statistically different across the strategy 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 1,962 participants.⁸² 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%), but this difference was not statistically significant (p=NS reported with no specific value given).⁸² The differences in rates of maternal fever, five-minute Apgar scores less than seven, and NICU admission were not statistically significant (test results 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 nulliparous 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.¹¹⁴ 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).^{51, 91} In the first trial,⁵¹ 315 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%) followed by the two-hour group (11.1%) and the three-hour group (14.2%).⁵¹ When the intervals were compared (2-hour vs. 3-hour, 3-hour vs. 4-hour, and 2-hour vs. 4-hour), only the results for the 4-hour versus the 3-hour were significant (OR=1.8, 95% CI: 1.1, 3.2).⁵¹ In the second trial,⁹¹ 1,490 women had a partogram with a 2-hour action line, and 1,485 women had a partogram with a 4-hour action line. The rate of cesarean birth in both groups was identical (9.1%).⁹¹ Both trials had rates of postpartum hemorrhage, 5-minute Apgar scores less than seven, and NICU admission that did not differ significantly across groups (see Tables 10 and 11).^{51, 91}

One trial in 4,988 women evaluated the addition of a computerized reference range to standard measurement of labor progress by plotting cervical dilatation against time in nulliparous women.⁹⁴ 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% CI: 0.92, 1.18).⁹⁴ 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.”¹¹³ The purpose of active management of labor is to decrease the incidence of dystocia, which should in turn decrease the cesarean rate.⁶⁶ 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% CI: 0.63, 0.94) when a trial in which more than one-third of participants become ineligible after randomization was removed from the analysis.¹¹⁵ The Cochrane review differed from this report in that it specifically sought studies examining active management regardless of low-risk status or primary aim of reducing cesarean.¹¹⁵

Six trials examined use of active management of labor for cesarean reduction; one demonstrated effectiveness (Table 8).^{50, 64, 66, 71, 83, 87} This trial of good quality in South Africa combined use of a partogram with aspects of active management.⁵⁰ 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.⁵⁰ 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% CI: 0.50, 0.93).⁵⁰ 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.⁵⁰ 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% CI: 0.37, 137.37).⁵⁰

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

Author, Year Country; Quality	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Pattinson et al., 2003 ⁵⁰ South Africa; Good	Expectant management (350)	23.4	7.4 lower
	Aggressive management (344)	16.0	
Rogers et al., 1997 ⁶⁴ US; Good	Usual care (205)	11.7	4.2 same
	Active management (200)	7.5	
Lopez-Zeno et al., 1992 ⁶⁶ US; Poor	Traditional management (354)	14.1	3.6 same
	Active management (351)	10.5	
Somprasit et al., 2005 ⁷¹ Thailand; Poor	Conventional management (640)	14.7	2.8 same
	Active management (320)	11.9	
Sadler et al., 2000 ⁸³ New Zealand; Poor	Routine management (331)	9.7	0.3 same
	Active management (320)	9.4	
Frigoletto et al., 1995 ⁸⁷ US; Poor	Active management (1009)	19.5	0.1 same
	Usual care (906)	19.4	

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

A New Zealand trial of poor quality randomized 551 nulliparous women to active (n=320) or routine (n=331) management when labor was diagnosed, which was defined as regular, painful contractions every five minutes or more lasting at least 40 seconds accompanied by either spontaneous rupture of membranes or complete cervical effacement with cervical dilatation of at least two centimeters.⁸³ In the active management group, amniotomy was encouraged at the time of labor diagnosis, and the cervix was assessed every two hours. Oxytocin augmentation was initiated if cervical dilation was less than one centimeter per hour, descent of the fetal head had

not occurred after 30 minutes of pushing, or contractions were more than five minutes apart without imminent birth during the second stage of labor. Oxytocin was started at 6 mU per minute and increased by 6 mU every 15 minutes to a maximum dose of 36 mU per minute. In the routine management group, the caregiver determined use of amniotomy, frequency of cervical examination, and use of oxytocin.⁸³ The cesarean rate was 9.4 percent in the active management group and 9.7 percent in the routine management group ($p=0.5$).⁸³ The groups did not differ significantly in maternal infection (RR = 1.12; 95% CI: 0.72, 1.74) or postpartum hemorrhage (RR=1.04, 95% CI: 0.72, 1.51; see Table 10).⁸³

In a U.S. trial of poor quality, nulliparous women were randomized to active management ($n=1,009$) or usual care ($n=906$) before 30 weeks' gestation.⁸⁷ Women in the active management group attended special childbirth classes to explain the protocol, while women in the usual care group were given payment to attend the classes of their choice. Active management was provided in a separate unit by nurse-midwives and nurses who worked exclusively for the study. Active management included one-to-one nursing care and standardized criteria for labor diagnosis (painful contractions with effacement of at least 80 percent, bloody show, or spontaneous rupture of membranes). Women in the active management group had amniotomy within one hour of labor diagnosis and cervical examinations at least every two hours. Women who had inefficient uterine action (cervical dilation of less than one centimeter per hour during first stage or greater than one hour between full dilatation and the fetal head reaching the pelvic floor during second stage) or more than 30 minutes elapsed between the fetal head reaching the pelvic floor and the birth received oxytocin (started at 4 mU per minute and increased by 4 mU every 15 minutes to a maximum dose of 40 mU per minute).⁸⁷ Care of women with failure to progress (cervical dilation less than one centimeter per hour after efficient uterine action was established with oxytocin or prolonged second stage) was assumed by the woman's regular provider. No constraints were placed on management of the usual care group. Use of amniotomy, initiation of oxytocin, and cervical examination were at the provider's discretion. When oxytocin was used, it was typically started at a dose of one to two mU per minute and increased by 1-2 mU per minute periodically. The rate of cesarean was 19.5 percent in the active management group and 19.4 percent in the usual care group (RR=1.0, 95% CI: 0.8, 1.2).⁸⁷ Among the protocol-eligible subgroup ($n=678$ active management, $n=585$ usual care), incidence of maternal fever was lower in the active management group than the usual care group (n not provided; RR=0.6, 95% CI: 0.4, 0.9).⁸⁷ There was no significant difference between groups in admission to the NICU (n and statistical test result not provided).⁸⁷

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.⁶⁶ 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 1 mU per minute and increased by 1-2 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 ($p=0.18$).⁶⁶

The active management group had a significantly lower rate of chorioamnionitis than the traditional management group (4.6% vs. 9.9% percent, $p < 0.01$).⁶⁶ Differences in five-minute Apgar scores less than seven and NICU admission rates were not significant (test result not reported, see Table 11).⁶⁶ No neonatal deaths occurred in either group.⁶⁶

Another U.S. trial of poor quality enrolled 405 nulliparous women.⁶⁴ 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.⁶⁴ 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.⁶⁴ Maternal and neonatal outcomes were similar in both groups (not statistically significant, no test results reported, see Tables 10 and 11).⁶⁴

In a poor quality trial of 960 nulliparous women in Thailand,⁷¹ 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 2 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.⁷¹ 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%) than the conventional management group (14.7%), but this difference was not significant (p -value not reported).⁷¹ 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 (Tables 10 and 11).⁷¹

Management of Abnormal Labor

Five trials assessed strategies for managing abnormal labor (see Table 9).^{41, 54, 79, 90, 104} One resulted in proven reduction of cesarean. 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.⁹⁰ 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.⁹⁰ Cesarean risk was identical in the two groups (14%), and there were no significant differences in postpartum hemorrhage (OR=0.87, 95% CI: 0.5, 1.4), five-minute Apgar scores (OR=1.6, 95% CI: 0.4, 7.0), NICU admission (OR=1.2, 95% CI: 0.4, 3.9), or neonatal death (OR=0.98, 95% CI: 0.06, 16) (Tables 10 and 11).⁹⁰

Two trials, one of good quality in the U.S.⁴¹ and one of fair quality in Finland,¹⁰⁴ 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.⁴¹ 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.⁴¹ The cesarean rate was 26.5 percent in the propranolol group and 51.1 percent in the placebo group (RR=0.58, 95% CI: 0.35, 0.93; p=0.02).⁴¹ 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.¹⁰⁴ 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.¹⁰⁴ 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 (Table 11).¹⁰⁴

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

Author, Year Country; Quality	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Sanchez-Ramos et al., 1996 ⁴¹ US; Good	Oxytocin plus placebo (47)	51.1	24.6 lower
	Oxytocin plus propranolol (49)	26.5	
Bidgood et al., 1987 ⁵⁴ 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 ⁷⁹ US; Poor	Control (75)	14.6	1.3 same
	Early aggressive management (75)	13.3	
Hinshaw et al., 2008 ⁹⁰ UK; Poor	Delayed oxytocin (204)	13.7	0 same
	Early oxytocin (208)	13.7	
Palomäki et al., 2006 ¹⁰⁴ 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 strategy 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.⁵⁴ 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).⁵⁴ 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.⁵⁴ Five-minute Apgar scores lower than seven (Table 11) did not differ significantly between groups (test result not reported).⁵⁴

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).⁷⁹ 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.⁷⁹ 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.⁷⁹

Amniotomy

Amniotomy, the surgical rupture of fetal membranes, 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.¹¹⁶ A fair quality trial in Nigeria, randomly assigned 128 women to amniotomy or no amniotomy upon presentation in labor.⁸⁸ 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).⁸⁸

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.⁵⁶ 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.⁵⁶ The percentage of women who had a cesarean birth was lower in the 250-ml group (9.9%) than the 125-ml group (17.0%), 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).⁵⁶

Oral Carbohydrate Solution

One trial of fair quality from the Netherlands evaluated the effect of an oral carbohydrate solution during labor based on the rationale that carbohydrate intake might reduce the cesarean rate and improve labor progress, similar to the effects of carbohydrate intake on the exercise capacity and fatigue among athletes.¹⁰⁶ Women received a carbohydrate (n=102) or placebo (n=99) solution to drink at will. They were not offered other food or drinks but could have small amounts of either upon request.¹⁰⁶ The percentage of women who had a cesarean birth was higher in the carbohydrate group (20.6%) than the placebo group (7.1 percent; RR=2.91, 95% CI: 1.29, 6.54).¹⁰⁶ Maternal and infant outcomes we extracted were not reported (Tables 10 and 11).¹⁰⁶

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 ^{56, 71, 82} (3)	0.9-19.1 ^{56, 64, 66, 71, 83} (5)	2.2-22.1 ^{51, 56, 64, 83, 90-91, 117} (7)	NR
Amniotomy at admission ⁸⁸	NR	NR	NR	NR
High-dose oxytocin ⁵⁴	NR	NR	NR	NR
Low-dose oxytocin ⁵⁴	NR	NR	NR	NR
Early aggressive management ^{50, 79}	NR	NR	NR	NR
Increased IV fluids ⁵⁶	14.9	14.9	4.0	NR
Computerized range for labor progress ⁹⁴	NR	NR	NR	NR
Early oxytocin ⁹⁰	NR	NR	19.7	NR
Home-based triage ¹⁰²	NR	NR	NR	NR
2-hour partogram ^{51, 91}	NR	NR	12.4-12.5	NR
3-hour partogram ⁵¹	NR	NR	12.9	NR
4-hour partogram ^{51, 91}	NR	NR	12.5	NR
Active management ^{64, 66, 71, 83, 87}	8.1 ⁷¹	0-14 ^{66, 83a}	4.0-15.0 ^{64, 83}	NR
Early labor assessment ⁶⁸	NR	NR	NR	NR
Oxytocin plus propranolol ^{41, 104}	NR	NR	NR	NR
Partogram plus standard labor progress notes ⁸²	11.8	NR	NR	NR
Midwife-led unit ⁷²	NR	NR	1.7	NR
Oral carbohydrate solution ¹⁰⁶	NR	NR	NR	NR

^aP<0.01⁶⁶; NR=not reported

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 \pm SD (n Studies)	Mortality, % (n Studies)
Control	0-6.3 ^{41, 50-51, 54, 56, 64, 66, 68, 71-72, 82, 88, 90-91, 94, 102} (16)	2.0-11.0 ^{41, 51, 56, 64, 66, 72, 82, 90-91, 102, 104} (11)	NR	0-0.5 ^{50, 66, 90} (3)
Amniotomy at admission ⁸⁸	7.8 ^a	NR	NR	NR
High-dose oxytocin ⁵⁴	0.0	NR	NR	NR
Low-dose oxytocin ⁵⁴	4.8	NR	NR	NR
Early aggressive management ^{50, 79}	0.9 ^{50,d}	NR	NR	0.9 ^{50,e}
Increased IV fluids ⁵⁶	1.0	9.9	NR	NR
Computerized range for labor progress ⁹⁴	2.0	NR	NR	NR
Early oxytocin ⁹⁰	2.5 ^b	2.9	NR	0.5
Home-based triage ¹⁰²	1.2	8.1 ^c	NR	NR
2-hour partogram ^{51, 91}	1.5-1.9	1.3-1.4	NR	NR
3-hour partogram ⁵¹	1.3	0.3	NR	NR
4-hour partogram ^{51, 91}	1.6-2.0	0.6-2.0	NR	NR
Active management ^{64, 66, 71, 83, 87,f}	0.3-1.9	0.5-4.0 ^{64, 66}	NR	0 ⁶⁶
Early labor assessment ⁶⁸	1.0	NR	NR	NR
Oxytocin plus propranolol ^{41, 104}	2.0 ⁴¹	2.0-11.0	NR	NR
Partogram plus standard labor progress notes ⁸²	1.2	3.4	NR	NR
Midwife-led unit ⁷²	1.0	8.0	NR	NR
Oral carbohydrate solution ¹⁰⁶	NR	NR	NR	NR

NICU=neonatal intensive care unit; IV=intravenous; NR=not reported

^aOne-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.

^bApgar scores \leq 7

^cIncludes admission to Level II or Level III nursery

^dApgar < 8 at 10 minutes

^eIncludes an intrauterine death known prior to trial enrollment

^fOne-minute Apgar scores (five-minute Apgar scores not reported)

Psychosocial Support

“Doula” is a Greek word that refers to a woman caregiver⁹⁶ or an experienced woman who helps another woman or a new mother.^{46, 48, 118} Today, the word has come to mean a woman experienced in childbirth who provides continuous physical and emotional support throughout labor and birth.^{42, 46, 48, 96, 118} Continuous one-on-one nursing support is uninterrupted support by staff nurses with training in labor support.⁸⁶ Labor support is defined as “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.”⁸⁶ 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^{42, 46, 48, 67, 73, 86, 96, 118} 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.⁴⁸ Three studies were conducted in the United States,^{46, 48, 96} one in Mexico,⁴² one study in the United States and Canada,⁸⁶ one in Canada,⁷³ and one in Finland.⁶⁷ All interventions took place in labor and delivery. Three studies were conducted in community practices^{42, 46, 48} and three were conducted in academic single sites.^{67, 73, 96} One study was conducted in multiple settings, including nine academic and four non-academic sites.⁸⁶ Five of the studies were restricted to nulliparous women, two included nulliparous and parous women.^{67, 86} We separated the seven studies into three categories: doulas as providers of labor support,^{42, 46, 48} a female friend or family member as a provider of labor support,⁹⁶ and nurses and midwifery students as providers of labor support.^{67, 73, 86} There was one trial of fair quality⁸⁶ and six of poor quality (Appendices E and H).^{42, 46, 48, 67, 73, 96}

Key Points

- Low strength of evidence for 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).^{42, 46, 48} 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 Mexico⁴² 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.⁴²

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

Author, Year Country; Quality	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Trueba et al., 2000 ⁴² Mexico; Poor	Standard care (50)	24.0	22.0 lower
	Childbirth educator trained as doula (50)	2.0	
McGrath and Kennell, 2008 ⁴⁶ US; Poor	Routine care (196)	25.0	11.6 lower
	Doula support (224)	13.4	
Kennell et al., 1991 ⁴⁸ US; Poor	Control group assigned after delivery (204)	18.0	10.0 lower 5.0
	Received support of a doula (212)	8.0	
	Observed by an inconspicuous observer (200)	13.0	

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

The proportion of births by cesarean for the doula supported and usual care groups were 2 and 24 percent respectively ($p < 0.003$).⁴² 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 ($p < 0.001$).⁴²

In a U.S. trial,⁴⁶ 224 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.⁴⁶ Women in the doula supported group had significantly fewer cesarean births (13.4% vs. 25.0%, $p = 0.002$) and fewer epidurals (64.7% vs. 76.0%, $p = 0.008$). Five-minute Apgar scores did not differ ($p = 0.30$) (Table 14).⁴⁶

Another U.S. trial⁴⁸ 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.⁴⁸ 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.⁴⁸ 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).⁴⁸ When pair wise comparisons were made, significant differences remained (doula vs. observed, $p = 0.009$ and doula vs. 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 ($p = 0.0006$).⁴⁸ Forceps-assisted births occurred in 26.3 percent of women in the control group ($p = 0.006$, doula support group vs. control group). Among participants who had spontaneous vaginal births, epidural use varied significantly for the doula, observed, and control groups ($p < 0.0001$).⁴⁸ 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.⁴⁸ Labor augmentation occurred less frequently in the support group compared to the control group ($p < 0.0001$).⁴⁸ The percentages for oxytocin use for labor augmentation were 17, 23 and 43.6

percent, across groups ($p < 0.0001$).⁴⁸ Maternal fever was more common in the observed and control groups than in the supported group, but there was no statistical analysis provided (Table 13).⁴⁸ 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).⁴⁸

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 ^{48, 86} (2)	NR	2.6 ⁸⁶	0 ⁴⁶
Doula support ^{42, 46, 48}	1.4 ^{48a}	NR	NR	0 ⁴⁶
Observation by inconspicuous observer ⁴⁸	7.0	NR	NR	NR
Nursing support ^{73, 86}	0.7 ⁸⁶	NR	2.7 ⁸⁶	NR
Midwifery student support ⁶⁷	NR	NR	NR	NR
Trained friend or family member as labor support ⁹⁶	NR	NR	NR	NR

^aOne study⁴⁶ reported fever $\geq 37.5^\circ$ for the total study population: 17.4%; $\geq 38^\circ$: 6.9%; NR=not reported

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 \pm SD (n Studies)	Mortality, % (n Studies)
Control	0.7-3.1 ^{46, 86, 96} (3) ^{a, b, c}	4.9-7.3 ^{73, 86} (2)	NR	0-0.03 ^{48, 86} (2)
Doula support ^{42, 46, 48}	1.8 ^{46a, b}	NR	NR	0 ⁴⁸
Observation by inconspicuous observer ⁴⁸	NR	NR	NR	0
Nursing support ^{73, 86}	0.9 ⁸⁶ 8.9 \pm 0.9 ^{b73}	7.1-7.2 ^{73, 86}	NR	0.06 ⁸⁶
Midwifery student support ⁶⁷	9.12 \pm 0.48 ^b	NR	NR	NR
Trained friend or family member as labor support ⁹⁶	0.3 ^c	NR	NR	NR

NICU=neonatal intensive care unit; NR=not reported

^aPercent with Apgar ≤ 7 at 5 min^{46, 86}

^bReported mean Apgar \pm SD at 5 minutes--Control 8.98 \pm 0.45⁶⁷; Control: 9.0 \pm 0.8⁷³

^cPercent with Apgar ≤ 6 at 5 min⁹⁶

Trained Female Friend or Family Member as Provider of Labor Support

In the RCT that used family or friend supports,⁹⁶ 291 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.⁹⁶ 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.⁹⁶ 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 ($p=0.7$).⁹⁶ 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 proportion of five-minute Apgar scores above six ($p=0.006$).⁹⁶

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,^{73, 86} and one in Finland examined the effects of labor support by midwifery students.⁶⁷ 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	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Hemminki et al., 1990 ⁶⁷ Finland; Poor	Usual care (118)	5.0	3.0 same
	Midwifery student support (122)	2.0	
Gagnon, 1997 ⁷³ Canada; Poor	Usual nursing care (204)	16.2	2.3 same
	One-to-one nursing care (209)	13.9	
Hodnett et al., 2002 ⁸⁶ US & Canada; Fair	Usual care (3,461)	12.6	0.1 same
	Nurse support (3,454)	12.5	

^aSame indicates the use of cesarean was not statistically different across the strategy and comparison arms of the trial.

One randomized controlled Canadian trial⁷³ of poor quality, assigned 209 women to 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 strategy 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.⁷³

Cesarean risk was not significantly different.⁷³ The proportion of cesareans in the supported and usual care groups was 13.9 and 16.2 percent, respectively (RR=0.86, 95% CI: 0.54, 1.36). Use of oxytocin stimulation for women in the nurse supported group was 17 percent lower (RR=0.83; 95% CI: 0.67, 1.04).⁷³ There were no significant differences in epidural analgesia (RR=0.96, 95% CI: 0.84, 1.09), instrumented vaginal births (RR=1.06, 95% CI: 0.74, 1.53), five-minute Apgar scores (Mean difference=-0.1, 95% CI: 0.1, 1.05), and NICU admissions (RR=1.46, 95% CI: 0.64, 3.18).⁷³

A RCT⁸⁶ randomized 6,290 participants to continuous labor support or usual care. Study sites included nine tertiary care and four community hospitals. The strategy 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.⁸⁶ 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 ($p=0.44$).⁸⁶ Labor augmentation for the continuous labor support and usual care groups was 30.1 and 27.2 percent, respectively ($p=0.008$).⁸⁶ 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).⁸⁶

A study conducted in Finland⁶⁷ 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.⁶⁷ 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.⁶⁷

The 1987 trial randomized 79 women to midwifery student labor support or usual care.⁶⁷ 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.⁶⁷ 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).⁶⁷ The percentage of women whose contractions stopped was significantly lower in the supported group (5 vs. 15%; 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).⁶⁷

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.¹²⁰ 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 nonepidural 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.¹²¹

Overview of the Literature

Seven studies compared pain management strategies in labor with a goal of reducing cesarean births.^{49, 58, 63, 76, 95, 97, 103} Two studies were conducted in the United States,^{95, 97} three in Europe,^{49, 58, 63} and two in Asia.^{76, 103} Six of the studies were randomized clinical trials^{49, 58, 63, 76, 95, 103} and one was a quasi-randomized trial.⁹⁷ 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 study¹⁰³ required previous childbirth, and one was restricted to women who had not previously had births.⁴⁹ Five of the

studies included both nulliparous and parous women.^{58, 63, 76, 95, 97} 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,⁹⁷ medication dose,^{49, 63} or ability to ambulate.⁵⁸ Two trials compared epidural to analgesia given intravenously (IV) or by intramuscular (IM) injection^{95, 103} and one evaluated paracervical block with tranquilizer to tranquilizer only.⁷⁶ Two studies were assessed as being of fair,^{95, 103} and the remaining five were poor quality (Appendices E and H).^{49, 58, 63, 76, 97}

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.⁴⁹
- Cesarean risk among women receiving epidural analgesia as compared to IV or IM analgesia did not differ.^{95, 103}

Detailed Synthesis

Seven studies evaluated the effect of various pain management strategies to reduce cesarean births.^{49, 58, 63, 76, 95, 97, 103} 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	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Skrablin et al., 2011 ⁴⁹ Croatia; Poor	Continuous epidural (104)	14.4	9.4 lower
	Intermittent epidural (101)	5.0	
Karraz, 2003 ⁵⁸ 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 ⁶³ 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 ⁷⁶ Iran; Poor	Promethazine only (50)	4.0	2.0 same
	Paracervical block with promethazine (50)	2.0	
Gambling et al., 1998 ⁹⁵ US; Fair	Intravenous meperidine analgesia (607)	4.0	2.0 same
	Combined spinal-epidural anesthesia (616)	2.0	
Norris et al., 2001 ⁹⁷ US; Poor	Epidural analgesia (1112)	13.4	-1.1 same
	Combined spinal-epidural anesthesia (1071)	14.5	
Jalil et al., 2009 ¹⁰³ Malaysia; Fair	IM pethidine analgesia (98)	7.1	-4.6 same
	Epidural ropivacaine 0.2% with fentanyl 2µg/ml (94)	11.7	

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

Two studies examined whether the amount of epidural anesthesia received influences cesarean risk.^{49, 63} The most recent study conducted in 205 women in Croatia⁴⁹ reported lower use of cesarean among nulliparous women who received an intermittent epidural (5%) compared to a continuous epidural (14.4%) (RR=2.9, 95% CI: 1.1, 7.7; p=0.03). The mean doses of levobupivacaine and fentanyl were significantly lower in the intermittent group.⁴⁹ A poor quality trial in Sweden with 1,000 participants⁶³ 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%) as compared to epidural with high dose of local anesthesia (bupivacaine 2.5 mg/ml with adrenaline 5µg/ml) (48.9%) (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.⁶³

A study of 2,182 births in the U.S.⁹⁷ compared CSE to epidural only and reported no significant difference in cesarean use (14.5% for the CSE group and 13.4% 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.⁹⁷ Additionally data sheets were missing for more than 600 women. A French study⁵⁸ 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.⁵⁸

A U.S. study with 1,223 participants⁹⁵ compared CSE (sufentanil, bupivacaine and fentanyl) to IV meperidine but did not find differences in cesarean (6% and 5.5% respectively, p=ns).⁹⁵ The use of forceps was higher in the subset of nulliparous women, but not different between the groups (10% for CSE and 9% for IV only; p=NS). A Malaysian study of 192 parous women¹⁰³ compared epidural (0.2% ropivacaine with fentanyl 2 µg/ml) to IM pethidine/meperidine with no statistically significant difference in cesarean (11.7% among women who received epidurals vs. 7.1% in the IM arm; p=0.19).¹⁰³ Women who received epidurals were more likely to have an instrumented birth and prolonged first and second stages of labor.¹⁰³ A study of 100 women in Iran⁷⁶ 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.⁷⁶

Data on maternal harms were reported in only three studies (Table 17).^{49, 95, 97} In the first, incidence of fever was similar in the intermittent (23%) and continuous (20%) epidural treatment groups and postpartum hemorrhage was reported in three women.⁴⁹ Gambling and colleagues⁹⁵ 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.⁹⁷ reported low rates of accidental dural puncture (1.3% 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).^{76, 95, 103}

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 ⁹⁵	NR	NR	0.0 ¹⁰³
Intermittent epidural ⁴⁹	23.0	NR	1.0	NR
Continuous epidural ⁴⁹	20.0	NR	2.0	NR
Combined spinal-epidural ^{95, 97}	22.0 ⁹⁵	NR	NR	NR
Epidural with high dose local anesthetic ⁶³	NR	NR	NR	NR
Epidural; ¹⁰³ ambulatory ⁵⁸	NR	NR	NR	NR
Paracervical block with tranquilizer ⁷⁶	NR	NR	NR	NR

NR=not reported

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 ^{63, 76, 95, 103} (4)	NR	NR	0 ^{76, 95, 103} (3)
Intermittent epidural ⁴⁹	3.0	NR	NR	NR
Continuous epidural ⁴⁹	1.9	NR	NR	NR
Combined spinal-epidural ^{95, 97}	0 ^{95a}	NR	NR	0 ⁹⁵
Epidural with high dose local anesthetic ⁶³	4.5	NR	NR	NR
Epidural; ¹⁰³ ambulatory ⁵⁸	1.1 ¹⁰³	NR	NR	0 ¹⁰³
Paracervical block with tranquilizer ⁷⁶	0	NR	NR	0

NICU=neonatal intensive care unit; NR=not reported

^aMean Apgar scores of 9 in both groups⁹⁷

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 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, slowing down as a contraction begins. Accelerations (increases in the fetal heart rate meeting specific criteria) often indicate the fetus is well oxygenated at the time they are observed. 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 is sometimes used in conjunction with EFM, with a trend towards less use over time in the United States.⁴³ 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 1990s.⁷⁰ It is another way that has been developed to continuously monitor the fetus during labor. It has been used for research purposed in the United States and is not in general use. 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.⁴³ 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.¹²²⁻¹²⁴ 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.^{122, 125-128}

Most recently, ST segment 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.⁹⁹ 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.^{43, 70, 74, 80, 99, 101} Two RCTs were conducted in the U.S.;^{80, 101} three are European studies conducted in Germany, France and Finland;^{43, 70, 99} and one was conducted in Australia.⁷⁴ 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.^{74, 80, 101} One study compared the use of fetal pulse oximetry in addition to fetal heart monitoring and fetal scalp sampling to fetal heart monitoring and fetal scalp sampling alone.⁴³ Two studies compared the use of fetal ST-segment analysis of fetal cardiotocography to cardiotocography either alone or with an additional monitoring device.^{70, 99} Of six studies, one was good quality⁸⁰ with five being of fair quality (Appendices E and H).^{43, 74, 99, 101}

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).
- Three of the four studies looking at the use of fetal pulse oximetry demonstrated a significant reduction in cesarean performed for fetal distress; however, knowledge of intrapartum fetal oxygen saturation had no significant effect on overall use of cesarean.

- 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 fetal ST-segment 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^{43, 74, 101} 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	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Kuhnert et al., 2004 ⁴³ 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 ⁷⁴ 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 ⁸⁰ US; Good	Fetal pulse oximetry with oxygen saturation not displayed to clinician (2,712)	27.5	1.2 same
	Fetal pulse oximetry with oxygen saturation displayed to clinician (2,629)	26.3	
Garite et al., 2000 ¹⁰¹ 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 strategy and comparison arms of the trial.

CTG=cardiotocography

The first study was a U.S. multicenter trial at nine centers.¹⁰¹ 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=1,010) underwent FHR monitoring with either Doppler or scalp electrode, or both.¹⁰¹ For patients in the intervention group a fetal oxygen sensor was placed against the fetal cheek and connected to a monitor. For women in the control group, only an electronic FHR monitor 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: 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.¹⁰¹

Despite randomization, the intervention arm included more women with induced labors and use of prostaglandins for cervical ripening.¹⁰¹ There was a 50 percent relative reduction, in the number of cesareans performed for nonreassuring fetal status (intervention group 4.5% vs. 10.2% for controls) with no significant difference in overall cesarean use between the two groups (29% in the intervention group and 26% 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 outcomes (including placental abruption, postpartum hemorrhage, wound infection, intrapartum fever, and endometritis).¹⁰¹ Neonatal outcomes were similar with five neonatal deaths, three in the intervention group and two in the control group.¹⁰¹ 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).¹⁰¹

In a German trial,⁴³ 146 patients were recruited with nonreassuring FHR patterns (defined by International Federation of Gynaecology and Obstetrics [FIGO] score less than 8).¹²⁹ Women in the 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: triple fetal surveillance with a FHR monitor, fetal scalp sampling, and fetal pulse oximetry (n=73) or a control group in which women received only FHR monitoring and fetal scalp sampling (n=73).⁴³ After randomization, management of labor varied by group. 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 nonreassuring 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.⁴³

There was no difference between the two groups in incidence of nonreassuring FHR patterns in the first and second stages of labor.⁴³ 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% vs. 37%), and the proportion of operative vaginal births for nonreassuring fetal status was also significantly lower in the intervention versus control group (17.8% vs. 30.1%) 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).⁴³

The third trial, called the FOREMOST trial, was conducted in four Australian academic hospitals.⁷⁴ 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.⁷⁴ Monitoring continued from the time a 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.⁷⁴

The primary outcome measured was operative birth (cesarean, forceps, vacuum) for nonreassuring fetal status.⁷⁴ 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% vs. 32.2%; RR=0.77, 95% 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% CI: 0.48, 0.99; p=0.042).⁷⁴ However, the overall rate of operative births between the two groups did not differ (intervention group 73% vs. control group 71%; RR=0.77, 95% 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), or serious adverse events (Table 21).⁷⁴

The fourth study was conducted by the National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network.⁸⁰ 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.⁸⁰ If the oximeter was not placed within three attempts or if a signal registration was not accomplished by 15 minutes the attempt was considered unsuccessful, and the patient was not randomized. One hundred seventy women had failed attempts at sensor placement and 42 other attempts were abandoned secondary to prolonged FHR decelerations during placement. Ultimately, 5,341 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.⁸⁰

Nonreassuring FHR patterns were defined according to the criteria used by Garite.¹⁰¹ Intrapartum management in both groups was otherwise left to the discretion of the attending physician.⁸⁰ 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.⁸⁰

Cesarean births did not differ between the oximetry and masked groups (26.3 and 27.5%; p=0.31).⁸⁰ Cesarean births for nonreassuring FHR (7.1 and 7.9%; p=0.30) and dystocia (18.6 and 19.2%; p=0.76) were also similar. Results were similar in the subgroup (n=2,168) 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.⁸⁰

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 ^{74, 101} (2)	10.7 ^{80a}	3.2 ¹⁰¹	NR
Fetal monitoring with CTG, fetal pulse oximetry and fetal blood sampling ⁴³	NR	NR	NR	NR
Fetal monitoring with CTG and fetal pulse oximetry ^{74, 101}	9.0-30.8 ^{74, 101}	NR	3.0 ¹⁰¹	NR
Fetal pulse oximetry with oxygen saturation displayed to clinician ⁸⁰	NR	10.7 ^a	NR	NR
Fetal monitoring with CTG and STAN ⁷⁰	NR	NR	NR	NR
Fetal monitoring with STAN ⁹⁹	NR	NR	NR	NR

CTG=cardiotocography; STAN=ST analysis; NR=not reported; ^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 ^{70, 74, 80, 99, 101, a} (5)	1.5-14.7 ^{70, 74, 80, 99, 101} (5)	NR	0-0.4 ^{70, 80, 99, 101} (4)
Fetal monitoring with CTG, fetal pulse oximetry and fetal blood sampling ⁴³	NR	NR	NR	NR
Fetal monitoring with CTG and fetal pulse oximetry ^{74, 101}	1.6-16.7 (2)	3.0-18.1 (2)	NR	0.6 ¹⁰¹
Fetal pulse oximetry with oxygen saturation displayed to clinician ⁸⁰	0.2 ^a	4.8	NR	0
Fetal monitoring with CTG and STAN ⁷⁰	1.5	1.3	NR	0
Fetal monitoring with STAN ⁹⁹	1.3	3.6	NR	0

NICU=neonatal intensive care unit; CTG=cardiotocography; STAN=ST analysis; NR=not reported; ^a Percent with Apgar < 4 at 5 min

Fetal ST-Segment Analysis Studies

Two RCTs assessed ST-segment analysis (STAN) to provide additional information.^{70, 99} 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	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Vayssiere et al., 2007 ⁷⁰ 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 ⁹⁹ Finland; Fair	Fetal monitoring with CTG (739)	4.7	-1.7 same
	Fetal monitoring with STAN (733)	6.4	

^aSame indicates the use of cesarean was not statistically different across the strategy 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.⁹⁹ A total of 1,483 women were randomly assigned to the intervention group, with monitoring by STAN through a scalp electrode, or the control group with monitoring by a conventional FHR monitor either via an internal intrauterine scalp electrode or an external ultrasound signal sensor.⁹⁹ Fetal blood sampling was optional in both groups, based on clinician 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.⁹⁹

An umbilical artery blood gas was available for 714 neonates in the intervention group and 722 in the control group.⁹⁹ 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% intervention vs. 4.7% control; p=0.24).⁹⁹ Fetal blood sampling was used less in the intervention group compared to the control group (7% vs. 15.6%; 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.⁹⁹

In the second study,⁷⁰ 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.⁷⁰ 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% for the study group vs. 37% for the control group; RR=0.91, 95% CI: 0.75,

1.10).⁷⁰ 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% compared with 62% in the control group; RR=0.44, 95% 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).⁷⁰

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 be used if an intrauterine pressure catheter is not available.⁴⁴

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 FHR decelerations are the most common type, seen in 50 to 80 percent of labors.⁹⁸ Recurrent variable decelerations have been shown to be due to cord compression in labor in women with oligohydramnios.¹³⁰ Oligohydramnios can be present before rupture of membranes or more commonly occurs in labor after rupture of membranes. Variable decelerations are common and may accompany each contraction. They are not specifically indicative of distress and are interpreted in the larger context of monitoring patterns; however, when severe or if they remain persistent, they may be associated with fetal compromise as a result of hypoxia and acidemia.¹³¹ As a result, severe variable decelerations when recurrent are often nonreassuring 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 has been associated with decreased use of cesarean but debate continues.^{44, 132}

Overview of the Literature

We identified eight RCTs addressing use of amnioinfusion to reduce cesarean birth rates.^{39, 44-45, 57, 59, 69, 81, 98} Three were conducted in India,^{39, 45, 98} two were conducted in South Africa,^{57, 69} one in Zimbabwe,⁶⁹ one in Egypt,⁴⁴ and one in the United States.⁵⁹ Four were found to be of fair quality^{44-45, 59, 69} with the remaining four being of poor quality (Appendices E and H).^{39, 57, 81, 98}

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,^{39, 45, 57, 69, 81} two studies evaluated use of amnioinfusion in the context of nonreassuring FHR tracings,^{44, 98} and one evaluated use of prophylactic amnioinfusion in the context of oligohydramnios.⁵⁹

Although all studies used either warmed or room temperature normal saline, the amnioinfusion protocols varied. In five studies^{39, 44-45, 69, 98} 500 ml of normal saline was initially infused over 30 minutes, followed by slow infusions up to either 1 liter total volume^{44-45, 69} or until birth.^{39, 98} Three studies infused normal saline at 15 ml per minute either to a volume of 1 liter,⁵⁷ 800 ml followed by a slower infusion until birth,⁸¹ or 250 ml to attain an amniotic fluid index greater than or equal to 8 centimeters.⁵⁹

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.^{39, 44-45, 98}
- 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^{39, 45, 57, 69, 81} 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	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Choudhary et al., 2010 ³⁹ India; Poor	Standard obstetric care without amnioinfusion (146)	63.7	34.2 lower
	Transcervical amnioinfusion (146)	29.5	
Rathor et al., 2002 ⁴⁵ India; Fair	Standard obstetric care without amnioinfusion (100)	36.0	15.0 lower
	Transcervical amnioinfusion (100)	21.0	
Moodley et al., 1998 ⁵⁷ South Africa; Poor	Standard obstetric care without amnioinfusion (30)	47.0	7.0 same
	Transcervical amnioinfusion (30)	40.0	
Mahomed et al., 1998 ⁶⁹ Zimbabwe; Fair	Standard obstetric care without amnioinfusion (336)	11.3 ^b	1.8 same
	Transcervical amnioinfusion (325)	9.5	
Hofmeyr et al., 1998 ⁸¹ 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 strategy and comparison arms of the trial.

^bReported as 12.3 in text, but should be 11.3 based on data presented in paper.

The first two^{39, 45} 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.³⁹ enrolled 292 participants who were randomly assigned to the intervention group and received transcervical amnioinfusion or the control group and 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% vs. 63.7% cesarean births) with a significantly higher rate of normal vaginal birth in the intervention group compared to the control group (70.5% vs. 31.5%).³⁹ 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 ^{39, 44-45, 59, 69, 81, 98} (7)	0 ⁹⁸	NR	NR
Transcervical amnioinfusion ^{39, 44-45, 57, 59, 69, 81, 98}	0.9-20 ^{39, 44-45, 59, 69, 81, 98} (7)	0 ⁹⁸	NR	NR

NR=not reported

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% vs. 23.3%; $p=0.000$).³⁹ 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% vs. 30.8% and 0.7% vs. 8.2%; $p=0.000$). Amnioinfusion was not associated with increasing any significant neonatal complications (Table 25).³⁹

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 \pm SD (n Studies)	Mortality, % (n Studies)
Control	0-13.2 ^{39, 44-45, 59, 69, 81, 98} (7) ^a	2.5-22.9 ^{44-45, 69, 81} (4)	3.0% ^{69b}	0-11 ^{39, 44-45, 57, 69, 81} (6)
Transcervical amnioinfusion ^{39, 44-45, 57, 59, 69, 81, 98}	0-4.1 ^{39, 44-45, 59, 69, 81, 98} (7) ^a	1.8-12.8 ^{44-45, 69, 81} (4)	1.6% ^{69b}	0-2 ^{39, 44-45, 57, 69, 81} (6)

NICU=neonatal intensive care unit; NR=not reported

^aReported mean Apgar at 5 minutes \pm SD--Intervention: 9.57 ± 0.67 ; Control: 9.33 ± 1.03 ⁵⁷

^bReported percent in NICU more than 4 days

In the second study, Rathor and colleagues⁴⁵ 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% vs. 36%) with cesarean for fetal distress also reduced to 12 percent in the amnioinfusion group compared to 26 percent in the control group.⁴⁵ 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).⁴⁵ Seven neonatal deaths occurred: two in the amnioinfusion group and five in the control group. Amnioinfusion was associated with a significant improvement in one-minute Apgar scores and fewer admissions to the NICU compared to the control group (Table 25).⁴⁵

The last two RCTs⁸¹ 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 those used to estimate sample size in Zimbabwe. Therefore the two sites, South Africa (CRAMP 1) and Zimbabwe (CRAMP 2) reported findings separately.^{69, 81}

The South African site (CRAMP 1)⁸¹ evaluated 176 women randomized to the amnioinfusion group and a control group of 176 who received standard obstetric care. All women allocated to the intervention group received amnioinfusion. 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% CI: 0.76, 1.26).⁸¹ There was no significant difference in assisted vaginal births (RR=0.72, 95% CI: 0.31, 1.67), nor was there significant difference in the incidence of maternal fever (RR=1.23, 95% CI: 0.65, 2.33).⁸¹ 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% in the amnioinfusion group vs. 0.03% in the control; RR=0.67, 95% 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% CI: 0.43, 5.18) or NICU admissions (RR=0.75, 95% CI: 0.17, 3.28) (Table 25).⁸¹

Of 661 women enrolled in the Zimbabwe study (CRAMP 2),⁶⁹ 325 were randomly assigned to amnioinfusion and 336 were assigned to standard obstetric care. 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.⁶⁹ Use of cesarean did not differ between groups (9.5% in the intervention group compared to 12.3% in the control; RR=0.84, 95% CI: 0.53, 1.32), nor were there significant differences in the rate of cesarean births secondary to fetal distress (RR=0.61, 95% CI: 0.24, 1.52).⁶⁹ MAS was significantly less frequent in the amnioinfusion group (3.1% vs. 12.8% in the control; RR=0.24, 95% 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% CI: 0.15, 0.61).⁶⁹ There were four neonatal deaths in the amnioinfusion group (1.2%) and twelve in the control group (3.6%), which was not significant (RR=0.34, 95% CI: 0.11, 1.06). There were significant reductions in five-minute Apgar scores less than seven (RR=0.35, 95% CI: 0.17, 0.73) as well as NICU admissions (RR=0.56, 95% CI: 0.39, 0.79). No complications of amnioinfusion were detected (Table 25).⁶⁹

In the fifth study, a separate study from South Africa, 60 patients were randomized into two groups, either amnioinfusion or standard obstetric care.⁵⁷ 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%) in the amnioinfusion group gave birth by cesarean, compared to 14 (47%) in the control group.⁵⁷ Of these, three (10%) in the study group and seven patients (23%) 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 hypoxic-ischemic encephalopathy (HIE) (zero vs. two controls) or MAS (one vs. four controls), neither statistically significant. There were no neonatal deaths (Table 25).⁵⁷

Two additional RCTs^{44, 98} 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	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Abdel-Aleem et al., 2005 ⁴⁴ Egypt; Fair	Standard obstetric care without amnioinfusion (219)	68.0	20.1
	Transcervical amnioinfusion (219)	47.9	lower
Regi et al., 2009 ⁹⁸ India; Poor	Standard obstetric care without amnioinfusion (75)	37.3	-1.1
	Transcervical amnioinfusion (75)	38.4	same

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

In a study in Egypt at a university hospital,⁴⁴ women with nonreassuring or ominous FHR tracings were approached for enrollment as long as immediate birth was not contemplated and 438 were randomized. The intervention group received amnioinfusion in addition to conventional treatment, and the control group received standard obstetrical care without amnioinfusion.⁴⁴ 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.⁴⁴

The amnioinfusion group had a significant reduction in use of cesarean for fetal distress compared to the control group (47.9% vs. 68%, respectively; RR=0.7, 95% CI: 0.60, 0.83).⁴⁴ This study also reported a reduction in nonreassuring and ominous FHR patterns in the amnioinfusion group compared to the control group (47.9% vs. 68%, respectively, RR=0.7, 95% 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% CI: 0.26, 0.55) and five (RR=0.31, 95% CI: 0.15, 0.64) minutes in the amnioinfusion group compared to the control group (Table 25).⁴⁴ Also, 14 newborns in the amnioinfusion group were admitted to the NICU, compared to 31 newborns in the control group (RR=0.45, 95% 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).⁴⁴

An Indian study enrolled 150 women in active labor with repetitive moderate or severe decelerations.⁹⁸ 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%) were nulliparous. Cesarean risk did

not differ between the intervention and control groups (38% vs. 37.3%, respectively).⁹⁸ Cesareans for fetal distress were less common in the amnioinfusion group (20%) compared to the control group (32%; $p=0.009$). 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).⁹⁸ 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).⁹⁸

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.⁵⁹ 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.⁵⁹ 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).⁵⁹ There were no differences in Apgar scores at one or five minutes between the two groups (Table 25).⁵⁹

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,^{53, 105} two assessing devices,^{55, 100} one assessing the effect of propranolol administration every four hours during labor,⁶⁰ and two on the role of activities such as walking⁷⁵ or eating⁹² during labor. Four of these studies were conducted in the United States,^{53, 55, 75, 105} two in the United Kingdom,^{92, 100} and one in Puerto Rico.⁶⁰ Five studies were completed in academic health sciences centers^{53, 55, 60, 75, 105} and two were conducted in a non-academic hospital setting.^{92, 100} All studies employed a usual care comparison group; one study¹⁰⁵ also included a sham procedure comparison. Two were good quality,^{92, 100} two were fair quality,^{53, 105} and the remaining three were poor quality (Appendices E and H).^{55, 60, 75}

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 strategies to reduce cesarean births.^{53, 55, 60, 75, 92, 100, 105} 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	Strategy (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Harper et al., 2006 ⁵³ US; Fair	Usual care (26)	39.0	22.0 same
	Acupuncture sessions (30)	17.0	
Matsuo et al., 2009 ⁵⁵ US; Poor	Usual care (32)	25.0	12.5 same
	Dental support device during active pushing (32)	12.5	
Adamsons et al., 1999 ⁶⁰ Puerto Rico; Poor	Usual care (23)	17.4	5.7 same
	Propranolol during labor (34)	11.7	
Bloom et al., 1998 ⁷⁵ US; Poor	Usual care (531)	6.0	2.0 same
	Walking during 1 st stage of labor (536)	4.0	
O'Sullivan et al., 2009 ⁹² UK; Good	Usual care (1,216)	30.0	0 same
	Allowed to eat during labor (1,227)	30.0	
Cox et al., 1999 ¹⁰⁰ UK; Good	Usual care (240)	3.8	-2.0 same
	Inflatable obstetric belt (260)	5.8	
Asher et al., 2009 ¹⁰⁵ US; Fair	Acupuncture (30)	20.0	-10.0 3.0 same
	Usual care (no acupuncture) (30)	10.0	
	Sham acupuncture (29)	7.0	

^aSame indicates the use of cesarean was not statistically different across the strategy 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.^{53, 105} In the first trial,⁵³ 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,¹⁰⁵ 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 studies¹⁰⁰ 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% respectively; $p=0.29$). There were fewer malpositions at birth in the belt group as compared with usual care (15% vs. 20.8%) but the difference was not statistically significant. Other neonatal and maternal outcomes were similar between the two groups (Tables 28 and 29).

Matsuo and colleagues⁵⁵ assessed whether the use of a molded dental device during active pushing ($n=32$) had an effect on cesarean as compared with usual care ($n=32$). The device was designed to optimize dental occlusion, based on evidence indicating this may improve isometric muscle strength.¹³³ 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 ^{75, 105} (2)	0-3.3 ^{60, 100, 105} (3)	0.08 ⁹²
Acupuncture ^{53, 105}	NR	23 ¹⁰⁵	10 ¹⁰⁵	NR
Sham acupuncture ¹⁰⁵	NR	21	7	NR
Propranolol ⁶⁰	NR	NR	0	NR
Inflatable obstetrical belt ¹⁰⁰	NR	NR	1.2	NR
Dental support device during pushing ⁵⁵	NR	NR	NR	NR
Walking during first stage labor ⁷⁵	NR	8	NR	NR
Allowed to eat during labor ⁹²	NR	NR	NR	0

NR=not reported

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 ^{75, 92} 9.0 ± 0.2 ^{105a} 9.0 ^{92b} (4)	3.3-9.4 ^{55, 92, 105} (3)	1.9 ± 0.5 ¹⁰⁵	0 ^{75, 100} (2)
Acupuncture ^{53, 105}	8.8 ± 0.8 ^{105a}	0 ¹⁰⁵	2.1 ± 0.5 ¹⁰⁵	NR
Sham acupuncture ¹⁰⁵	8.9 ± 0.4 ^a	0	2.0 ± 0.6 ¹⁰⁵	NR
Propranolol ⁶⁰	NR	NR	NR	NR
Inflatable obstetrical belt ¹⁰⁰	NR	NR	NR	0
Dental support device during pushing ⁵⁵	9 ^b	9.4	NR	NR
Walking during first stage labor ⁷⁵	0	NR	NR	0
Allowed to eat during labor ⁹²	1.3 ^c	5.0	NR	NR

NICU=neonatal intensive care unit; NR=not reported

^aReported mean Apgar at 5 minutes ± SD

^bReported median Apgar at 5 minutes

^cReported Apgar ≤ 7 at 5 minutes

Medical Interventions

One small RCT⁶⁰ found a modest, insignificant effect of a single intravenous 2 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 vs. 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), 4 percent and 6 percent respectively (p=0.25).⁷⁵ 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=1,227) as compared with those limited to water and ice consumption (n=1,216). This trial also found similar incidence of cesarean in both groups (30% in each).⁹² 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 Strategies

Overview of the Literature

We classified research as systems-level strategies 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 strategies were launched ranged from a national health ministry and multi-hospital quality improvement teams, to individual departments' decisions about labor and delivery routines. Strategies 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 systems-level strategies for reducing use of cesarean birth.^{78, 85, 89, 94, 134-162} Multiple publications from the same study were instances in which authors extended the length of followup. Because systems-level randomized trials are rare, we elected during design of this review that system-level strategies 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 strategy(ies) intended to decrease rates of cesarean.^{134-144, 146-148, 150-162} For brevity in tables and text we have called these pre-post assessments. There were seven unique pre-post studies of good quality^{137, 140, 142-144, 150, 157} and 22 of poor quality (Appendices E and H).^{146-149, 151-156, 158-162}

Four studies provide outcomes from randomized trials: three conducted outside the United States^{78, 85, 89} and one within a consortium of U.S. and Canadian hospitals.⁹⁴ Of the 27 pre-post assessment studies, 16 were conducted in the United States,^{136, 138-139, 141-142, 144, 146-148, 150-152, 154-155, 158, 160} four in Europe,^{134-135, 156-157} three in Asia,^{137, 153, 161} one in Australia,¹⁶² one in Canada,¹⁴³ one in South America,¹⁵⁹ and one spanned multiple continents.¹⁴⁰ There was one trial of fair quality⁷⁸ and three of poor quality.^{85, 89, 94}

Key Points

- No system-level strategies are supported by clinical trials. The content of strategies examined in observational studies is varied. Overall the evidence is insufficient to determine if systems-based strategies reduce cesarean (Table 34).
- 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 strategies.
- Twelve observational studies reported achieving a reduction of 5 percent or more.
- More than 16 categories of components have been used in various combinations in these systems strategies. 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 strategies, with a 5 percent or greater reduction, were tracking of progress in labor and protocols for active management of labor.
- These same components were also common in systems-level strategies 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 strategies 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 Strategies (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Sanchez-Ramos et al., 1990 ¹⁵² US Pre-post; Poor	Baseline: (4,350)	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 (5,163)	10.5	
Langrew et al., 1996 ¹⁵⁸ 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 ¹³⁴ Ukraine Pre-post; Poor	Baseline: (1,696)	29.9	14.5 lower
	Intervention: WHO Effective Perinatal Care training and implementation (2,439)	15.4	
Rust et al., 1993 ¹⁵⁴ 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 ¹⁴² 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 ¹⁴³ Canada Pre-post; 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 ¹⁶² 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 ¹⁴⁶ 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 ^{135b} 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 ¹⁶¹ 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. Protocol for selective trial of labor for women with prior CS. (7,937)	30.2	

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

Author, Year Country Study Type; Quality	Health Systems Strategies (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Meyers and Gleicher, 1988, 1993 ^{141, 145} US Pre-post; Poor	Baseline: (1,697)	17.5	5.6 lower
	Intervention: Implementation of six key guidelines with data feedback to individual providers (3,218)	11.9	
Boylan et al., 1991 ¹⁴⁴ 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 ¹³⁹ 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 ¹⁵⁹ 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 ¹³⁷ 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 ¹⁵⁰ and Dillon et al., 1992 ¹⁴⁹ 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	
Kiwauka and Moore, 1993 ¹⁵⁶ UK Pre-post; Poor	Baseline: (1,895)	15.9	3.2 lower
	Intervention: Audit and feedback (2,216)	12.7	
Kazandjian and Lied, 1998 ¹⁴⁰ 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 ¹⁵⁷ UK Pre-post; Good	Baseline: (12,628)	12.0	2.5 lower
	Intervention: Medical audit(8,497)	9.5	
Smith et al., 2000 ¹³⁶ 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	

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

Author, Year Country Study Type; Quality	Health Systems Strategies (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Calvo et al., 2009 ^{135b} 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 ⁷⁸ 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 ¹⁵¹ 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 ¹⁶⁰ US Pre-post; Poor	Baseline: (NR)	24.5	1.0 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 ¹⁵³ 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., ⁸⁵ 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 (34,735)	24.7	
Elferink-Stinkens et al., 2004 ⁸⁹ 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 ¹³⁸ 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 ⁹⁴ 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	

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

Author, Year Country Study Type; Quality	Health Systems Strategies (n)	Cesarean Birth, %	Change in Cesarean, % ^a
Oleske et al., 1992 ¹⁴⁸ 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 ¹⁴⁷ 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 ¹⁵⁵ 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 strategy and comparison arms of the trial.

^bTwo entries in table to reflect sites with data that could not be combined and had different outcomes.

^cStatistical 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 strategy while the other member of the pair continued usual practice.^{78, 85, 89, 94} 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.⁸⁹
- **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. The authors 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.⁷⁸
- **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 with 24.7 in the hospitals that did not implement the requirements.⁸⁵

- **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 reference 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.⁹⁴

Observational Data

The 27 nonrandomized 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.^{134-144, 146-148, 150-162} 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).

Eight studies explicitly included policies about management of vaginal birth after cesarean among other components of a systems-level strategy.^{138, 141-142, 147-148, 152, 154-155} Other studies that provide limited detail and describe only implementation of uniform policies or review of all cesareans may also have included this element. Since it was a common element, these studies are included. It is important to note that this departs from the overall structure of this review since it means that women who are not at low risk for cesarean are included. This situation would be expected whenever a full health care system implements a policy for all births. However it is a limitation since it means, in the related studies, that some of the change in cesarean use may have been accomplished (or failed) because of the VBAC elements.

Five international studies achieved reductions in cesarean of 5 or more percent from baseline.^{134-135, 143, 161-162} 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.¹³⁴ 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.¹⁶² 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 10 percent through implementing protocols for vaginal birth after cesarean, management of breech, and diagnosis of dystocia.¹⁴³ Another small study in two Spanish hospitals used audit and feedback of data to providers along with appropriateness ratings of all cesareans.¹³⁵ The authors reported a 7 percent decline in cesarean at one site, and a 1.7 percent decrease at a second site.¹³⁵ 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%) 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.¹⁶¹

Table 31. Components of strategies in the United States with at least 5-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 ¹⁵²	•	•		•		•	•	•	•		•			8	17.0
Langrew et al., 1996 ¹⁵⁸	•	•	•		•			•	•					6	15.7
Rust et al., 1993 ¹⁵⁴	•			•	•	•	•	•						6	10.9
Socol et al., 1993 ¹⁴²	•	•	•	•	•					•		•		7	9.4
Poma, 1998 ¹⁴⁶		•	•			•								3	7.2
Meyers and Gleicher, 1998, 1993 ^{141, 145}	•	•	•	•			•		•				•	7	5.6
Boylan et al., 1991 ¹⁴⁴	•				•									2	5.5
Main et al., 1999 ¹³⁹		•	•											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 strategies 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 strategies 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 strategies are destined to succeed.

Table 32. Components of strategies 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 ¹⁵¹	•					•	•							3	1.6
Studnicki et al., 1997 ¹⁶⁰		•				•								2	1.5
Gregory et al., 1999 ¹³⁸	•	•	•	•	•	•		•	•	•		•		10	-0.5
Hamilton et al., 2004 ⁹⁴	•													1	-0.7
Oleske et al., 1992 ¹⁴⁸				•					•					2	-1.2
Porreco, 1990 ¹⁴⁷	•			•			•	•	•		•			6	-2.0
Pridjian et al., 1991 ¹⁵⁵				•										1	-3.4
Total studies (n)	4	2	1	4	1	3	2	2	3	1	1	1	0		

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

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?

No studies addressed KQ3. It is discussed as a part of Future Research. All studies compared the novel strategy to usual care or to a variation on the same strategy.

We did not identify comparisons of distinctive strategies, for instance doula support vs. active management of labor, or pain management strategies compared to fetal monitoring strategies. Several comparisons evaluated different approaches to the same strategy like different approaches to epidural dosing or to monitoring progress of labor. These comparisons of variations on like strategies are noted in the sections that discuss those interventions. For now, there is no evidence to inform prioritization of one type of intervention to another.

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?

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 KQs 1–2. These include events such as fever, infection, and hemorrhage. We have not considered these to be direct adverse effects, instead we have summarized the adverse effects that are plausibly caused by the strategy, for example dural puncture for epidural and perineal tears for education on pushing. Many of the studies included in this review, such as those related to psychosocial support have no known adverse effects. Of the studies reporting outcomes of strategies employed to reduce cesarean, 18^{39-40, 44, 47, 49, 54, 59-60, 65, 80, 84, 90, 92, 95, 97-98, 100, 105} reported data about outcomes that could be classified as adverse events or harms related to the strategy implemented to reduce cesarean (Table 33).

Key Points

Few of the adverse effects presented have a direct relationship to the strategy being used to prevent cesarean birth.

The adverse effects 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 adverse effects that were directly causally linked to the strategy used to prevent cesarean.

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

Author, Year Country	Strategy (n)	Key Adverse Effects
Abdel-Aleem et al., 2005 ⁴⁴ Egypt	G1: Transcervical amnioinfusion (219) G2: Standard obstetric care without amnioinfusion (219)	<ul style="list-style-type: none"> 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 ¹⁰⁵ US	G1: Acupuncture (30) G2: Sham acupuncture (29) G3: Usual care (no acupuncture) (30)	<ul style="list-style-type: none"> 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 ⁶⁰ Puerto Rico	G1: Propranolol during labor (34) G2: Usual care (23)	<ul style="list-style-type: none"> No anesthesia-related morbidity in either group

Table 33. Overview of adverse effects reported in studies of strategies to reduce cesarean birth (continued)

Author, Year Country	Strategy (n)	Key Adverse Effects
Barakat et al., 2009 ⁸⁴ Spain	G1: Exercise training (80) G2: No exercise training (80)	<ul style="list-style-type: none"> No exercise-related injuries in either group 2 preterm births in the training group vs. 3 in the control group
Bidgood et al., 1987 ⁵⁴ UK	G1: High-dose oxytocin (19) G2: Low-dose oxytocin (21) G3: Observation (20)	<ul style="list-style-type: none"> 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 ⁸⁰ US	G1: Fetal pulse oximetry with oxygen saturation displayed to clinician (2,629) G2: Fetal pulse oximetry with oxygen saturation not displayed to clinician (2,712)	<ul style="list-style-type: none"> 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 ³⁹ India	G1: Transcervical amnioinfusion (146) G2: Standard obstetric care without amnioinfusion (146)	<ul style="list-style-type: none"> No significant difference in maternal fever--3% of the amnioinfusion group compared to 5% of standard care (p=0.238)
Cox et al., 1999 ¹⁰⁰ UK	G1: Inflatable obstetric belt (260) G2: Usual care (240)	<ul style="list-style-type: none"> Significantly more women in the control group had an intact perineum (16.5% vs. 9.6%; OR=1.870; 95% CI: 1.094, 3.193) or 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 ⁹⁵ US	G1: Combined spinal-epidural anesthesia (616) G2: Intravenous meperidine analgesia (607)	<ul style="list-style-type: none"> 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
Harvey et al., 1996 ⁴⁷ Canada	G1: Nurse-midwife care (101) G2: Physician care (93)	<ul style="list-style-type: none"> Postpartum hemorrhage and retained placenta were more common in the nurse-midwife group (5.9% vs. 3.2 and 2.9% vs. 2.2). Two women in the nurse-midwife group compared to one woman in the physician care group had a fever.
Hinshaw et al., 2008 ⁹⁰ UK	G1: Early oxytocin (208) G2: Delayed oxytocin (204)	<ul style="list-style-type: none"> 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 Edinburgh Postnatal Depression Scale (20% vs. 15%; p=0.22)

Table 33. Overview of adverse effects reported in studies of strategies to reduce cesarean birth (continued)

Author, Year Country	Strategy (n)	Key Adverse Effects
Norris et al., 2001 ⁹⁷ US	G1: Combined spinal-epidural anesthesia (1,071) G2: Epidural analgesia (1,112)	<ul style="list-style-type: none"> 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 ⁹² UK	G1: Allowed to eat during labor (1,227) G2: Usual care (1,216)	<ul style="list-style-type: none"> 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 ⁶⁵ Australia	G1: Structured education for pushing (50) G2: Standard care (50)	<ul style="list-style-type: none"> Reported episiotomy and perineal tear rates No significant difference in 3rd degree tear rates (p=0.142)
Regi et al., 2009 ⁹⁸ India	G1: Transcervical amnioinfusion (75) G2: Standard obstetric care without amnioinfusion (75)	<ul style="list-style-type: none"> Intrapartum temperature $\geq 38.3^{\circ}\text{C}$ in 2.7% of the amnioinfusion group, 0% in standard care group.
Skrablin et al., 2011 ⁴⁹ Croatia	G1: Continuous epidural (104) G2: Intermittent epidural (101)	<ul style="list-style-type: none"> Maternal fever ($>38.5^{\circ}\text{C}$) did not differ between groups (21 vs. 23 women; p=0.38). Hypotension was more common in the women who received intermittent epidural (22 vs. 33 women; relative risk=1.53).
Spallicci et al., 2007 ⁴⁰ Brazil	G1: Hyaluronidase injection in cervix (83) G2: Placebo cervical injection (85)	<ul style="list-style-type: none"> No significant difference in those reporting cramps between the two groups (p=0.2709).
Strong et al., 1990 ⁵⁹ US	G1: Amnioinfusion (30) G2: Standard care (30)	<ul style="list-style-type: none"> Maternal fever ($>38^{\circ}\text{C}$) was more common in amnioinfusion group (20% vs. 7%; p=0.06). Meconium (13% vs. 37%; p=0.04), severe variable decelerations (7% vs. 27%; p=0.04), and end-stage bradycardia (1 vs. 7; p=0.05) were more common in the standard care group.

Adverse Effects of Strategies Used During Pregnancy

In the Brazilian trial of hyaluronidase injections into the cervix the authors provided little information related to adverse effects. However, they did report that the p-value for cramps was p=0.2709.⁴⁰ The Australian trial of structured education for pushing reported more common occurrence of chorioamnionitis and postpartum hemorrhage and/or uterine atony among the women who received traditional acupuncture compared to those who received no or sham acupuncture.⁶⁵ In the Canadian trial of nurse-midwifery care compared to physician care postpartum hemorrhage and retained placenta were more common in the nurse-midwifery group.⁴⁷ There were no exercise related injuries in either the control or intervention group in the trial of exercise training and preterm births were more common in the control group.⁸⁴

Adverse Effects of Strategies Used During Labor

Management of Abnormal Labor

Two trials of strategies used to manage abnormal labor reported various adverse effects of the intervention.^{54, 90} Bidgood and colleagues reported seven women with hyperstimulation within 15 minutes after infusion, all in the high-dose oxytocin group.⁵⁴ In a trial of early and delayed oxytocin there were no significant differences in maternal fever, postpartum hemorrhage, need for blood transfusion, or major depression.⁹⁰

Pain Management

Two U.S. studies comparing combined spinal-epidural anesthesia and IV meperidine analgesia⁹⁵ and epidural⁹⁷ reported several adverse effects. Maternal fever greater than 38°C was more common in the combined spinal-epidural group (22% vs. 3%; $p < 0.005$).⁹⁵ In addition this study reported that eight infants were delivered by emergency cesarean due to profound fetal bradycardia within one hour of analgesia. Norris and colleagues reported higher rates of accidental dural puncture, intravascular catheterization, failed epidural and positional headache among women who received the combined spinal-epidural.⁹⁷ However, proportion of participants experiencing a blood patch was higher in the epidural group.⁹⁷ Maternal fever did not differ significantly among participants in the Croatian trial of continuous versus intermittent epidural.⁴⁹ Hypotension was more common among women who received the intermittent epidural.⁴⁹

Fetal Assessments

Only one study of fetal pulse oximetry reported adverse effects.⁸⁰ There were no significant differences in the proportion of chorioamnionitis (10.7% in each group), endometritis, or wound complications. The sensor used in the trial resulted in facial marks on 5.8 percent of infants in the open group versus 3.4 percent in the masked group.⁸⁰

Amnioinfusion

Three of the four studies of amnioinfusion reported higher numbers of maternal fever in the amnioinfusion group compared to standard care without amnioinfusion.^{44, 59, 98} However, this was not seen in the study by Choudhary and colleagues.³⁹

Unique Strategies

Four studies of unique strategies to reduce cesarean report adverse effects.^{60, 92, 100, 105} Chorioamnionitis was more common among women who received acupuncture in the study of acupuncture compared to sham acupuncture and no acupuncture (23% vs. 21% and 7%).¹⁰⁵ There were no significant differences in postpartum hemorrhage and uterine atony across the three groups. Adamsons and colleagues compared propranolol during labor to usual care and reported no anesthesia-related morbidity among study participants.⁶⁰ In the study examining the effectiveness of an inflatable obstetrical belt,¹⁰⁰ significantly more women in the control group experienced a 3rd degree perineal tear (6.5% vs. 0.4%). Six women in the obstetrical belt group needed catheter insertion for urinary retention compared to two women in the standard care group.¹⁰⁰ In the study by O'Sullivan and colleagues there was no difference in the percent of women who vomited among those who were allowed to eat in labor versus those only allowed to have ice chips and water.⁹²

Overall the included trials were small and unlikely to detect rate, but potential important events. Those strategies that were directly associated with adverse effects were primarily procedural such as risk of dural puncture with epidural. While this is a known risk of epidural it is not the case that it would be uniquely associated with the particular dosing strategy to be used, for instance continuous versus intermittent dosing. We have considered these sorts of complications as not specific to the intention of the use, and because this is not a review of all the uses of these categories of strategy (social support in labor, fetal monitoring devices, etc), we do not provide estimates per se of these sorts of adverse effects. Overall no adverse effects were identified that were unique or notably exacerbated by use of the intervention for the purpose of attempting to decrease use of cesarean.

Discussion

State of the Literature

We identified 6,107 nonduplicate publications through the search process, with 1,025 proceeding to full text review (Figure 2). Ninety-seven publications were included, 68 randomized controlled trials (RCTs) and 29 pre-post studies of large scale health systems changes, representing 96 distinct study populations. Using uniform criteria for assessment we found 16 of these studies to be good quality; 28 fair; and 53 poor. The most common reasons for exclusion were irrelevance to the topic and ineligible study design. Nine articles pertain to Key Question (KQ) 1, 88 articles to KQ2, no articles to KQ3, and 18 articles to KQ4. Few strategies have been studied in more than three trials. Most included trials were the only randomized study of the strategy.

Summary of Outcomes by KQ

KQ1. Strategies During Pregnancy

Collaborative consistent midwifery care during pregnancy and in labor, compared to conventional care, reduced cesarean births by 4.5–11.1 percent in two RCTs. 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% to 18%) 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 strategies. Each of these strategies 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 strategies. 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 was evaluated in six studies and did not reduce the use of cesarean.

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. Care in a midwife-led unit did not reduce the use of cesarean compared to a normal

unit and special unit. 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. An oral carbohydrate solution increased 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 threefold reduction in cesarean rates for women who received intermittent epidural (5%) as compared to continuous epidural (15%, $p=0.03$).⁴⁹ 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% compared with 49% in the high dose group, $p<0.00001$).⁶³ 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. Three of four studies investigating use of fetal pulse oximetry demonstrated a significant reduction in cesarean performed for fetal distress. Reduction in cesareans performed for fetal distress ranged from 5.7 to 24.6 percent however, knowledge of intrapartum fetal oxygen saturation did not have a significant effect on overall use of cesarean. 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. In total, of the six studies only reported significant reduction in overall cesarean use.

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 Strategies

Seven studies explored the influence of various other unique strategies 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 strategies 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 Strategies

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 5 percent or more. More than 16 broad categories of components have been used in various combinations in these systems strategies.

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 5 percent or more. Of the eight studies in which the primary intervention was audit and feedback of cesarean data (not embedded in a larger quality improvement program), five achieved a reduction of use of cesarean ranging from 7.2 to 2.5 percent. This is compatible with systematic reviews of obstetrics and general use of audit and feedback¹⁶³ suggesting it is effective for changing provider behavior.¹⁶⁴

The next most common components of successful strategies, with a 5 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 interpreting this literature. Both trials and observational studies have limitations in assuring the intervention is the cause of change, or lack of change, in cesarean use. To be a site of a randomized trial, at minimum, the leadership of units involved were invested in the importance of research on reducing cesarean and willing to participate in a study about how best to accomplish that goal. In the included randomized studies, trial assignment could not possibly be masked at all levels-sites would have been able to infer their status. 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 Table 32 as an example. This table presents the same analysis of components of strategies as that in Table 31 which features successful strategies 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 strategy was worse than control or baseline. Overall, these less successful strategies 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 strategies 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 health care 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 strategies published before 1990, significantly reduced cesarean by almost 2 and 6 percent.^{145, 151}
- From 1990 up to 1995, there were 14 reports of which seven reported a significant decrease in cesarean.^{142-144, 152, 154, 156, 162}
- From 1995 up to 2000, there were eight studies of which four reported a significant decrease.^{158 157 146 140}
- In 2000 and after, four of nine reported a significant decrease.^{94, 134, 159, 161}

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%) 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 5 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 strategies 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 or to a variation on the same strategy. We did not identify comparisons of distinctive strategies, for instance doula support versus active management of labor, or pain management strategies compared to fetal monitoring strategies.

Several comparisons evaluated different approaches to the same strategy like different approaches to epidural dosing or to monitoring progress of labor. These comparisons of variations on like strategies are noted in the sections that discuss those interventions. For now, there is no evidence to inform prioritization of one type of intervention to another.

KQ4. Adverse Effects of Strategies

Few of the adverse effects presented have a direct relationship to the strategy used to prevent cesarean birth. The adverse effects 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 strategies like amnioinfusion were associated in some studies with significant improvements in neonatal outcomes. Many of the studies included in this review, such as those related to psychosocial support have no known adverse effects.

Strength of the Evidence for Effectiveness of Strategies

Overview

Overall the strength of evidence to answer the KQs 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 KQ (Appendix G).

Strength of the Evidence by KQ

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
<i>KQ1. Effectiveness of Strategies During Pregnancy to Reduce Cesarean Birth (n=9)</i>					
Antenatal Care Model 4 (4,337)	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 3 fair-quality studies , 1 poor-quality study
Exercise training 1 (160)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
Management of fear of childbirth 1 (176)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 poor-quality study
Induction of labor for at-risk 1 (270)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
Education on pushing 1 (100)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
Hyaluronidase 1 (168)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
<i>KQ2. Effectiveness of Strategies During Labor to Reduce Cesarean Birth</i>					
<i>Management of Labor (n=21)</i>					
Early labor assessment 2 (1,668)	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 2 fair-quality studies with conflicting findings
Midwife-led unit 1 (1,111)	High	N/A	Direct	Imprecise	Insufficient; 1 poor-quality study
Measurement of labor progress 4 (10,823)	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 good-quality studies, 1 fair-quality and 1 poor-quality study
Active management of labor 6 (5,330)	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 2 good-quality studies, 2 fair-quality studies
Management of abnormal labor 5 (2,764)	Moderate	Inconsistent	Direct	Imprecise	Insufficient; 2 good-quality studies, 2 fair-quality studies, 1 poor-quality study
Amniotomy 1 (128)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study
Increased IV fluids 1 (195)	Low	N/A	Direct	Imprecise	Insufficient; 1 good-quality study
Oral carbohydrate solution 1 (201)	Moderate	N/A	Direct	Imprecise	Insufficient; 1 fair-quality study

Table 34. 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 (continued)					
Psychosocial Support (n=7)					
Doula support 3 (1,136)	High	Consistent	Direct	Precise	Low strength of evidence for benefit; 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-quality and 1 fair-quality studies
Pain Management (n=7)					
Pain management 7 (5,525)	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 4 poor-quality studies, 2 fair-quality studies, 1 good-quality study
Fetal Assessment (n=6)					
Fetal pulse oximetry 4 (7,098)	Moderate	Inconsistent	Direct	Imprecise	Low strength of evidence for lack of benefit; 1 good-quality study, 3 fair-quality studies
Fetal assessment by STAN 2 (2,271)	Moderate	Consistent	Direct	Imprecise	Low or moderate evidence for lack of benefit; 2 fair-quality studies
Amnioinfusion (n=8)					
Amnioinfusion for fetal distress 2 (588)	High	Inconsistent	Direct	Imprecise	Insufficient; 1 fair-quality and 1 poor-quality study
Amnioinfusion for meconium 5 (1,565)	High	Inconsistent	Direct	Imprecise	Insufficient; 3 poor-quality and 2 fair-quality studies
Amnioinfusion for oligohydramnios 1 (60)	High	NA	Direct	Imprecise	Insufficient; 1 fair-quality study
Unique Strategies (n=7)					
Other strategies (acupuncture) 2 (145)	High	Inconsistent	Direct	Imprecise	Insufficient; 2 fair-quality studies
Dental device 1 (64)	High	N/A	Direct	Imprecise	Insufficient; 1 poor-quality study
Allowing eating 1 (2,426)	Low	N/A	Direct	Precise	Insufficient; 1 good-quality study
Inflatable obstetric belt 1 (500)	Low	N/A	Direct	Imprecise	Insufficient; 1 good-quality study

Table 34. 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 (continued)					
Unique Strategies (n=7)					
Propranolol 1 (57)	High	N/A	Direct	Imprecise	Insufficient; 1 poor-quality study
Allowing walking 1 (916)	High	N/A	Direct	Precise	Insufficient; 1 poor-quality study
Systems-Level Strategies (n=33)					
Systems-level strategies 33	High	Inconsistent	Indirect	Precise	Insufficient
KQ4. Adverse Effects of Strategies to Reduce Cesarean Birth					
Adverse effects 18 (14,075)	Moderate	Inconsistent	Indirect	Imprecise	Insufficient; fair- to poor-quality studies with inconsistent reporting of multiple adverse events

N/A=not applicable

*See 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.

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. While we attempted to restrict the review to trials conducted in settings with clinical care settings similar to the United States, this was likely not the case in all instances. Even developed westernized countries may deploy medical resources and have patterns of care that dramatically differ from those in the United States. It is important to note that applicability for guiding care for women in the United States is best served by relatively contemporary U.S. data because cultural norms and health systems factors mitigate against international studies fully capturing the context of care and populations in the United States.

Strategies 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.

A particular challenge that is difficult to assess is the influence of baseline use of cesarean prior to initiation of the strategy to reduce cesarean. It is likely that the difficulty of changing rates is greater when use is already low. For this reason we have presented the proportion of births in the usual care arms of trials and the baseline data for systems intervention studies. While strategies may well be applicable across setting regardless of how low or high the initial use of cesarean is, it makes this literature more challenging to interpret. In particular, while there is no a priori reason to believe that strategies that work in settings that have low cesarean use could not work in settings with higher use, we recognize that it is harder to dismiss the potential for benefit of a strategy in a higher use setting that did not provide statistically meaningful reductions in a low use setting.

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.¹⁶⁵ 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

- Develop data-driven estimates of plausible decreases in cesarean for use in power calculations.
- Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.
- Include placebo, sham, or attention control comparison groups, and innovative means of masking patients and providers in studies of interventions.

- Conduct studies directly comparing and combining candidate strategies to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.
- Design studies with prespecified secondary outcomes and adequate power for these outcomes.
- Conduct studies that allow stratification on patient characteristics such as nulliparity and multiparity and have adequate power to detect differences across strata.
- Track and report total, primary, and repeat cesareans in studies not restricted to nulliparous women.
- Capture all categories of birth outcomes (cesarean, emergent cesarean, assisted vaginal and spontaneous births) and related complications in order to assess if reductions in cesarean occur at the cost of increased use of other interventions or increased complications.
- Include robust measures of maternal coping, satisfaction, and perceived quality of the birth experience. Expand infant outcomes to include a uniform panel of measures that capture infant status better than Apgar scores and NICU admission.
- Include maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications, as outcomes.
- Conduct multisite studies to improve applicability and assure power and precision.
- Conduct larger trials of health system interventions.
- Develop registries that capture both short term and long term outcomes.
- Determine the best measures of patient and provider route of birth preferences.
- Determine the scales/indices that best capture factors that mothers and partners value about the birth experience.
- Include longterm followup of infants into childhood to assure any reduction in cesarean is not achieved at the risk of future neurodevelopmental impairments and to determine if outcomes of infants born by cesarean are similar to those resulting from vaginal births.

Gaps in Areas of Research

We identified gaps using four general strategies: (1) review of the analytic framework and assessment of the degree to which strategies have been examined that attempt to reduce cesarean at different time-points (e.g. during prenatal care, in triage for admission to labor and delivery, during labor); (2) consideration of areas in which we expected to identify literature and did not (e.g. strategies to modify change of shift staffing plans, trials of midwifery care explicitly powered for reduction in cesarean); (3) promising areas of the observational literature not covered in this review that would benefit from examination in a randomized clinical trial; and (4) noting intriguing results from single or lower quality studies included in the review that could benefit from replication.

- Why do some patients prefer to undergo elective cesarean?
- What factors drive a patient's decision to undergo a primary cesarean during labor, e.g. prior cesarean, general fears, fear of future pelvic floor disorders?
- What patient preferences influence decisions to convert to primary cesarean during labor, e.g. pain management, progress of labor, fears about baby's well-being?

- What physician factors contribute to the use of elective cesarean, e.g. residency training, attitude toward elective cesarean, practice size, practice setting, shift/time of day, use of hospitalists, personal birth experience?
- What physician factors contribute to the use of cesarean during labor, e.g. residency training, attitude toward cesarean, practice setting, practice size, shift/time of day, use of hospitalists, personal birth experience?
- To what extent do non-financial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?
- What nurse or midwife factors contribute to the use of cesarean during labor?
- What nurse or midwife factors contribute to the use of elective cesarean?
- What hospital factors contribute to the use of cesarean during labor, e.g. teaching status, geographical region, urban location, socioeconomic status of patients, staffing and scheduling pattern, provider attitudes toward cesarean use?
- What hospital factors contribute to the use of elective cesarean, e.g. teaching status, geographical region, urban location, socioeconomic status of patients, staffing and scheduling pattern, provider attitudes toward cesarean use?
- Do audit and feedback interventions influence physician use of cesarean?
- Do interventions aimed at disrupting staffing and scheduling phenomena – like the increase in cesarean near change of shifts and differential rates through the week – have promise?
- Does use of cesareans correlate with specific days of the week or time of day?
- Do different staffing models like use of hospitalists and integration of midwives reduce the number of cesarean births?
- Do provider peer-review models change provider patterns of cesarean use?
- Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?
- Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?
- To what degree is use of cesarean driven by uniform compensation for vaginal and cesarean birth as tested by an RCT?
- Does public reporting of hospital primary and total cesarean rates affect hospital cesarean rates over time?
- Does public reporting of hospital primary and total cesarean rates affect hospital induction rates over time?
- Does public reporting of individual physician primary and total cesarean rates affect physician use of cesarean over time?
- Does public reporting of individual physician primary and total cesarean rates affect physician use of induction over time?
- Does use of informed medical decision making models change patient decisions about desire for cesarean or for procedures like induction that may increase risk of cesarean?
- Is the Bishop's score routinely used by providers as a decision making tool? If not, why not?
- To what extent do patient educational and decision support tools affect patient decisions to undergo elective cesarean?

- To what extent do educational tools that manage patient expectations and describe the risks of cesarean influence use of cesareans during labor?
- Do system level changes applied to all patients in a care setting with the goal of reducing cesarean increase risk of neurodevelopmental delays in children evaluated over years after birth?
- When strictly operationalized and compared in clinical trials what components of systems intervention are effective in reducing cesarean use?
- Can technologies to enhance fetal surveillance [specify most promising – are there any technology studies worth doing?] improve infant outcomes while reducing cesarean?
- Does a protocol for use of scalp pH sampling reduce use of cesarean?
- Does outpatient hyaluronidase injection into the cervix for cervical ripening at term reduce risk of cesarean (replication of single promising trial)?
- Does active management of labor, using updated US labor curves, reduce use of cesarean in US community care settings?
- Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?
- Does elective induction at 39 week vs. expectant management at 39 weeks influence use of cesarean?
- Can protocols supporting trial of induction of labor make it realistic for physicians to send a patient home if induction of labor does not progress in a timely fashion?
- What is the mechanism by which doula support exerts an effect?
- Does midwifery care through-out pregnancy in a hospital setting reduce use of cesarean among low-risk women when compared in a randomized clinical trial to obstetric care?
- Does midwifery care in labor in a hospital setting reduce use of cesarean among low-risk women when compared in a randomized clinical trial to obstetric care?
- Can tighter standards for elective induction among primiparous patients reduce use of cesarean?
- Can tighter standards for indicated induction among primiparous patients reduce use of cesarean?
- How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?
- How does implementing a standard indication list affect physician's use of cesarean?
- Would changing the definition of when active labor starts reduce use of cesarean?
- Would changing the timeframes for normal progress in latent and active labor reduce primary cesareans?
- Would a tighter definition of elective cesarean affect physician's use of cesarean?
- What scales/indices best capture factors that mothers and partners value about their birth?
- As assessed by sociologic models, to what extent are cesarean rates perceived as concerning or not among members of the public, women of childbearing age, obstetrical care providers, payors, and policy makers?
- What factors have resulted in the change in patterns of the diagnosis of dystocia over the decades?

Conclusions

No particular intervention strategy was uniformly successful in all trials of the strategy in reducing cesareans. Strength of evidence was low to insufficient across all strategies, with

involvement of doulas for personalized support in labor being the only strategy to achieve evidence of benefit which was low related to poor quality of trials.

Several strategies are not supported by the current literature. This does not mean the strategy has no merit and should not be investigated in the future, but does mean that based on the current literature there is not evidence of effectiveness for the purpose of reducing cesarean use among low risk women. These include measurement of progress in labor as the primary component of intervention, active management of labor, nursing and midwifery students as support in labor, modifications of pain management approaches, fetal pulse oximetry and fetal assessment by STAN. For the majority of strategies the evidence is insufficient, including many instances in which a single study is the only evidence about the approach. While certain components of systems-level interventions were common among successful interventions, none were supported by a randomized trial and for each instance of inclusion in a successful pre-post intervention there were instances of unsuccessful use of similar components.

This literature contains intriguing examples of single studies that deserve further exploration. Use of hyaluronidase to hasten cervical changes favorable to labor at term was studied using a vehicle for the injection which is not allowed in the United States. Modifications and safety evaluation would be a prerequisite to future trials. Further exploration of what elements of doula support were common across successful trials would be informative in order to conduct larger scale replications in U.S. populations. Similarly, use of amnioinfusion to reduce fetal distress appears to reduce cesareans for this indication. More information is needed about why it did not reduce overall use of cesarean. Potential explanatory factors include trials that were underpowered; versus use of outcome measurements that allow cesareans undertaken for varied reasons to be grouped in uninformative ways. We also need 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. Detailed research in the context of multi-site trials is warranted to more carefully parse which tools, individually and combined, have effect. Indeed the need for future research in this area is clear. Defining those needs better is the focus of a companion piece to this evidence review. The forthcoming report gathered information from multiple stakeholders including obstetricians, family physicians, midwives, insurers, advocacy groups, and individual women, and used a system of information gathering and surveys to prioritize which research is most urgently needed.

In conclusion, no approach dominated as a strategy appropriate to reduce use of cesarean in low-risk women in the United States. The literature spans the globe and may not have the level of applicability we would desire to contemporary U.S. populations. This is concerning as cesarean rates among low risk women continue to rise and the individual and public benefits of avoiding unnecessary cesarean may be substantial.

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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
°C	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
°F	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
mmHg	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
PCO ₂	partial pressure of carbon dioxide
pH	power of hydrogen
PICOTS	Population(s), Intervention(s), Outcome(s), Timing, and Setting
PO ₂	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

Appendix A. Exact Search Strings and Results

Table A1. PubMed search strategies

Search terms		Search results
#1	(cesarean section[mh:noexp] OR cesarean[tiab] OR caesarean[tiab] OR c-section[tiab]) AND pregnancy[mh]	38234
#2	randomized controlled trial[pt] OR controlled clinical trial[pt] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR "clinical trial"[tiab] OR random[tiab] OR randomized[tiab] OR randomly[tiab] OR control[tiab] OR controlled[tiab] OR controls[tiab] OR interrupted time series[tiab] OR ecologic[tiab] OR delivery of health care[majr] OR health services research[majr]	3072065
#3	#1 AND #2 AND eng[la] AND humans[mh]	6966
#4	#3 AND newspaper article[pt]	7
#5	#3 AND letter[pt]	102
#6	#3 AND comment[pt]	92
#7	#3 AND case reports[pt]	340
#8	#3 AND review[pt]	552
#9	#3 AND practice guideline[pt]	11
#10	#3 AND clinical conference[pt]	3
#11	#3 AND editorial[pt]	36
#12	#3 AND historical article[pt]	10
#13	#3 AND meta-analysis[pt]	149
#14	#3 AND congresses[pt]	5
#15	#3 AND in vitro[pt]	50
#16	#3 AND retracted publication[pt]	1
#17	#3 NOT (#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16)	5822

Key: [mh] Medical Subject Heading; [mh:noexp] Medical Subject Heading not including narrower subject terms; [majr] Medical Subject Heading as main focus of article; [tiab] title/abstract word; [pt] publication type

*Note: numbers do not tally as some articles are excluded in more than one category.

Table A2. CINAHL search results

Search terms		Search results
#1	"cesarean" OR (MH "Cesarean Section") OR "caesarean" OR "c-section"	7755
#2	(MH "Pregnancy") OR "pregnancy"	80117
#3	#1 AND #2	6447
#4	(MH "Clinical Trials") OR "randomized controlled trial" OR (MH "Random Assignment") OR "random allocation" OR "random assignment" OR "clinical trial" OR random OR randomized OR randomly OR controlled OR control OR controls OR "interrupted time series" OR ecologic OR (MH "Health Care Delivery") OR (MH "Health Services Research")	494241
#5	#3 AND #4 AND English Language	1684
#6	#5 AND Publication Type: Letter	77
#7	#5 AND Publication Type: Commentary	145
#8	#5 AND Publication Type: Case study	67
#9	#5 AND Publication Type: Review	81
#10	#5 AND Publication Type: Practice Guidelines	11
#11	#5 AND Publication Type: Editorial	24
#12	#5 AND Publication Type: Historical Material	0
#13	#5 AND Publication Type: Anecdote	5
#14	#5 AND Publication Type: Interview	1
#15	#5 AND Publication Type: Proceedings	2
#16	#6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15	337
#17	#5 NOT #16	1347
#18	#17 Exclude MEDLINE records	214

KEY: MH major heading

Appendix B. Excluded Studies

Reasons for exclusion:

X-1 = Ineligible study design

X-2 = Not original research

X-3 = Pregnant women not intending a vaginal birth

X-4 = Not relevant to strategies to reduce cesarean birth topic

X-5 = Does not state that intent was to improve/reduce cesarean rates

X-6 = Does not reflect US contemporary practice

X-7 = Not published in English

X-8 = Unable to obtain study

X-9 = Population was all cesarean

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Appendix C. Evidence Tables

Evidence Table C1. Strategies To Reduce Cesarean Birth

Evidence Table C2. Strategies To Reduce Cesarean Birth—Systems Interventions

Evidence Table C1. Strategies to reduce cesarean birth

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Abdel-Aleem et al., 2005 Country: Egypt Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 04/2003 to 03/2004 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Transcervical amnioinfusion (1000 mL warmed saline) and 1 g amoxicillin IV Groups: G1: Amnioinfusion and conventional obstetric care G2: Conventional obstetric care only N at enrollment: G1: 219 G2: 219 N at birth: G1: 219 G2: 219 Age: NR Race/ethnicity: NR Parous: NR Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Single fetus • Vertex presentation • Gestational age > 37 weeks • Cervical dilation < 5 cm • Nonreassuring fetal heart rate trace indicating fetal distress Exclusion criteria: <ul style="list-style-type: none"> • Vaginal bleeding • Fetal anomalies • Uterine scars • Uterine anomalies • Malpresentation • Intrauterine growth retardation • Maternal temperature > 38° C • Grand multiparity (> 5) • Severe pre-eclampsia 	Cervical dilation at admission, mean cm ± SD: G1: 3.9 ± 1.1 G2: 3.8 ± 1.3 Cervical effacement at admission: NR	Labor progression: NR Labor augmented, n (%): G1: 22 (10.1) G2: 23 (10.5) AROM: NR Internal monitoring (method NR), n (%): G1: 219 (100) G2: 219 (100) Amnioinfusion, n (%): G1: 214 (97.7) G2: 0 Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth for fetal distress, n (%): G1: 105 (47.9) G2: 149 (68) G1/G2: RR = 0.70 (95% CI: 0.60-0.83) Vaginal, assisted: NR Vaginal, spontaneous: NR Maternal harms, n (%): Maternal pyrexia (> 38°C): G1: 16 (7.3) G2: 14 (6.4) G1/G2: RR = 1.14 (95% CI: 0.57-2.28) Maternal mortality: NR Infant outcomes Neonatal mortality, n (%): G1: 0 G2: 1 (< 1) Apgar score < 7, n (%): 1 minute: G1: 29 (13.2) G2: 77 (0.35) G1/G2: RR = 0.38 (95% CI: 0.26-0.55) 5 minutes: G1: 9 (4.1) G2: 29 (13.2) G1/G2: RR = 0.31 (95% CI: 0.15-0.64) NICU admission, n (%): G1: 14 (6.4) G2: 31 (14.2) G1/G2: RR = 0.45 (95% CI: 0.25-0.83)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Adamsons et al., 1999 Country: Puerto Rico Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 04/1998 to 10/1998 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Propranolol 2 mg IV given every 4 hours until delivery, started upon admission to labor room after an initial period of observation revealed no evidence of abnormal fetal heart rate patterns. Groups: G1: Propranolol G2: Usual care N at enrollment: G1: 34 G2: 23 N at birth: G1: 34 G2: 23 Age: NR Race/ethnicity: NR Parous: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparity • No contraindication for vaginal delivery or use of propranolol (e.g., history of bronchial asthma) • Investigator available to be present through complete labor and delivery period Exclusion criteria: <ul style="list-style-type: none"> • See inclusion criteria 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, total time of labor, mean hours (range): G1: 7.92 (2.25-11.0) G2: 6 (2.0-11.25) G1/G2: $P = NS$ Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	<u>Maternal outcomes</u> Cesarean birth, n (%): G1: 4 (11.7) G2: 4 (17.6) G1/G2: $P = 0.367$ Vaginal, assisted: NR Vaginal, spontaneous: NR Maternal harms, n: Anesthesia related morbidity: G1: 0 G2: 0 Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality, n: G1: 0 G2: 0 Apgar score: NR NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Ajadi et al., 2006 Country: Nigeria Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Amniotomy in labor Groups: G1: Amniotomy G2: Control/no amniotomy N at enrollment: G1: 64 G2: 64 N at birth: G1: 64 G2: 64 Age, mean \pm yrs SD: G1: 29.4 \pm 5.7 G2: 28.6 \pm 6.9 Race/ethnicity: NR Parous: NR Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> Uncomplicated pregnancy presenting in labor Spontaneous onset of labor at ≥ 37 weeks to < 42 weeks Singleton fetus in cephalic presentation Cervical dilatation ≥ 4 cm but < 6 cm Intact membranes Exclusion criteria: <ul style="list-style-type: none"> High-risk pregnancies, such as previous cesarean, hemoglobinopathies, hypertension in pregnancy, malpresentations and multiple pregnancies, antepartum hemorrhage, suspected intrauterine growth restriction, advanced labor (≥ 6 cm), ruptured membranes, and fetal distress 	Cervical dilation at randomization, mean \pm SD: G1: 4.60 \pm 0.32 G2: 4.70 \pm 0.30 G1/G2: $P = NS$ Cervical effacement at admission: NR	Labor progression, vaginal deliveries, mean minutes \pm SD: Duration randomization to delivery: G1: 208.27 \pm 22.52 (n=58) G2: 292.07 \pm 23.41 (n=59) G1/G2: $P \leq 0.05$ Labor augmented, n (%): G1: 4 (6.25) G2: 6 (9.4) G1/G2: $P = NS$ AROM, n (%): G1: 64 (100) G2: NR ¹ Internal monitoring: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 1 (1.6) G2: 1 (1.6) G1/G2: $P = NS$ Vaginal, assisted, n (%): G1: 6 (9.3) G2: 5 (7.8) G1/G2: $P = NS$ Vaginal, spontaneous, n (%): G1: 57 (89.1) G2: 58 (90.6) G1/G2: $P = NS$ Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 1 minute, n (%): G1: 5 (7.8) G2: 4 (6.3) NICU admission: NR

¹ Patients could have amniotomy if progress was not satisfactory.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Asher et al., 2009 Country: US Participant source: Academic single site Intervention setting: Clinic Enrollment period: 02/2005 to 03/2007 Funding: American Academy of Family Physicians Foundation, American Academy of Family Physicians, UNC Dept. Family Medicine, NIH Author industry relationship disclosure: None Design: RCT	Intervention: Traditional Chinese Medicine (TCM) acupuncture, sham acupuncture, or usual care only group. Acupuncture point at LI4, SP6, BL32, and BL54 were needled bilaterally Groups: G1: TCM acupuncture G2: Sham acupuncture G3: No acupuncture N at enrollment: G1: 30 G2: 29 G3: 30 N at birth: G1: 30 G2: 29 G3: 30 Age, mean yrs \pm SD: G1: 30.4 \pm 3.9 G2: 29.6 \pm 4.8 G3: 28.9 \pm 5.7 Race/ethnicity: NR Parous, n: G1: 0 G2: 0 G3: 0 Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Between 38-41 weeks gestation • Able to communicate in English • ≥ 18 years old Exclusion criteria: <ul style="list-style-type: none"> • Uncertain dating • Transportation difficulties • Breech presentation • Previous inability to tolerate acupuncture 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: NR Labor augmented: NR AROM, n (%): G1: 16 (53) G2: 16 (55) G3: 17 (57) P = 0.99 Internal monitoring: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor, n (%): G1: 7 (23) G2: 6 (21) G3: 2 (7) P = 0.20	Maternal outcomes Cesarean birth, n (%): G1: 6 (20) G2: 2 (7) G3: 3 (10) P = 0.37 Vaginal, assisted: NR Vaginal, spontaneous: NR Maternal harms: Endometritis, n: G1: 0 G2: 0 G3: 0 P = 1.0 Postpartum hemorrhage and/or uterine atony), n (%): G1: 3 (10) G2: 2 (7) G3: 1 (3) P = 0.70 Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, mean \pm SD: 1 minute: G1: 7.7 \pm 1.8 G2: 7.9 \pm 1.6 G3: 8.2 \pm 1.4 P = 0.44 5 minutes: G1: 8.8 \pm 0.8 G2: 8.9 \pm 0.4 G3: 9.0 \pm 0.2 P = 0.36

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Asher et al., 2009 (continued)					NICU admission, n (%): G1: 0 G2: 0 G3: 1 (3.3) P = 0.66

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Barakat et al., 2009 Country: Spain Participant source: Academic single site Intervention setting: Other Enrollment period: 01/2000 to 03/2002 Funding: Spanish Ministry of Education Author industry relationship disclosure: NR Design: RCT	Intervention: Light-intensity resistance exercise training performed during 2 nd and 3 rd trimesters (three sessions per week for approximately 26 weeks) Groups: G1: Exercise sessions G2: Control N at enrollment: G1: 80 G2: 80 N at birth: G1: 72 G2: 70 Age, mean yrs \pm SD: G1: 30.4 \pm 2.9 G2: 29.5 \pm 3.7 Race/ethnicity: NR Parous, n (%): 0: G1: 52 (72.2) G2: 40 (57.1) 1: G1: 16 (22.2) G2: 25 (35.7) 2: G1: 4 (5.6) G2: 5 (7.1) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • 25-35 years old • Sedentary (not exercising > 20 minutes on > 3 days per week) • Singleton • Uncomplicated gestation Exclusion criteria: <ul style="list-style-type: none"> • High risk for preterm birth (more than one previous PTB) 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, mean minutes \pm SD: Dilation time: G1: 426 \pm 20 G2: 378 \pm 13 G1/G2: $P > 0.1$ Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 50 (69.4) G2: 48 (68.6) G1/G2: $P > 0.1$ Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 11 (15.3) G2: 11 (15.7) Vaginal, assisted, n (%): G1: 10 (13.9) G2: 9 (12.9) Vaginal, spontaneous, n (%): G1: 51 (70.8) G2: 50 (71.4) G1/G2: $P > 0.1$ Maternal harms, n (%): Exercise related injuries: G1: 0 G2: 0 Preterm deliveries: G1: 2 (2.8) G2: 3 (4.3) Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, mean \pm SD: 1 minute: G1: 8.9 \pm 1.1 G2: 8.8 \pm 1.2 5 minutes: G1: 9.9 \pm 0.2 G2: 9.9 \pm 0.3 NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Bernitz et al., 2011 Country: Norway Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: Regional Health Trust, National Advisory Committee for Obstetrics in Norway and Østfold Hospital Trust Author industry relationship disclosure: 0/6 Design: RCT	Intervention: Midwife-led unit: care designed for low risk women wanting minimal intervention (no epidural or augmentation unless required for second phase of second stage). If extended surveillance needed woman transferred to Normal or Special Unit. Normal unit: organized for women with expected normal births with access to extended surveillance, epidural and operative vaginal delivery. Special unit: organized for women who need extended surveillance in the antenatal period, during labor and after birth. Groups: G1: Midwife-led unit G2: Normal unit G3: Special unit N at enrollment: G1: 282 G2: 412 G3: 417 N at birth: G1: 282 G2: 412 G3: 417 Age, n (%): < 25 years: G1: 103 (25) G2: 100 (24)	Inclusion criteria: <ul style="list-style-type: none"> • Healthy, low risk women without any disease known to influence the pregnancy • Singleton fetus in cephalic position • Pre-pregnant BMI ≤ 32 • Not smoking more than 10 cigarettes/day • No prior operation on uterus • No prior complicated deliveries • Spontaneous onset of labor between 36⁺¹ and 41⁺⁶ weeks Exclusion criteria: <ul style="list-style-type: none"> • See above 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: NR Labor augmented, n (%): G1: 108 (26.2) G2: 153 (36.7) G3: 107 (38.0) <i>P</i> < 0.01 AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 65 (16.0) G2: 97 (23.0) G3: 70 (25.0) <i>P</i> < 0.01 Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 24 (6.0) G2: 24 (6.0) G3: 23 (8.0) <i>P</i> = NS Vaginal, assisted, n (%): G1: 43 (10.0) G2: 51 (12.0) G3: 30 (11.0) <i>P</i> = NS Vaginal, spontaneous, n (%): G1: 345 (84.0) G2: 342 (82.0) G3: 229 (81.0) <i>P</i> = NS Maternal harms (post partum hemorrhage > 1000 ml), n (%): G1: 7 (1.7) G2: 9 (2.2) G3: 9 (3.2) <i>P</i> = NS Maternal mortality: NR Infant outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, n (%): G1: 4 (1.0) G2: 6 (1.0) G3: 1 (0.5) <i>P</i> = NS NICU admission, n (%): G1: 32 (8.0) G2: 26 (6.0) G3: 19 (7.0) <i>P</i> = NS

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Bernitz et al., 2011 (continued)	<p>G3: 64 (22.7)</p> <p>25-35 years:</p> <p>G1: 263 (63.8)</p> <p>G2: 270 (64.7)</p> <p>G3: 181 (64.2)</p> <p>> 35 years:</p> <p>G1: 46 (11.2)</p> <p>G2: 47 (11.3)</p> <p>G3: 37 (13.1)</p> <p>Race/ethnicity: NR</p> <p>Parous, n (%):</p> <p>G1: 134 (32.5)</p> <p>G2: 132 (31.7)</p> <p>G3: 98 (35.4)</p> <p>Medicaid: Not applicable</p>				

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Bidgood and Steer, 1987 Country: UK Participant source: Academic single site Intervention setting: Antenatal clinic Labor and delivery suite Enrollment period: NR Funding: Action Research for the Crippled Child Author industry relationship disclosure: NR Design: RCT	Interventions: <ul style="list-style-type: none"> G1: Oxytocin deferred for 8 hours then given at treating physician's discretion G2: If uterine activity < 700 kPas/15 min, oxytocin at 2 mU/min and increased by 2 mU/min every 15 minutes until uterine activity stable or > 1500 kPas/15 min, then infusion rate halved to maintenance level 2mU/min G3: Oxytocin at 7 mU/min and increased by 7 mU/min every 15 minutes, limited by a frequency of 7 contractions in 15 minutes or by abnormality in the fetal heart rate (FHR) trace. Groups: G1: No oxytocin for 8 hours G2: Automatic infusion/low-dose oxytocin G3: High-dose oxytocin N at enrollment: G1: 20 G2: 21 G3: 19 N at birth: G1: 20 G2: 21 G3: 19	Inclusion criteria: <ul style="list-style-type: none"> First spontaneous labor Vertex presentation Within 3 weeks of term Slow progress of labor Exclusion criteria: <ul style="list-style-type: none"> See inclusion criteria 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, mean hours \pm SD: G1: 27 \pm 8.1 G2: 25 \pm 6.7 G3: 23 \pm 7.8 Labor augmented, n (%): Oxytocin stimulation: G1: 5 (25.0) G2: 13 (61.9) G3: 19 (100.0) AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n: Total: 58/60 Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 9 (45) G2: 7 (33.3) G3: 5 (26.3) Vaginal, assisted, n (%): Kielland forceps and low forceps: G1: 8 (40) G2: 9 (42.8) G3: 8 (41) Vaginal, spontaneous, n (%): G1: 3 (15) G2: 5 (23.8) G3: 6 (31.5) Maternal harms, n: Hyperstimulation: G1: 0 G2: 0 G3: 7 Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, n: G1: 1 G2: 1 G3: NR NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Bidgood and Steer, 1987 (continued)	Age: NR Race/ethnicity: NR Parous: NR Medicaid: Not applicable				

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Bloom et al., 2006 Country: US Participant source: Academic multi site Intervention setting: Labor and delivery suite Enrollment period: 05/2002 to 02/2005 Funding: NIH Author industry relationship disclosure: NR Design: RCT	Intervention: Knowledge of intrapartum fetal oxygen saturation through a display to the clinician on a fetal pulse oximeter Groups: G1: Open, fetal oxygen saturation displayed G2: Masked, fetal oxygen saturation not displayed N at enrollment: G1: 2,629 G2: 2,712 N at birth: G1: 2,629 G2: 2,712 Age, mean yrs \pm SD: G1: 23.5 \pm 5.5 G2: 23.5 \pm 5.5 Race/ethnicity, n (%): White: G1: 1,348 (51.3) G2: 1,414 (52.1) Black: G1: 817 (31.1) G2: 838 (30.9) Asian: G1: 39 (1.5) G2: 34 (1.3) Other: G1: 425 (16.2) G2: 426 (15.7) Hispanic or Latino: G1: 641 (24.4) G2: 668 (24.6) Not Hispanic or Latino: G1: 1,988 (75.6) G2: 2,044 (75.4) Parous, n: G1: 0 G2: 0 Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Singleton, cephalic, living fetus • ≥ 36 weeks of gestation • Cervical dilatation 2-6 cm Exclusion criteria: <ul style="list-style-type: none"> • Planned cesarean delivery • Maternal fever ($\geq 38^{\circ}\text{C}$) • Known HIV or hepatitis virus infection • Heart or renal disease • Diabetes mellitus 	Cervical dilation at admission, mean cm \pm SD: G1: 4.7 \pm 1.0 G2: 4.7 \pm 1.0 Cervical effacement at admission: NR	Labor progression: NR Labor augmented, n (%): Oxytocin: G1: 1,859 (70.7) G2: 1,913 (70.5) AROM: NR Internal monitoring, n (%): Electronic fetal monitoring: G1: 2,629 (100) G2: 2,712 (100) Amnioinfusion: NR Epidural: NR Regional analgesia, n (%): G1: 2266 (86.2) G2: 2362 (87.1) Maternal infection in labor, n (%): Chorioamnionitis: G1: 282 (10.7) G2: 291 (10.7) G1/G2: $P = 1.00$	Maternal Outcomes Cesarean birth, n (%): G1: 692 (26.3) G2: 747 (27.5) G1/G2: RR = 0.96 (95% CI: 0.87-1.04), $P = 0.31$ Vaginal, assisted, n (%): G1: 380 (14.5) G2: 400 (14.7) G1/G2: RR = 0.98 (95% CI: 0.86-1.12), $P = 0.76$ Vaginal, spontaneous, n (%): G1: 1557 (59.2) G2: 1565 (57.7) G1/G2: RR = 1.03 (95% CI: 0.98-1.07), $P = 0.26$ Maternal harms, n (%): Postpartum endometritis: G1: 114 (4.3) G2: 120 (4.4) G1/G2: $P = 0.87$ Wound complications: G1: 4 (0.2) G2: 3 (0.1) G1/G2: $P = 0.72$ Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 0 G2: 1 (< 0.1) G1/G2: $P = 1.00$ Apgar score < 4, 5 minutes, n (%): G1: 6 (0.2) G2: 3 (0.1) G1/G2: $P = 0.34$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Bloom et al., 2006 (continued)					NICU admission, n (%): G1: 126 (4.8) G2: 147 (5.4) G1/G2: $P = 0.30$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Bloom et al., 1998 Country: US Participant source: Non-academic single site Community Intervention setting: Labor and delivery suite Enrollment period: 09/1996 to 10/1997 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Walking as desired during 1 st stage of labor, as compared with supine, lateral or sitting position in labor bed (usual care) Groups: G1: Walking group G2: Usual care group Ga: Women who actually walked Gb: Women who did not walk N at enrollment: (1st stage of labor) G1: 536 G1a: 380 G1b: 156 G2: 531 N at birth: G1: 536 G2: 531 Age, mean years ± SD: G1: 22.4 ± 5 G2: 22.5 ± 5 Race/ethnicity, n (%): White: G1: 24 (4) G2: 26 (5) Black: G1: 67 (12) G2: 74 (14) Hispanic: G1: 440 (82) G2: 425 (80) Other: G1: 5 (1) G2: 6 (1) Parous, n (%): G1: 264 (49) G2: 259 (49) Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> Regular uterine contractions Cervical dilatation of 3-5 cm Cephalic presentation 36-41 weeks gestation Exclusion criteria: <ul style="list-style-type: none"> Any known complications of pregnancy, including breech presentation 	Cervical dilation at admission, mean cm ± SD: G1: 4.0 ± 0.9 G2: 4.0 ± 0.8 G1/G2: <i>P</i> = 0.74 Cervical effacement at admission: NR	Labor progression: Length of 1 st stage, mean hours ± SD: G1: 6.1 ± 3.6 G1a: 6.2 ± 3.5 G1b: 5.5 ± 3.6 G2: 6.1 ± 3.5 G1a/G1b: <i>P</i> = 0.05 G1a/G2: <i>P</i> = 0.36 Duration of labor 1 st stage, nulliparous women, mean hours ± SD: G1: 7.6 ± 3.9 G2: 7.3 ± 3.9 G1/G2: <i>P</i> = 0.47 Duration of labor 1 st stage, parous women, mean hours ± SD: G1: 4.6 ± 2.4 G2: 4.7 ± 2.4 G1/G2: <i>P</i> = 0.60 Duration of labor 2 nd stage, mean hours ± SD: G1: 0.6 ± 3.6 G2: 0.6 ± 0.7 G1/G2: <i>P</i> = NS Duration of labor 2 nd stage, nulliparous women, mean hours ± SD: G1: 1.0 ± 0.9 G2: 0.9 ± 0.8 G1/G2: <i>P</i> = 0.46 Duration of labor 2 nd stage, parous women, mean hours ± SD: G1: 0.2 ± 0.3 G2: 0.2 ± 0.3 G1/G2: <i>P</i> = 0.42 Labor augmented, n (%): Oxytocin: G1: 122 (23) G1a: 85 (22) G2: 137 (26) G1a/G2: <i>P</i> = 0.23	Maternal outcomes Cesarean birth, n (%): Cesarean birth: G1: 23 (4) G2: 31 (6) G1/G2: <i>P</i> = 0.25 Cesarean birth, nulliparous women: G1: 19 (7) G2: 21 (8) G1/G2: <i>P</i> = 0.74 Cesarean birth, parous women: G1: 4 (2) G2: 10 (4) G1/G2: <i>P</i> = 0.10 Vaginal, assisted, n (%): Forceps: G1: 23 (4) G2: 17 (3) G1/G2: <i>P</i> = 0.35 Forceps, nulliparous women: G1: 21 (8) G2: 15 (6) G1/G2: <i>P</i> = 0.30 Forceps, parous women: G1: 2 (1) G2: 2 (1) G1/G2: <i>P</i> = 0.99 Vaginal, spontaneous, n (%): G1: 490 (91) G2: 483 (91) G1/G2: <i>P</i> = 0.39 Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 0 G2: 0

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Bloom et al., 1998 (continued)				<p>Oxytocin, nulli-parous women: G1: 95 (35) G2: 99 (36) G1/G2: $P = 0.72$</p> <p>Oxytocin, parous women: G1: 27 (10) G2: 38 (15) G1/G2: $P = 0.12$</p> <p>AROM: NR</p> <p>Internal monitoring: NR</p> <p>Amnioinfusion: NR</p> <p>Epidural only, n (%): G1: 29 (5) G2: 31 (6)</p> <p>Epidural and IV analgesia, n (%): G1: 138 (26) G2: 153 (29)</p> <p>Maternal infection in labor, n (%): Chorioamnionitis: G1: 43 (8) G2: 42 (8)</p>	<p>Apgar score < 3, 5 minutes, n: G1: 0 G2: 0</p> <p>NICU admission: NR</p>

Among the 380 women in G1 who actually walked, 278 (73%) were asked if they would choose to walk again during a future labor, and 274 (99%) said yes.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Campbell et al., 2006 Country: US Participant source: Academic single site Intervention setting: Ambulatory care center, diner, homes, various locations Enrollment period: 1998 to 2002 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Lay doulas (personally chosen, additional support people who received training from a certified doula) Groups: G1: Doulas support in labor G2: Control/standard care N at enrollment: G1: 298 G2: 300 N at birth: G1: 291 G2: 295 Age, mean yrs: G1: 22.2 G2: 22.6 Race/ethnicity, %: White: G1: 56 G2: 56 Black: G1: 36 G2: 29 Indian: G1: 0.4 G2: 0.6 Chinese: G1: 0.7 G2: 0.2 Filipino: G1: 0.4 G2: 0.6 Other: G1: 6 G2: 12 Hispanic: G1: 18 G2: 21 Non-Hispanic: G1: 78 G2: 72 Other: G1: 4 G2: 7	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Singleton pregnancy • Low-risk pregnancy at the time of enrollment in the study • Able to identify a female friend or family member willing to act as a lay doula Exclusion criteria: <ul style="list-style-type: none"> • Contraindication to labor (e.g., placenta previa, planned cesarean) 	Cervical dilation at admission, mean cm \pm SD: G1: 4.3 ± 1.3 G2: 3.9 ± 1.2 G1/G2: $P = 0.007$ Cervical effacement at admission: NR	Length of labor, vaginal births, mean hours \pm SD: G1: 10.4 ± 4.3 G2: 11.7 ± 4.8 G1/G2: $P = 0.004$ Labor augmented, %: Pitocin: G1: 46 G2: 49 AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, %: G1: 85 G2: 88 G1/G2: $P = 0.4$ Maternal infection in labor: NR	Maternal outcomes Cesarean birth, %: G1: 18.9 G2: 17.9 G1/G2: $P = 0.7$ Vaginal, assisted: NR Vaginal, spontaneous: NR Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score > 6, %: 1 minute: G1: 95 G2: 90 G1/G2: $P = 0.04$ 5 minutes: G1: 99.7 G2: 97.0 G1/G2: $P = 0.006$ NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Campbell et al., 2006 (continued)	<p>Parous, n: G1: 0 G2: 0</p> <p>Medicaid: NR</p> <p>Low income, %: G1: 100 G2: 100</p>				

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Choudhary et al., 2010 Country: India Participant source: Academic single site Intervention setting: Hospital, labor and delivery suite Enrollment period: NR Funding: NR Author industry relationship disclosure: None Design: RCT	Intervention: Transcervical amnioinfusion during labor complicated by meconium-stained amniotic fluid in a setting with limited peripartum facilities Groups: G1: Amnioinfusion G2: Standard labor management without amnioinfusion N at enrollment: G1: 146 G2: 146 N at birth: G1: 146 G2: 146 Age, mean yrs \pm SD: G1: 24.0 \pm 3.8 G2: 25.3 \pm 4.7 Race/ethnicity: NR Parous, %: Multigravida: G1: 56.2 G2: 56.5 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Term pregnancy > 37 weeks • Singleton pregnancy • Cephalic presentation • Moderate or thick meconium • Adequate pelvis Exclusion criteria: <ul style="list-style-type: none"> • Indications for immediate delivery such as cord prolapsed • Persistent fetal bradycardia • Chorioamnionitis • Antepartum hemorrhage • Fetal malpresentation • Fetal congenital anomaly • Polyhydramnios • Maternal cardiac or pulmonary disease • Multiple gestation 	Cervical dilation at admission: NR Cervical effacement at admission: NR When meconium detected, cm \pm SD: G1: 3.8 \pm 1.0 G2: 3.5 \pm 1.4	Labor progression, time from meconium detection to delivery, minutes, mean \pm SD: G1: 178.3 \pm 101.8 G2: 130.5 \pm 70.4 G1/G2: $P = 0.000$ Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion, n (%): G1: 146 (100) G2: 0 Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 43 (29.5) G2: 93 (63.7) Vaginal, assisted, n (%): G1: 0 G2: 7 (4.8) Vaginal, spontaneous, n (%): G1: 103 (70.5) G2: 46 (31.5) Maternal harms, n (%): Pyrexia: G1: 4 (3) G2: 8 (5) G1/G2: $P = 0.238$ Incoordinate uterine activity: G1: 0 G2: 3 (2.1) Cord prolapse during amnioinfusion: G1: 0 G2: 0 Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 2 (1.4) G2: 16 (11) G1/G2: $P = 0.01$ Apgar score < 7, n (%): 1 minute: G1: 15 (10) G2: 45 (31) G1/G2: $P < 0.001$ 5 minutes: G1: 1 (0.7) G2: 12 (8.2) G1/G2: $P = 0.000$ NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Cohen et al., 1987 Country: US Participant source: Community practice Intervention setting: Labor and delivery suite Enrollment period: 09/1985 to 06/1986 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Early aggressive management consisted of amniotomy if required, insertion of a fetal electrode, an intrauterine pressure cannula and oxytocin infusion within 30 minutes of presentation to the labor suite. Groups: G1: Early aggressive management group G2: Control group N at enrollment: G1: 75 G2: 75 N at birth: G1: 75 G2: 75 Age, mean yrs (SEM): G1: 19.5 (0.4) G2: 20.6 (0.4) G1/G2: <i>P</i> = NS Race/ethnicity, %: White: G1: 54.7 G2: 66.7 Black: G1: 37.4 G2: 21.3 Hispanic: G1: 8.0 G2: 10.7 G1/G2: <i>P</i> = NS Parous, n (%): Primigravid: G1: 75 (100) G2: 75 (100) Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> • Low risk • Primigravid • 37 to 42 weeks • Met standard criteria for admission to labor suite (uterine contractions accompanied by cervical dilation of 3 cm or ruptured membranes) • Demonstrated an inadequate pattern (frequency of < 3 contractions lasting 40 seconds each in a 10 minute time period). Exclusion criteria: <ul style="list-style-type: none"> • See inclusion criteria 	Cervical dilation at admission, mean cm \pm SD: G1: 2.6 \pm 0.1 G2: 3.0 \pm 0.1 G1/G2: <i>P</i> = 0.03 Cervical effacement at admission, mean (SEM): G1: 82.3 (2.3) G2: 85.3 (2.5) G1/G2: <i>P</i> = NS	Labor progression, subjects achieving vaginal delivery, mean hours (SEM): Duration of labor, latent period: G1: 1.42 (0.33) G2: 2.15 (0.29) G1/G2: <i>P</i> = NS Duration of labor, active phase: G1: 4.38 (0.36) G2: 4.14 (0.36) G1/G2: <i>P</i> = NS Duration of labor, deceleration phase: G1: 0.27 (0.07) G2: 0.27 (0.06) G1/G2: <i>P</i> = NS Labor augmented, n (%): G1: 75 (100)* G2: 28 (37)* AROM: NR Internal monitoring, n (%): Fetal electrode: G1: 75 (100) G2: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 10 (13) G2: 11 (15) G1/G2: <i>P</i> = NS Vaginal, assisted, n (%): G1: 6 (8) G2: 3 (4) G1/G2: <i>P</i> = NS Vaginal, spontaneous, n (%): G1: 59 (79) G2: 61 (81) G1/G2: <i>P</i> = NS Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, 5 minutes, mean (SEM): G1: 8.97 (0.06) G2: 8.95 (0.06) G1/G2: <i>P</i> = NS Cord pH, mean \pm SD: G1: 7.31 (0.01) G2: 7.31 (0.01) G1/G2: <i>P</i> = NS NICU admission: NR

* Calculated by reviewer.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Cox et al., 1999 Country: UK Participant source: Non-academic single site Intervention setting: Labor and delivery suite Enrollment period: 05/1996 to 01/1998 Funding: Nycomed UK Author industry relationship disclosure: NR Design: RCT	Intervention: Inflatable obstetric belt; synchronized to apply uniform fundal pressure during contraction, used for the 2 nd stage of labor Groups: G1: Inflatable obstetric belt during 2 nd stage of labor G2: Standard care with 1 hour of passive 2 nd stage and 1 hour active pushing; instrumental delivery if not imminent N at enrollment: G1: 260 G2: 240 N at birth: G1: 260 G2: 240 Age, mean yrs ± SD: G1: 30.3 ± 4.1 G2: 30.1 ± 4.5 Race/ethnicity, n (%): White: G1: 224 (93.3) G2: 204 (85) Other: G1: 36 (13.8) G2: 36 (15) Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Singleton • Cephalic presentation • Age 20-40 years • Term delivery (> 37 weeks gestation) • Functioning epidural analgesia • < 10 cm cervical dilatation at admission • Weight < 100 kg • Written informed consent Exclusion criteria: <ul style="list-style-type: none"> • History of cancer • Significant cardiovascular, renal, hepatic, GI, respiratory, endocrine, metabolic, hematopoietic, or neurological disorders • Current drug or alcohol abuse • Previous surgery of the myometrium • Moderate to severe PIH • History of antepartum hemorrhage in current pregnancy • Abnormal fetus • Uterine overextension • Hydramnios • Abnormal uterine activity • Signs of placental abruption 	Cervical dilation at insertion of epidural, median cm (range): G1: 4 (3-5) G2: 3 (2.5-4.25) Cervical effacement at admission: NR	Labor progression, median minutes (IQR): Duration of 1 st stage: G1: 450 (320-622.5) G2: 495 (340-645) Length of total 2 nd stage: G1: 136 (107-160) G2: 136 (95.5-165) G2/G1: Δ = -1 (95% CI: -10, 7), <i>P</i> = 0.8053 Labor augmented, n (%): Oxytocin: G1: 166 (63.8) G2: 151 (62.9) Induced: G1: 79 (30.4) G2: 66 (27.5) AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 260 (100) G2: 240 (100) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 15 (5.8) G2: 9 (3.8) G2/G1: OR = 0.64 (95% CI: 0.27-1.49), <i>P</i> = 0.292 Vaginal, assisted, n (%): Lift-out instrumental: G1: 108 (41.5) G2: 101 (42.1) G2/G1: OR = 1.02 (95% CI: 0.71-1.46), <i>P</i> = 0.902 Rotational instrumental: G1: 26 (10) G2: 36 (15) G2/G1: OR = 1.59 (95% CI: 0.92-2.73), <i>P</i> = 0.090 Vaginal, spontaneous, n (%): G1: 111 (42.7) G2: 94 (39.2) G2/G1: OR = 0.86 (95% CI: 0.60-1.24), <i>P</i> = 0.423 Maternal harms, n (%): 3rd degree tear: G1: 17 (6.5) G2: 1 (0.4) G2/G1: OR = 16.72 (95% CI: 2.81-∞), <i>P</i> < 0.001 Catheter insertion for urinary retention: G1: 6 (2.3) G2: 2 (1.3) Maternal mortality, n: G1: 0 G2: 0

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Cox et al., 1999 (continued)					<u>Neonatal outcomes</u> Neonatal mortality, n: G1: 0 G2: 0 Apgar score: NR NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: East et al., 2006 Country: Australia Participant source: Academic multisite Intervention setting: Labor and delivery suite Enrollment period: 07/1999 to 09/2004 Funding: Australian National Health and Medical Research Council, Queensland Health, The University of Queensland, TYCO Inc. Author industry relationship disclosure: NR Design: RCT	Intervention: Cardiotocography monitoring with fetal pulse oximetry Groups: G1: Cardiotocography with fetal pulse oximetry G2: Cardiotocography only N at enrollment: G1: 306 G2: 295 N at birth: G1: 306 G2: 295 Age, mean yrs \pm SD: G1: 29.7 \pm 5.8 G2: 28.9 \pm 5.6 Race/ethnicity: NR Parous, n (%): G1: 58 (19.0) G2: 69 (23.4) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Non-reassuring cardiotocograph during labor • Early or active labor • Able to give informed consent • Gestational age \geq 36 weeks • Ruptured amniotic membranes or eligible and consenting to artificial rupture of membranes Exclusion criteria: <ul style="list-style-type: none"> • Multiple gestation • Non-vertex presentation • Placenta previa • Abruptio placentae • Antepartum hemorrhage • Uterine anomaly • Fetal anomalies • Known significant viral infection • Other contraindication to invasive monitoring 	Cervical dilation at admission, median cm (IQR): G1: 3 (2-3.9) G2: 3 (2-4) Cervical effacement at admission: NR Prior cesarean, n (%): G1: 19 (6.2) G2: 16 (5.4) Multiple gestation, n: G1: 0 G2: 0	Labor progression, median minutes (IQR): G1: 186 (109, 306) G2: 147 (94, 248) G1/G2: $P = 0.01$ Labor augmented, n (%): Oxytocin infusion: G1: 254 (83.3) G2: 238 (80.7) Prostaglandin: G1: 86 (28.2) G2: 88 (29.8) AROM, n (%): G1: 162 (53.1) G2: 171 (58.0) Internal monitoring, n (%): G1: 305 (100) G2: 295 (100) Amnioinfusion: NR Epidural, n (%): G1: 274 (89.8) G2: 254 (86.1) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 140 (45.9) G2: 142 (48.1) G1/G2: RR = 0.95 (95% CI: 0.80-1.13), $P = 0.584$ Vaginal, assisted, n (%): G1: 84 (27.5) G2: 67 (22.7) G1/G2: RR = 1.21 (95% CI: 0.92-1.60), $P = 0.173$ Vaginal, spontaneous, n (%): G1: 81 (26.6) G2: 86 (29.2) G1/G2: RR = 0.91 (95% CI: 0.70-1.18), $P = 0.478$ Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 4, 1 minute, n (%): G1: 12 (3.9) G2: 9 (3.1) G1/G2: RR = 1.29 (95% CI: 0.55-3.02), $P = 0.556$ Apgar score < 7, 5 minutes, n (%): G1: 5 (1.6) G2: 6 (2) G1/G2: RR = 0.81 (95% CI: 0.25-2.61), $P = 0.719$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
East et al., 2006 (continued)					<p>Apgar score, median (IQR): 1 minute: G1: 8 (7-9) G2: 9 (7-9) G1/G2: $P = 0.344$</p> <p>5 minutes: G1: 9 (9-9) G2: 9 (9-9) G1/G2: $P = 0.802$</p> <p>NICU admission, n (%): G1: 9 (3) G2: 11 (3.7) G1/G2: $RR = 0.79$ (95% CI: 0.33-1.88), $P = 0.596$</p>

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Frigoletto et al., 1995 Country: US Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 01/1991 to 07/1993 Funding: NIH Author industry relationship disclosure: NR Design: RCT	Intervention: Active management labor protocol: One-to-one nursing care. Standardized criteria for diagnosis of labor (painful contractions accompanied by effacement at least 80%, bloody show or spontaneous rupture of membranes). Management of labor- amniotomy within one hour of diagnosis. Cervical exams at least every two hours. Oxytocin to treat inefficient uterine action (rate of cervical dilation < than 1 cm/hour during 1 st stage of labor, time between full dilation and fetus head at pelvic floor > 1 hour during 2 nd stage. Infusion begun at 4mU per minute and increased by 4mU per minute to maximum dose of 40 mU per minute Groups: G1: Active management G2: Usual care N at enrollment: G1: 1017 G2: 917 N at birth: G1: 1009 G2: 906	Inclusion criteria: <ul style="list-style-type: none"> • Full-term pregnancy • Vertex presentation • Spontaneous onset of labor Exclusion criteria: <ul style="list-style-type: none"> • Pregnancy related complications: • Pregnancy-induced hypertension • Nonreassuring fetal-heart pattern at admission • Gestational diabetes • Intrauterine growth retardation • Oligo hydramnios • Placenta previa • Prolapsed cord • Score of < 6 out of 8 on a biophysical profile • Treatment with systemic steroids during pregnancy • Fetus with congenital anomaly • Active herpes • Maternal medical conditions: • Diabetes • HIV infection with CD4 lymphocyte count < 500 • Serious chronic medical condition 	Cervical dilation at admission, mean \pm SD: Protocol eligible (n): G1: (678) 3.3 \pm 2.0 G2: (585) 3.6 \pm 2.1 Cervical effacement at admission: NR	Labor progression: NR Labor augmented, n (%):Protocol eligible G1: (70) G2: (56) G1/G2: RR=1.3 (95% CI:1.2-1.4) AROM, n (%):Protocol eligible subgroup G1: (61) G2: (51) G1/G2: RR=1.2 (95% CI:1.1-1.3) Internal monitoring: NR Amnioinfusion: NR Epidural, %: Protocol eligible subgroup: G1: 54 G2: 64 G1/G2: RR = 0.8 (95% CI: 0.8-0.9) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): ITT: G1: 197 (19.5) G2: 176 (19.4) G1/G2: RR= 1.0 (95% CI: 0.8-1.2) Cesarean birth, %: Protocol eligible subgroup: G1: 10.9 G2: 11.5 G1/G2: RR = 0.9 (95% CI: 0.4-1.9) Vaginal, assisted, n (%): Protocol eligible subgroup: G1: (10.8) G2: (14.4) G1/G2: RR= 0.8 (95% CI: 0.6-1.2) Vaginal, spontaneous, n (%): Protocol eligible subgroup: G1: (78.3) G2: (74.2) G1/G2: RR = 1.1 (95% CI: 0.8-1.4) Maternal harms, n (%): Fever: G1/G2: RR 0.6 (95% CI: 0.4 -0.9) Maternal mortality: See comment below ¹ Infant outcomes Neonatal mortality: NR Apgar score < 5, five minutes, n: G1: 2 G2: 2

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Frigoletto et al., 1995 (continued)	Proctol-eligible: G1: 678 G2: 585 Age: NR Race/ethnicity: NR Parous: NR Medicaid: NR				NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Gagnon et al., 1997 Country: Canada Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 01/1993 to 07/1994 Funding: Fonds de la recherche en santé du Québec (FRSQ) Author industry relationship disclosure: NR Design: RCT	Intervention: One-to-one intrapartum nursing care from the time of randomization until one hour after birth Groups: G1: One-to-one intrapartum nursing care G2: No intervention/usual nursing care N at enrollment: G1: 209 G2: 204 N at birth: G1: 198 G2: 204 Age, mean yrs: G1: 27.6 G2: 27.8 Race/ethnicity: NR Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Singleton • > 37 weeks gestation • In labor (regular painful contractions \leq 5 minutes apart) Exclusion criteria: <ul style="list-style-type: none"> • Scheduled cesarean • Scheduled induction • IUGR • Preeclampsia • Paid labor support • Cervical dilation > 4 cm • Nonreactive non-stress test • Absence of fetal heart tones 	Cervical dilation at admission, mean cm \pm SD: G1: 2.7 ± 1.0 G2: 2.7 ± 1.0 Cervical effacement at admission: NR Multiple gestation, n: G1: 0 G2: 0	Labor duration from randomization, mean hours \pm SD: G1: 9.1 ± 4.1 G2: 9.4 ± 4.7 G1/G2: $\Delta = -0.3$ (95% CI: -1.0, 0.4) Labor augmented, n (%): Pre-randomization (oxytocin): G1: 55 (26.3) G2: 45 (22.1) Post-randomization (oxytocin): G1: 82 (39.2) G2: 96 (47.1) G1/G2: RR = 0.83 (95% CI: 0.67-1.04) AROM, n (%): G1: 128 (61.1) G2: 126 (61.8) Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): Before randomization: G1: 36 (17.2) G2: 41 (20.1) Post-randomization: G1: 139 (66.5) G2: 142 (69.6) G1/G2: RR = 0.96 (95% CI: 0.84-1.09) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 29 (13.9) G2: 33 (16.2) G1/G2: RR = 0.86 (95% CI: 0.54-1.36) Vaginal, assisted, n (%): G1: 48 (23.0) G2: 44 (21.6) G1/G2: RR = 1.06 (95% CI: 0.74-1.53) Vaginal, spontaneous, n (%): G1: 131 (63.1) G2: 127 (62.3) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, mean \pm SD: 1 minute: G1: 8.0 ± 1.4 G2: 8.3 ± 0.9 G1/G2: $\Delta = -0.3$ (95% CI: -0.5, -0.1) 5 minutes: G1: 8.9 ± 0.9 G2: 9.0 ± 0.8 G1/G2: $\Delta = -0.1$ (95% CI: -0.3, 0.1) NICU admission, n (%): G1: 15 (7.2) G2: 10 (4.9) G1/G2: RR = 1.46 (95% CI: 0.67-3.18)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Gambling et al., 1998 Country: US Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 08/1994 to 02/1995 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Combined spinal epidural (CSE) arm: IV bolus 500 mL Ringer's lactate; 10 µg sufentanil injected into subarachnoid space; 0.25% bupivacaine administered via epidural in 3-5 mL increments to achieve bilateral T10-T8 sensory level, followed by epidural infusion 0.125% bupivacaine and 2µg/mL fentanyl at 8-10 mL/hour (rate halved at start of 2nd stage) Meperidine group: initial dose of 50 mg meperidine and 25 mg promethazine IV; then 50 mg meperidine on request every hour (max 200 mg in 4 hours) Groups: G1: Combined spinal-epidural analgesia G2: IV meperidine analgesia (50 mg on demand/ max 200 mg in 4 hours) N at enrollment: G1: 616 G2: 607 N at birth: G1: 616 G2: 607 Age, mean yrs ± SD: G1: 21.7 ± 4.9 G2: 22.4 ± 4.9	Inclusion criteria: <ul style="list-style-type: none"> • Healthy parturient • In spontaneous labor • Term pregnancy Exclusion criteria: <ul style="list-style-type: none"> • Pregnancy complication • Cervical dilatation > 5 cm on admission • Other than singleton cephalic gestation 	Cervical dilation at admission, median cm (IQR): G1: 4.0 (3.0, 5.0) G2: 4.0 (3.25, 5.0) Cervical effacement at admission: NR	Labor progression: First analgesia to delivery interval, mean hours ± SD: G1: 5.0 ± 3.3 G2: 4.0 ± 3.1 G1/G2: $P = 0.0001$ First analgesia to delivery interval, nulliparous women, mean hours ± SD: G1: 6.0 ± 3.4 G2: 4.9 ± 3.2 G1/G2: $P < 0.0002$ First analgesia to delivery interval, protocol compliant women, mean minutes ± SD: G1: 298 ± 199 G2: 177 ± 131 G1/G2: $P < 0.005$ Second stage of labor, mean minutes ± SD: G1: 48 ± 50 G2: 31 ± 34 G1/G2: $P = 0.0001$ Second stage > 2 hours, n (%): G1: 61 (10) G2: 24 (4) Second stage of labor, nulliparous women, mean minutes ± SD: G1: 64 ± 54 G2: 43 ± 38 G1/G2: $P < 0.0002$ Second stage > 2 hours, nulliparous women, n (%): G1: 54 (16) G2: 19 (6)	Maternal outcomes Cesarean birth, n (%): Cesarean birth: G1: 39 (6) G2: 34 (5.5) G1/G2: $P = NS$ Cesarean birth for dystocia: G1: 23 (3.5) G2: 25 (4.0) G1/G2: $P = NS$ Cesarean birth, nulliparous women: G1: 30 (10) G2: 25 (9) G1/G2: $P = NS$ Cesarean birth for dystocia, nulliparous women: G1: 21 (7) G2: 24 (8) G1/G2: $P = NS$ Cesarean birth, protocol compliant nulliparous women: G1: 27 (11) G2: 8 (5) G1/G2: $P = 0.023$ Vaginal, assisted, n (%): Outlet forceps: G1: 10 (1.5) G2: 10 (1.5) Low forceps: G1: 41 (6.5) G2: 24 (4) Vaginal, spontaneous, n (%): G1: 526 (86) G2: 539 (89) G1/G2: $P = NS$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Gambling et al., 1998 (continued)	Race/ethnicity, n (%) White: G1: 64 (10) G2: 54 (9) Black: G1: 180 (29) G2: 177 (29) Hispanic: G1: 360 (59) G2: 366 (60) Other: G1: 12 (2) G2: 10 (2) Parous, n (%): G1: 280 (45.5) G2: 293 (48.3) Medicaid: NR				Vaginal, spontaneous, nulliparous women, n (%): G1: 229 (77) G2: 230 (80) G1/G2: $P = \text{NS}$ Maternal harms, n (%): Maternal fever > 38°C, protocol compliant nulliparous women: G1: 88 (22) G2: 11 (3) G1/G2: $P < 0.005$ Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar score < 7, 5 minutes, n (%): G1: 0 G2: 1 (0.2) NICU admission: NR

* Calculated by reviewer.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Garite et al., 2000 Country: US Participant source: Academic multi site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: Nellcor Division of Mallinckrodt, Inc. Author industry relationship disclosure: NR Design: RCT	Intervention: Fetal pulse oximetry (Nellcor FS14 fetal oxygen sensor inserted transcervically until it rests against fetal cheek; connected to Nellcor N-400 monitor), in addition to FHR monitoring Groups: G1: Fetal pulse oximetry with FHR monitoring G2: FHR monitoring alone N at enrollment: G1: 508 G2: 502 N at birth: G1: 508 G2: 502 Age, mean yrs: G1: 27.6 G2: 27.3 Race/ethnicity, n (%): White: G1: 331 (65) G2: 303 (60) Black: G1: 51 (10) G2: 72 (14) Hispanic: G1: 103 (20) G2: 104 (21) Asian: G1: 18 (4) G2: 20 (4) Parity, mean: G1: 0.7 G2: 0.7 Medicaid, n (%): G1: 171 (34) G2: 181 (36)	Inclusion criteria: <ul style="list-style-type: none"> • ≥ 36 weeks gestational age • In active labor • One or more of the FHR patterns included • Singleton in a cephalic presentation • Cervix dilated ≥ 2 cm and at the -2 station or below • Ruptured membranes Exclusion criteria: <ul style="list-style-type: none"> • Planned cesarean • Placenta previa • Need for immediate delivery • Active genital herpes or known HIV infection • Participation in other studies 	Cervical dilation at admission, mean cm: G1: 5.7 G2: 5.5 Cervical effacement at admission: NR Prior cesarean, n (%): G1: 64 (13) G2: 60 (12) Multiple gestation, n: G1: 0 G2: 0	Labor progression: NR Labor augmented, n (%): Prostaglandin: G1: 157 (31) G2: 123 (25) AROM (amniotomy), n (%): G1: 340 (67) G2: 318 (63) Internal monitoring (scalp pH monitoring), n (%): G1: 15 (3) G2: 26 (5) Amnioinfusion, n (%): G1: 177 (35) G2: 180 (36) Epidural, n (%): G1: 487 (96) G2: 471 (94) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): All indications: G1: 147 (29) G2: 130 (26) G1/G2: $P = 0.49$ Non-reassuring fetal status: G1: 23 (5) G2: 51 (10) G1/G2: $P < 0.0001$ Fetal intolerance with dystocia: G1: 27 (5) G2: 35 (7) G1/G2: $P = NS$ Dystocia: G1: 94 (19) G2: 43 (9) G1/G2: $P < 0.0001$ Vaginal, assisted, n (%): G1: 120 (24) G2: 117 (23) G1/G2: $P = NS$ Vaginal, spontaneous, n (%): G1: 241 (47) G2: 255 (51) G1/G2: $P = NS$ Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 3 (0.6) G2: 2 (0.4)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Garite et al., 2000 (continued)					<p>Apgar score < 7, 5 minutes, n: G1: 8 G2: 19</p> <p>G1/G2: $P = 0.05$ Apgar score, mean: 1 minute: G1: 7.5 G2: 7.6</p> <p>5 minutes: G1: 8.7 G2: 8.8</p> <p>NICU admission, n: G1: 92 G2: 74</p>

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Garite et al., 2000 Country: US Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Lactated Ringer's or isotonic saline IV infusion, 125 or 250 mL/hr Groups: G1: 125 mL/hr fluid infusion G2: 250 mL/hr fluid infusion N at enrollment: G1: 94 G2: 101 N at birth: G1: 94 G2: 101 Age, mean yrs: G1: 21.2 G2: 21.5 Race/ethnicity, n (%): White: G1: 18 (19.1) G2: 23 (22.7) Hispanic: G1: 63 (67.0) G2: 66 (65.3) Black: G1: 3 (3.1) G2: 1 (0.9) Asian: G1: 7 (7.4) G2: 7 (6.9) Other: G1: 3 (3.1) G2: 4 (3.9) Parous, n: G1: 0 G2: 0 Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> Nulliparous Spontaneous active labor Singleton pregnancy ≥ 36 weeks gestation Cephalic presentation Dilatation 2-5 cm, with or without ruptured membranes Exclusion criteria: <ul style="list-style-type: none"> Labor induction Preeclampsia Cardiac or renal disease Previous cesarean Chorioamnionitis, pyelonephritis, or other febrile illness 	Cervical dilation at randomization, mean cm: G1: 3.6 G2: 3.8 Cervical effacement at admission, mean %: G1: 87.2 G2: 89.6	Labor progression, duration of labor, mean minutes: G1: 552 G2: 484 Labor augmented, n (%): Oxytocin: G1: 61 (65) G2: 51 (49) AROM, n (%): G1: 29/48 (60) G2: 22/54 (41) Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 73 (77.6) G2: 76 (75.2) Maternal infection in labor, n (%): Endometritis: G1: 8 (9) G2: 3 (3) Chorioamnionitis (maternal temp > 38°C): G1: 18 (19) G2: 15 (15)	Maternal outcomes Cesarean birth, n (%): G1: 16 (17.0) G2: 10 (9.9) G1/G2: $P = 0.22$ Vaginal, assisted, n (%): G1: 15 (16) G2: 22 (21) G1/G2: $P = 0.68$ Vaginal, spontaneous, n (%):* G1: 63 (67) G2: 69 (68) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 0 G2: 0 Apgar score < 7, 5 minutes, n (%): G1: 0 G2: 1 (0.9) NICU admission, n (%): G1: 8 (8.5) G2: 10 (9.9)

* The number of spontaneous vaginal births was calculated by the reviewer, subtracting the number of operative vaginal and cesarean deliveries from the overall N for the group

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Harper et al., 2006 Country: US Participant source: Academic single site Intervention setting: Clinic Enrollment period: 07/2004 to 02/2005 Funding: Bowes Cefalo Young Researcher Award, North Carolina Academic Alliance for Integrative Medicine Pilot Funding Author industry relationship disclosure: NR Design: RCT	Intervention: Acupuncture treatments 3 out of 4 consecutive days. Needles inserted and left in place for 30 minutes, following treatment regimen from Shanghai College of Medicine text. Groups: G1: Acupuncture G2: Control/no acupuncture N at enrollment: G1: 30 G2: 26 N at birth: G1: 30 G2: 26 Age, mean yrs \pm SD: G1: 29.2 \pm 4.9 G2: 29.1 \pm 4.8 Race/ethnicity, n (%): Caucasian: G1: 27 (90) G2: 22 (85) Black: G1: 1 (3) G2: 3 (11) Hispanic: G1: 2 (7) G2: 1 (4) Parous: NR Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> Nulliparous 39 4/7 to 41 weeks gestation Singleton pregnancy Vertex fetus Cervical Bishop score < 7 Exclusion criteria: <ul style="list-style-type: none"> Uncertain dating as described by ACOG criteria Contraindications to vaginal delivery (breech, previa) Previous inability to tolerate acupuncture 	Cervical dilation at admission, mean cm: G1: 3.3 G2: 2.7 G1/G2: $P = 0.28$ Cervical effacement at admission: NR	Labor progression, time from enrollment to delivery, mean hours \pm SD: G1: 124 \pm 86.7 G2: 145 \pm 82.7 G1/G2: $P = 0.36$ Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, %: G1: 17 G2: 39 G1/G2: OR = 3.13 (95% CI: 0.99-10.8), $P = 0.07$ Vaginal, assisted: NR Vaginal, spontaneous: NR Maternal harms: NR Maternal mortality: NR Infant outcomes Neonatal mortality: NR Apgar score: G1: NR G2: NR G1/G2: $P = NS$ NICU admission: G1: NR G2: NR G1/G2: $P = NS$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Harvey et al., 1996 Country: Canada Participant source: Non-academic multi site Intervention setting: Clinic Labor and delivery suite Enrollment period: 02/1992 to 08/1994 Funding: Alberta Foundation for Nursing research and Alberta Association of Registered Nurses Author Industry Relationship Disclosure: NR Design: RCT	Intervention: Nurse-midwife care- a team of seven nurse-midwives. Seen by an OB at initial visit and at 36 weeks to confirm their low-risk status. Groups: G1: Nurse-midwife care G2: Physician care N at enrollment: G1: 101 G2: 93 N at birth: G1: 101 G2: 93 Age, mean yrs: G1: 30.26 ± 3.77 G2: 30.9 ± 4.33 Race/ethnicity, n (%): White: G1: 97 (96.1) G2: 91 (97.8) Asian: G1: 3 (2.8) G2: 2 (2.2) Aboriginal: G1: 1 (1.1) G2: 0 (0) Parous, n (%): G1: 45 (44.6) G2: 49 (52.7) Medicaid: NA	Inclusion criteria: <ul style="list-style-type: none"> Requested midwifery care Low risk for medical complications according to the Alberta perinatal risk scoring system Provided informed consent Exclusion criteria: <ul style="list-style-type: none"> Prior cesarean Primigravida < 17 or > 37 years of age > 20 weeks gestation at time of entry into study 	Cervical dilation at admission mean ± SD: NR Cervical effacement at admission mean ± SD: NR	Labor progression induction, n (%): G1: 8 (8) G2: 14 (15.6) Labor augmented, n (%): G1: 14 (14) G2: 19 (21.1) AROM, n (%): G1: 17 (16.8) G2: 28 (30.1) Internal monitoring, n (%): NR Amnioinfusion, n (%): NR Epidural, n (%): G1: 13 (12.9) G2: 22 (23.7) Maternal infection in labor, n (%): NR	Maternal Outcomes Cesarean birth, n (%): G1: 4 (4.0) G2: 14 (15.1) G1/G2: $P = 0.01$ (95% CI: 2.89-19.3) Vaginal, assisted, %: G1: 5.9 G2: 7.6 Vaginal, spontaneous, n (%): G1: 89 (88.2) G2: 71 (76.3) Maternal harms, postpartum hemorrhage, n (%): G1: 6 (5.9) G2: 3 (3.2) Fever > 38°, n (%): G1: 1 (1) G2: 2 (2.2) Retained placenta, n (%): G1: 3 (2.9) G2: 2 (2.2) Maternal mortality, n (%): G1: 0 G2: 0 Infant outcomes Neonatal mortality, n (%): G1: 0 G2: 0 Apgar score, < 7 at 1 minute, n (%): G1: 14 (13.9) G2: 27 (29.0) G1/G2: $P = 0.013$ (95% CI: 3.75-26.6%)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Harvey et al., 1996 (continued)					Apgar score, < 7 at 5 minute, n (%): G1: 4 (4.0) G2: 4 (4.3) NICU admission, n (%): G1: 8 (7.9) G2: 18 (19.35) G1/G2: <i>P</i> = 0.02 (95% CI: 1.8-21%)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Hemminki et al., 1990 Country: Finland Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 1987 to 1988 Funding: Finnish Academy of Science Author industry relationship disclosure: NR Design: Two RCTs	Intervention: Two trials of midwifery student support during labor Groups: G1a: Midwifery students G2a: Usual care Ga: 1987 trial Gb: 1988 trial N at enrollment: G1a: 41 G2a: 38 G1b: 81 G2b: 80 N at birth: G1a: 41 G2a: 38 G1b: 81 G2b: 80 Age, mean yrs \pm SD: G1a: 30 \pm 5.2 G2a: 28.1 \pm 5.1 G1b: 27.3 \pm 5.3 G2b: 29.5 \pm 5.6 Race/ethnicity: NR Parous, %: G1a: 54 G2a: 37 G1b: 49 G2b: 59 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> For 1987 trial, enrolled in reception or labor wards (including women entered from antenatal ward or arrived at the time when no free students were on duty) For 1988 trial, enrolled in labor ward only Exclusion criteria: <ul style="list-style-type: none"> Planned cesarean section Gestation < 35 weeks Breech presentation Multiple pregnancy Serious disease (e.g., diabetes, serious preeclampsia) Cervical dilatation > 8 cm and/or delivery expected in less than 3 hours 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: Admission to birth, mean hours \pm SD: G1a: 8.3 \pm 6.2 (n=34) G2a: 10.0 \pm 6.8 (n=31) G1b: 7.6 \pm 4.9 (n=71) G2b: 9.2 \pm 6.1 (n=73) G1: 7.8 \pm 5.3 G2: 9.5 \pm 6.3 G1a/G2a: $P = NS$ G1b/G2b: $P = NS$ G1/G2: $P < 0.05$ Admission to birth > 11 hours, %: G1a: 12 (n=34) G2a: 29 (n=31) G1b: 16 (n=71) G2b: 23 (n=73) G1: 15 G2: 25 G1a/G2a: $P = NS$ G1b/G2b: $P = NS$ G1/G2: $P = NS$ Randomization to birth, mean hours \pm SD: G1a: NR G2a: NR G1b: 5.1 \pm 3.8 G2b: 5.7 \pm 3.7 G1b/G2b: $P = NS$ Randomization to birth \geq 11 hours, %: G1a: NR G2a: NR G1b: 5 G2b: 15 G1b/G2b: $P < 0.05$ Labor augmented, %: Oxytocin: G1a: 8 G2a: 8 G1b: 10 G2b: 20	Maternal outcomes Cesarean birth, %: G1a: 0 G2a: 8 G1b: 3 G2b: 4 G1: 2 G2: 5 G1a/G2a: $P = NS$ G1b/G2b: $P = NS$ G1/G2: $P = NS$ Vaginal, assisted, %: G1a: 7 G2a: 3 G1b: 4 G2b: 6 G1: 5 G2: 5 G1a/G2a: $P = NS$ G1b/G2b: $P = NS$ G1/G2: $P = NS$ Vaginal, spontaneous, %: G1a: 93 G2a: 89 G1b: 93 G2b: 90 G1: 93 G2: 90 Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, 5 minutes, mean \pm SD: G1: 9.12 \pm 0.48 G2: 8.98 \pm 0.45 G1/G2: $P < 0.05$ NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Hemminki et al., 1990 (continued)				G1a/G2a: $P = NS$, G1b/G2b: $P = NS$ AROM: NR Internal monitoring, n (%): Fetal blood sampling: G1a: NR G2a: NR G1b: NR G2b: NR G1a/G2a: $P = NS$ G1b/G2b: $P = NS$ Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	

* The proportion of spontaneous vaginal deliveries was calculated by the reviewer, subtracting assisted vaginal and cesarean deliveries from 100%.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Hinshaw et al., 2008 Country: UK Participant source: Non-academic multi site Intervention setting: Clinic Enrollment period: 01/1999 to 12/2001 Funding: NHS, Northern and Yorkshire Region Research Programme Author industry relationship disclosure: NR Design: RCT, not blinded	Intervention: All patients had amniotomy if membranes intact prior to randomization. Oxytocin started within 20 minutes of randomization; starting dose 2 mu/min increased by doubling every 30 minutes until contraction rate of 4-5 in 10 minutes achieved, or a max dose of 32 mu/minute reached. Groups: G1: Immediate oxytocin G2: Conservative management (oxytocin withheld up to 8 hours) N at enrollment: G1: 208 G2: 204 N at birth: G1: 208 G2: 204 Age, median yrs (IQR): G1: 22 (20-28) G2: 23 (19-29) Race/ethnicity: NR Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Low-risk • Nulliparous • Spontaneous labor (≥ 2 contractions in 10 minutes and dilation ≥ 3 cm) at term (37 to 42 weeks) • Primary dysfunctional labor (dilation progressed by ≤ 2 cm over 4 hours from an initial dilation of 3-6 cm) • Singleton, vertex fetus Exclusion criteria: <ul style="list-style-type: none"> • Did not receive information sheet about trial during the antenatal period 	Cervical dilation at admission, median (IQR): G1: 4.0 (3.0-4.0) G2: 4.0 (3.0-4.0) Cervical dilation immediately prerandomization, median (IQR): G1: 5.0 (4.0-5.5) G2: 5.0 (4.0-5.5) Cervical effacement at admission: NR Prior cesarean, n: G1: 0 G2: 0 Multiple gestation, n: G1: 0 G2: 0	Labor progression: NR Labor augmented, n: G1: 202 G2: 30 AROM, n (%): G1: 155 (75) G2: 158 (79) Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): Pre-randomization: G1: 49 (24) G2: 48 (24) Post-randomization: G1: 111 (53) G2: 120 (59) G1/G2: OR = 0.80 (95% CI: 0.5-1.2) Maternal infection in labor, n (%): Pyrexia: G1: 4 (1.9) G2: 8 (3.9) G1/G2: OR = 0.48 (95% CI: 0.14-1.6)	Maternal outcomes Cesarean birth, n (%): G1: 28 (14) G2: 28 (14) G1/G2: OR = 0.98 (95% CI: 0.6-1.7) Vaginal, assisted, n (%): G1: 47 (23) G2: 62 (30) G1/G2: OR = 0.67 (95% CI: 0.4-1.0) Vaginal, spontaneous, n (%): G1: 133 (64) G2: 114 (56) G1/G2: OR = 1.40 (95% CI: 0.9-2.1) Postpartum haemorrhage (> 500 ml), n (%): G1: 41 (20) G2: 45 (22) G1/G2: OR = 0.87 (95% CI: 0.5-1.4) Blood transfusion, n (%): G1: 10 (4.8) G2: 10 (4.9) Major depression (EPDS > 12), n (%): G1: 30/150 (20) G2: 24/163 (15) G1/G2: $P = 0.22$ Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 1 G2: 1 G1/G2: OR = 0.98 (95% CI: 0.06-16)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Hinshaw et al., 2008 (continued)					Apgar score ≤ 7, 5 minutes, n (%): G1: 5 (2.5) G2: 3 (1.5) NICU admission, n (%): G1: 6 (2.9) G2: 5 (2.5) G1/G2: OR = 1.2, (95% CI: 0.4-3.9)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Hodnett et al., 2002 Country: US & Canada Participant source: Multi-site (9 academic and 4 non-academic) Intervention setting: Labor and delivery suite Enrollment period: 05/1999 to 05/2001 Funding: NIH Author industry relationship disclosure: NR Design: RCT	Intervention: Continuous labor support by specially trained nurse during labor (support for a minimum of 80% of time from randomization to delivery) Groups: G1: Continuous labor support by trained support nurse G2: Usual care by a nurse who had not received the labor support training N at enrollment: G1: 3,454 G2: 3,461 N at birth: G1: 3,454 G2: 3,461 N at follow-up: G1: 2,836 G2: 2,765 Age, mean yrs ± SD: G1: 29.4 ± 5.5 G2: 29.5 ± 5.7 Race/ethnicity, n (%): White: G1: 2,561 (74.2) G2: 2,594 (75) Asian/Pacific Islander: G1: 335 (9.7) G2: 333 (9.6) Black: G1: 158 (4.6) G2: 130 (3.8) Hispanic: G1: 182 (5.3) G2: 183 (5.3) Native American/ Native Canadian: G1: 124 (3.6) G2: 137 (4)	Inclusion criteria: <ul style="list-style-type: none"> • Live singleton fetus or twins • No contraindications to labor • Competent to give informed consent • In established labor but 2nd stage not imminent Exclusion criteria: <ul style="list-style-type: none"> • Gestational age < 34 weeks at labor onset • Planning cesarean delivery • Already enrolled in labor/delivery management study with incompatible protocol • Expecting continuous support from either midwives or doulas/labor coaches • Such high-risk that a 1:1 patient-nurse ratio was deemed medically necessary 	Cervical dilation at admission, n (%): < 3 cm: G1: 706 (20.4) G2: 718 (20.8) 3-6 cm: G1: 1,732 (50.1) G2: 1,772 (51.2) > 6 cm: G1: 72 (2.1) G2: 80 (2.3) Unknown: G1: 944 (27.3) G2: 891 (25.7) Cervical effacement at admission: NR Prior cesarean, n (%): G1: 188 (5.4) G2: 153 (4.4) Multiple gestation, n (%): G1: 22 (0.6) G2: 12 (0.3)	Labor progression, time from active labor to delivery, median hours (IQR): G1: 7.1 (4.4-10.8) G2: 6.9 (4.3-10.6) Labor augmented, n (%): G1: 1,040 (30.1) G2: 942 (27.2) G1/G2: <i>P</i> = 0.008 AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 2,282 (66.1) G2: 2,352 (68) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 432 (12.5) G2: 437 (12.6) G1/G2: <i>P</i> = 0.44 Vaginal, assisted, n (%): G1: 541 (15.7) G2: 561 (16.2) G1/G2: <i>P</i> = 0.54 Vaginal, spontaneous, n (%): G1: 2,481 (71.8) G2: 2,463 (71.2) G1/G2: <i>P</i> = 0.54 Maternal harms, n (%): Fever: ¹ G1: 23 (0.7) G2: 16 (0.5) Hemorrhage: ² G1: 93 (2.7) G2: 91 (2.6) Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 2 (0.06) G2: 1 (0.03) Apgar score < 7, n (%): 1 minute: G1: 317 (9.1) G2: 367 (10.6) G1/G2: <i>P</i> = 0.04 5 minutes: G1: 30 (0.9) G2: 25 (0.7) G1/G2: <i>P</i> = 0.5

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Hodnett et al., 2002 (continued)	Other: G1: 94 (2.7) G2: 83 (2.4) Parous, n (%): G1: 1,753 (50.7) G2: 1,767 (51) Medicaid: NR				NICU/ Intermediate care admission, n (%):³ G1: 246 (7.1) G2: 254 (7.3) G1/G2: <i>P</i> = 0.7

¹Oral temperature of $\geq 38^{\circ}\text{C}$ on two occasions, at least 24 hours apart, not including the first 24 hours after delivery.

²Hemorrhage during postpartum stay (blood volume ≥ 1000 mL)

³Newborns admitted to a higher level of care (intermediate and/or neonatal intensive care nursery)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Hofmeyr et al., 1998 [See Mahomed et al., 1998] Country: South Africa Participant source: Academic multisite Intervention setting: Labor and delivery suite Enrollment period: 1991 to 1996 Funding: South African Medical Research Council, University of Witwatersand, UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development, and Research Training in Human Reproduction, Utah Medical Author industry relationship disclosure: NR Design: RCT	Intervention: Transcervical amnioinfusion of 800 mL of saline at 15 mL/min followed by maintenance infusion at 3 mL/min Groups: G1: Amnioinfusion G2: Control/routine care N at enrollment: G1: 176 G2: 176 N at birth: G1: 167 G2: 159 Age, mean yrs \pm SD: G1: 25.4 \pm 6.4 G2: 25.7 \pm 6.7 Race/ethnicity: NR Parous, n (%): G1: 88/163 (54)* G2: 79/160 (49.4)* Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • In labor • ≥ 37 weeks gestation • Singleton • Cephalic presentation • Moderate or heavy meconium staining of amniotic fluid Exclusion criteria: <ul style="list-style-type: none"> • See inclusion criteria 	Cervical dilation at admission, mean cm \pm SD: G1: 4.7 \pm 1.8 G2: 4.9 \pm 1.5 Cervical effacement at admission: NR Prior cesarean, n (%): G1: 12/152 (7.9) G2: 10/153 (6.5)	Labor progression: NR Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion, n (%): G1: 167 (100) G2: 0 Epidural: NR Maternal infection in labor, n (%): Postpartum temperature $> 38^{\circ}\text{C}$: G1: 19/149 (13) G2: 15/145 (10)	Maternal outcomes Cesarean birth, n (%): G1: 70/167 (42) G2: 68/159 (43) G1/G2: RR = 0.98 (95% CI: 0.76-1.26) Vaginal, assisted, n (%): G1: 9/167 (5.4) G2: 12/159 (7.5) G1/G2: RR = 0.72 (95% CI: 0.31-1.67) Vaginal, spontaneous, n (%): G1: 88 (52)* G2: 79 (49)* Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 0 G2: 0 Apgar score < 7, 5 minutes, n (%): G1: 6/166 (3.6) G2: 4/165 (2.4) G1/G2: RR = 1.49 (95% CI: 0.43-5.18) Cord pH, 7.2: G1: 18/96 (19) G2: 20/105 (19) G1/G2: RR = 0.98 (95% CI: 0.55-1.75) NICU admission, n (%): G1: 3/164 (1.8) G2: 4/163 (2.5) G1/G2: RR = 0.75 (95% CI: 0.17-3.28)

* Calculated by reviewer

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Homer et al., 2001 Country: Australia Participant source: NR Intervention setting: Antenatal clinics, public hospital labor and delivery suite Enrollment period: 01/1997 to 04/1998 Funding: Australian National Health and Medical Research Council, New South Wales Health Department Author industry relationship disclosure: NR Design: RCT	Intervention: Community-based model providing continuity of midwifery care throughout antenatal, intrapartum, and postnatal periods via two teams of six full-time midwives Groups: G1: Community-based model G2: Standard care N at enrollment: G1: 640 G2: 643 N at birth: G1: 550 G2: 539 Age, mean yrs: G1: 28.2 G2: 28 Language of country of birth, n (%): English: G1: 256 (46.5) G2: 256 (47.5) Chinese: G1: 90 (16.4) G2: 93 (17.3) Arabic: G1: 86 (15.6) G2: 87 (16.1) Other non-English: G1: 116 (21.1) G2: 98 (18.2) Unknown: G1: 2 (0.4) G2: 5 (0.9) Parous, n (%): G1: 297 (54) G2: 291 (54) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> < 24 weeks gestation at first visit Reside in designated catchment area Planned to have baby in hospital delivery suite Exclusion criteria: <ul style="list-style-type: none"> Presence of significant maternal disease (e.g., renal disease with impaired renal function, essential hypertension, insulin dependent diabetes) Two previous cesareans Previous classical cesarean 	Cervical dilation at admission: NR Cervical effacement at admission: NR Prior cesarean, n (%): G1: 33 (6.0) G2: 44 (8.2) Multiple gestation (twins), n (%): Total: 10 (0.9) Grandmultiparity (> 5 births), n (%): G1: 10 (1.8) G2: 7 (1.3) Past significant postpartum haemorrhage, n (%): G1: 7 (1.3) G2: 8 (1.5) Previous pre-eclampsia, n (%): G1: 28 (5.1) G2: 21 (3.9) Previous gestational diabetes, n (%): G1: 10 (1.8) G2: 15 (2.8) Antenatal complications, n (%): Antenatal admission: G1: 53 (9.6) G2: 72 (13.4) Day assessment unit: G1: 27 (4.9) G2: 30 (5.6) Antepartum haemorrhage: G1: 9 (1.6) G2: 14 (2.6)	Labor progression: NR Labor augmented, n (%): G1: 227 (41.3) G2: 200 (37.1) AROM: NR Internal monitoring (electronic fetal monitoring), n (%): G1: 252 (45.8) G2: 275 (51.0) Amnioinfusion: NR Epidural/spinal anesthesia, n (%): G1: 157 (28.5) G2: 172 (31.9) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): Total: G1: 73 (13.3) G2: 96 (17.8) Elective: G1: 21 (3.8) G2: 34 (6.3) Emergency: G1: 52 (9.5) G2: 62 (11.5) Vaginal, assisted, n (%): Forceps/vacuum extraction: G1: 71 (12.9) G2: 63 (11.7) Vaginal, spontaneous, n (%):* G1: 406 (73.8) G2: 381 (70.7) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 4 G2: 4 Apgar score, 5 minutes, mean: G1: 8.9 G2: 8.8 G1/G2: $P = 0.3$ Apgar score < 7, 5 minutes, n (%): G1: 12 (2.2) G2: 13 (2.4) G1/G2: $P = 0.8$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Homer et al., 2001 (continued)			Pre-eclampsia: G1: 33 (6.0) G2: 34 (6.3) Gestational diabetes: G1: 42 (7.6) G2: 37 (6.9) Threatened preterm labour: G1: 8 (1.5) G2: 12 (2.2) Other: G1: 76 (13.8) G2: 96 (18)		NICU (special care nursery) admission, n (%): G1: 80 (14.5) G2: 102 (18.9) G1/G2: $P = 0.12$

* Number of spontaneous vaginal births calculated by the reviewer, subtracting the number of cesarean and assisted vaginal births from overall total births.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Jalil et al., 2009 Country: Malaysia Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 2005 to 2006 Funding: Universiti Sains Malaysia Author industry relationship disclosure: NR Design: RCT	Intervention: Epidural analgesia: 12ml of 0.2% ropivacaine followed by continuous 0.2% ropivacaine with 2 µg/ml fentanyl at 7-10 ml/hr; IV bolus ≥ 500 mL lactated Ringer's Intramuscular (IM) pethidine: 75-100 mg with 25 mg of promethazine hydrochloride at first request followed by 75 mg pethidine (up to 300 mg in 4 hr) upon request. Groups: G1: Epidural ropivacaine G2: IM pethidine N at enrollment: G1: 94 G2: 98 N at birth: G1: 94 G2: 98 Age, mean yrs ± SD: G1: 28.7 ± 5.6 G2: 29.5 ± 5.1 Race/ethnicity, n (%): Malay: G1: 86 (91.5) G2: 96 (98) Non-Malay: G1: 8 (8.5) G2: 2 (2) Parous, n (%): G1: 94 (100) G2: 98 (100) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Laboring women with ASA 1-11 • 2nd to 5th pregnancy with tested pelvis • Full term • Spontaneous labor • Age 18-40 years • Singleton with cephalic presentation • 3-5 cm OS • Height > 150 cm • Weight < 100 kg • Good working epidural (pain score VAS ≤ 30 mm after 15 min of epidural administration) Exclusion criteria: <ul style="list-style-type: none"> • Bad obstetric history • Post date • History of allergy to local anesthetic • Patient refusal • Failed epidural • Contraindications for epidural analgesia 	Cervical dilation at admission, mean cm ± SD: G1: 3.7 ± 0.71 G2: 3.85 ± 0.78 G1/G2: <i>P</i> = 0.401 Cervical effacement at admission: NR	Labor progression, mean minutes ± SD: 1 st stage of labor: G1: 506.6 ± 151.7 G2: 392.1 ± 190.7 G1/G2: <i>P</i> = 0.001 2 nd stage of labor: G1: 24.0 ± 11.1 G2: 10.1 ± 9.8 G1/G2: <i>P</i> = 0.001 Labor augmented, n (%): Oxytocin: G1: 29 (30.8) G2: 79 (80.6) G1/G2: <i>P</i> = 0.001 AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 94 (100) G2: 0 Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 11 (11.7) G2: 7 (7.1) G1/G2: <i>P</i> = 0.186 Vaginal, assisted, n (%): G1: 11 (11.7) G2: 2 (2.1) G1/G2: <i>P</i> = 0.007 Vaginal, spontaneous, n (%): G1: 72 (76.6) G2: 89 (90.8) G1/G2: <i>P</i> = 0.007 Maternal harms: NR Maternal mortality, n: G1: 0 G2: 0 Neonatal outcomes Neonatal mortality, n: G1: 0 G2: 0 Apgar score 7, 5 minutes, n (%): G1: 1 (1.1) G2: 0 G1/G2: <i>P</i> = 0.306 NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Jansen et al., 2006 Country: Canada Participant source: Multi site (all but one hospital with obstetric services in Vancouver and suburbs) Intervention setting: Other Enrollment period: 08/2001 to 10/2004 Funding: Canadian Institutes of Health Author industry relationship disclosure: NR Design: RCT	Intervention: Home-based triage at time of painful contractions at term, with nursing assessment of maternal vital signs, abdominal palpitation, auscultation of fetal heart rate, assessment of contractions and examination of cervix. Groups: G1: Home visit G2: Telephone triage N at enrollment: G1: 728 G2: 731 N at birth: G1: 728 G2: 731 Age, mean yrs \pm SD: G1: 28.6 \pm 5.1 G2: 28.3 \pm 5.1 Race/ethnicity, n (%): White: G1: 342 (47.0) G2: 309 (42.3) East Asian: G1: 158 (21.7) G2: 151 (20.7) South Asian: G1: 177 (24.3) G2: 223 (30.5) First Nation: ¹ G1: 10 (1.4) G2: 10 (1.4) Black: G1: 6 (0.8) G2: 10 (1.4) Other: G1: 35 (4.8) G2: 27 (3.7)	Inclusion criteria: <ul style="list-style-type: none"> Lived within a 30-minute drive of a hospital in the study Ages 16-42 years 37-41 weeks of gestation Nulliparous Carrying a singleton fetus in the vertex position Spoke English, Cantonese, Mandarin, Punjabi, Korean, or Farsi Also included patients with labor induced on an outpatient basis with prostaglandins Exclusion criteria: <ul style="list-style-type: none"> Type 1 diabetes Cardiovascular disease 3rd trimester bleeding Fetal anomalies Abnormal fetal biophysical profile Any other condition arising from or coexisting with the pregnancy that were deemed to be a contraindication to laboring at home Women whose primary caregivers were midwives 	Cervical dilation at admission \leq 3 cm, n (%): G1: 324 (44.7) G2: 385 (52.8) G1/G2: RR = 0.85 (95% CI: 0.76-0.94) Cervical effacement at admission: NR	Labor progression: NR Labor augmented (spontaneous labor patients only), n (%): G1: 421 (61.2) G2: 439 (64.5) G1/G2: RR = 0.95 (95% CI: 0.88-1.04) AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 476 (65.4) G2: 499 (68.3) G1/G2: RR = 0.95 (95% CI: 0.89-1.01) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 208 (28.6) G2: 186 (25.4) G2/G1: RR = 1.12 (95% CI: 0.94-1.32) Vaginal, assisted, n (%): G1: 184 (25.3) G2: 216 (29.5) G2/G1: RR = 0.86 (95% CI: 0.73-1.02) Vaginal, spontaneous, n (%): G1: 336 (46.2) G2: 329 (45.0) G2/G1: RR = 1.03 (95% CI: 0.92-1.15) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, n (%): 1 minute: G1: 90 (12) G2: 92 (13) G2/G1: RR = 0.97 (95% CI: 0.75-1.30) 5 minutes: G1: 9 (1.2) G2: 6 (0.8) G2/G1: RR = 1.52 (95% CI: 0.54-4.23)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Jansen et al., 2006 (continued)	Missing: G1: 0 G2: 1 Parous, n: G1: 0 G2: 0 Medicaid: Not applicable				NICU admission, n (%): G1: 14 (1.9) G2: 6 (0.8)

¹ First Nation = Native American.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Karraz et al., 2003 Country: France Participant source: Non-academic single site Intervention setting: Labor and delivery suite Enrollment period: 02/1999 to 04/2001 Funding: Hospital departmental funds Author industry relationship disclosure: NR Design: RCT	Intervention: All received intermittent epidural bolus injections 0.1% ropivacine and 0.6 µg/mL sufatenil, plus ambulatory instructions (walking, sitting, or semisupine reclining) or remaining supine (not allowed to walk, sit, or go to restroom) Groups: G1: Ambulatory group with epidural G2: Non-ambulatory group with epidural N at enrollment: G1: 144 G2: 77 N at birth: G1: 141 G2: 74 Age, mean yrs ± SD: G1: 27.4 ± 4.3 G2: 27.5 ± 4.6 Race/ethnicity: NR Parous, n (%): G1: 44 (30.7) G2: 27 (36.5) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • 36-42 weeks gestation • Singleton pregnancy • Cephalic presentation • Uncomplicated pregnancies presenting in spontaneous labor or scheduled for induction Exclusion criteria: <ul style="list-style-type: none"> • Pre-eclampsia • Previous cesarean 	Cervical dilation at epidural insertion, mean ± SD: G1: 3.27 ± 1.3 G2: 3.37 ± 1.4 Cervical effacement at admission: NR	Labor progression, mean minutes ± SD: G1: 173 ± 110 G2: 236 ± 131 G1/G2: <i>P</i> = 0.001 Labor augmented, n (%): Oxytocin: G1: 120/141 (85.1)* G2: 64/74 (86.5)* AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 144 (100) G2: 77 (100) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 13 (9.2) G2: 12 (16.2) G1/G2: <i>P</i> = 0.15 Vaginal, assisted, n (%): G1: 11 (7.8) G2: 6 (8.1) G1/G2: <i>P</i> = 0.93 Vaginal, spontaneous, n (%): G1: 117 (83.0) G2: 56 (75.7) G1/G2: <i>P</i> = 0.45 Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score: NR NICU admission: NR

* Calculated by reviewer

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Kennell et al., 1991 Country: US Participant source: Community practice Intervention setting: Labor and delivery suite Enrollment period: NR Funding: NR Author industry relationship disclosure: NR Design: RCT for 2 groups but the 3 rd group was non-random	Intervention: Doula support: the doula stayed with the study participant from admission through delivery, soothing and touching her patient and giving encouragement. In addition, the doula explained to her patient what to expect during labor. When necessary, the doula translated medical instructions for the patient. Women in the observed group received routine hospital care. Women in the control group received doula support. Groups: G1: Supported group G2: Observed group G3: Control group N at enrollment: G1: 212 G2: 200 G3: 204 N at birth: G1: 212 G2: 200 G3: 204 Age, mean yrs ± SD: G1: 19.9 ± 3.5 G2: 19.7 ± 3.6 G3: 20.3 ± 3.8	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Singleton • Term • Uncomplicated pregnancy • Admitted in active labor • Cervical dilation 3-4 cm • 13-34 years of age Exclusion criteria: <ul style="list-style-type: none"> • Pregnancy induced hypertension • Breech presentation • Gestational diabetes • History of drug or alcohol abuse • Other high risk conditions 	Cervical dilation at admission, n (%): 3 cm: G1: 34 (16) G2: 34 (17) G3: 51 (25) 4 cm: G1: 178 (84) G2: 166 (83) G3: 153 (75) G1/G2/G3: $P = 0.04$	Labor progression, duration of labor, mean hours ± SD: G1: 7.4 ± 3.8 G2: 8.4 ± 4.2 G3: 9.4 ± 4.2 G1/G2: $P < 0.02$ G1/G3: $P < 0.02$ G2/G3: $P < 0.02$ G1/G2/G3: $P = 0.0001$ Labor augmented, n (%): Oxytocin: G1: 36 (17) G2: 46 (23) G3: 89 (43.6) G1/G2: $P = NS$ G1/G3: $P < 0.0001$ G2/G3: $P < 0.0001$ G1/G2/G3: $P < 0.0001$ AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 14/179 (7.8) G2: 31/137 (22.6) G3: 68/123 (55.3) G1/G2/G3: $P < 0.0001$ Maternal infection in labor, n: NR	Maternal outcomes Cesarean birth, n (%): G1: 17 (8) G2: 26 (13) G3: 37 (18) G1/G2: $P = NS$ G1/G3: $P = 0.004$ G2/G3: $P = NS$ G1/G2/G3: $P = 0.009$ Vaginal, assisted, n (%): Forceps: G1: 16 (8.2) G2: 37 (21.3) G3: 44 (26.3) Vaginal, spontaneous, n (%): G1: 179 (84.4)* G2: 137 (68.5)* G3: 123 (60.2)* Maternal harms, n (%): Maternal fever: G1: 3 (1.4) G2: 14 (7.0) G3: 21 (10.3) G1/G2: $P = 0.009$ G1/G3: $P = 0.002$ G2/G3: $P = NS$ G1/G2/G3: $P = 0.0007$ Maternal mortality: NR Infant outcomes Neonatal mortality, n: G1: 0 G2: 0 G3: 0 Apgar score: NR NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Kennell et al., 1991 (continued)	<p>Race/ethnicity, n (%):</p> <p>White:</p> <p>G1: 21(10)</p> <p>G2: 21 (11)</p> <p>G3: 29 (14)</p> <p>Black:</p> <p>G1: 53 (25)</p> <p>G2: 50 (25)</p> <p>G3: 56 (27)</p> <p>Hispanic:</p> <p>G1: 136 (64)</p> <p>G2: 129 (65)</p> <p>G3: 116 (57)</p> <p>Asian:</p> <p>G1: 2 (1)</p> <p>G2: 0</p> <p>G3: 3 (1)</p> <p>Nulliparous, n (%):</p> <p>G1: 212 (100)</p> <p>G2: 200 (100)</p> <p>G3: 204 (100)</p> <p>Medicaid:</p> <p>NR</p>				

* Calculated by reviewer.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Kuhnert et al., 2004 Country: Germany Participant source: NR Intervention setting: NR Enrollment period: NR Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Fetal pulse oximetry and electronic fetal heart rate (FHR) monitoring and fetal scalp monitoring (a Nellcor FS 14° C fetal oxygen sensor was placed and connected to a Nellcor N-400 monitor. The flexible FS 14° C sensor inserted transcervically until it rests against the fetal cheek). Groups: G1: Fetal pulse oximetry, FHR monitoring, fetal scalp sampling G2: FHR monitoring, fetal scalp sampling N at enrollment: G1: 73 G2: 73 N at birth: G1: 73 G2: 73 Age: NR Race/ethnicity: NR Parous: NR Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • ≥ 36 weeks gestation • Active labor • Non-reassuring FHR • Single fetus • Cephalic presentation • Cervix dilated to ≥ 2 cm and at ≤ -2 station • Ruptured membranes Exclusion criteria: <ul style="list-style-type: none"> • Planned cesarean • Placenta previa • Need for immediate delivery • Active genital herpes • Known HIV infection • Multiple pregnancies 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: NR Labor augmented: NR AROM: NR Internal monitoring, n (%): Fetal oxygen sensor: G1: 73 (100) G2: 73 (100) Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 12 (16.4) G2: 27 (37.0) Vaginal, assisted, n (%): G1: 13 (17.8) G2: 22 (30.1) Vaginal, spontaneous, n (%): G1: 48 (65.8) G2: 24 (32.9) G1/G2: $P \leq 0.001$ Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score: NR NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Lavender et al., 2006 Country: UK Participant source: Academic single site Intervention setting: Labor and delivery Suite, birthing center Enrollment period: 08/1998 to 03/2005 Funding: Liverpool Women's Foundation Trust Author industry relationship disclosure: NR Design: RCT	Intervention: Partogram with action line 2 or 4 hours to the right of alert line. When progress crosses the action line, a diagnosis of prolonged labor is made and managed according to standard protocol Groups: G1: Partogram with 2-hour action line G2: Partogram with 4-hour action line N at enrollment: G1: 1,503 G2: 1,497 N at birth: G1: 1,490 G2: 1,485 Age, mean yrs \pm SD: G1: 25.4 \pm 5.5 G2: 25.3 \pm 5.5 Race/ethnicity: NR Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Primigravid • Spontaneous labor • At term (\geq 37 weeks gestation) • Live, singleton, cephalic presentation Exclusion criteria: <ul style="list-style-type: none"> • Significant medical disease • Pregnancies with fetal malformations • Required high-dependency intrapartum care 	Cervical dilation at randomization 3-10 cm, n (%): G1: 1,421 (95.4) G2: 1,409 (94.9) Cervical effacement at randomization, n (%): G1: 1,285 (86.2) G2: 1,276 (85.9)	Labor progression, randomization-delivery interval, mean minutes \pm SD: G1: 539.6 \pm 260.3 G2: 566.4 \pm 289.7 G1/G2: $P = 0.008$ Labor augmented, n (%): Oxytocin: G1: 696 (46.7) G2: 607 (40.9) AROM, n (%): G1: 715 (48) G2: 657 (44.2) Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 479 (32.1) G2: 473 (31.9) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 136 (9.1) G2: 135 (9.1) G1/G2: RR = 1 (95% CI: 0.80-1.26) Vaginal, assisted, n (%): G1: 294 (19.7) G2: 320 (21.5) G1/G2: RR = 0.92 (95% CI: 0.80-1.05) Vaginal, spontaneous: NR Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, n (%): G1: 22 (1.5) G2: 29 (2) G1/G2: RR = 0.79 (95% CI: 0.44-1.30) NICU admission, n (%): G1: 21 (1.4) G2: 30 (2) G1/G2: RR = 0.85 (95% CI: 0.49-1.47)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Lavender et al., 1998 Country: UK Participant source: Academic single site Intervention setting: Labor and delivery site Enrollment period: 01/1996 to 08/1997 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Assessment of the effects of three different partograms on cesarean rate and maternal satisfaction Groups: G1: Partogram, with 2 hour action line G2: Partogram with 3 hour action line G3: Partogram with 4 hour action line N at enrollment: ¹ G1: 315 G2: 302 G3: 311 N at birth: G1: 315 G2: 302 G3: 311 Age, mean yrs ± SD: G1: 25.1 ± 5.1 G2: 24.8 ± 5.4 G3: 25 ± 5.1 Race/ethnicity: NR Parous, n: G1: 0 G2: 0 G3: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Primigravid women • Spontaneous labor • At term • Live • Singleton • Cephalic presentation Exclusion criteria: <ul style="list-style-type: none"> • Diabetes • Pregnancies complicated by fetal malformations • Women requiring high dependency intrapartum care • Unsatisfactory admission cardiotocograph 	Cervical dilation at admission, 3-10 cm, n (%): G1: 256 (81.3) G2: 243 (80.5) G3: 241 (77.7) Cervical effaced admission, n (%): G1: 270 (85.7) G2: 245 (81.1) G3: 259 (83.5)	Labor progression, duration of labor from randomization to delivery, median minutes (IQR): G1: 516 (330-737) G2: 532.5 (332.5-739.3) G3: 517 (302-734) Labor augmented, n (%): Syntocinon: G1: 144 (45.7) G2: 136 (45) G3: 129 (41.6) AROM only, n (%): G1: 120 (38) G2: 122 (40.4) G3: 121 (39) Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 120 (38) G2: 99 (32.8) G3: 101 (32.6) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 35 (11.1) G2: 43 (14.2) G3: 26 (8.4) G1/G2: OR = 0.8 (95% CI: 0.5-1.2) G2/G3: OR = 1.8 (95% CI: 1.1-3.2) G1/G3: OR = 1.4 (95% CI: 0.8-2.4) Vaginal, assisted, n (%): G1: 66 (20.9) G2: 68 (22.5) G3: 73 (23.5) Vaginal, spontaneous, n (%): ² G1: 214 (67.9) G2: 191 (63.2) G3: 212 (68.1) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, n (%): G1: 6 (1.9) G2: 4 (1.3) G3: 5 (1.6) NICU admission, n (%): G1: 4 (1.3) G2: 1 (0.3) G3: 2 (0.6)

¹ 932 women were randomized, but four could not be traced due to inaccurate recording of demographic details.

² The number of spontaneous vaginal deliveries were calculated by the reviewer, subtracting the number of cesarean and operative deliveries from the overall group totals.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Lopez-Zeno et al., 1992 Country: US Participant source: Community practice Intervention setting: Labor and delivery suite Enrollment period: 02/1990 to 03/1991 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Active labor management. Amniotomy performed within one hour of the diagnosis of labor. Cervical exams performed hourly for the first three hours, then every two hours. When rate of cervical dilation < 1 cm/hr, oxytocin infused at an initial rate of 6 mU/min. Dose increased by 6 mU/min every 15 minutes (to a max of 36 mU/min) until there were 7 contractions every 15 minutes. The occurrence of more than 7 contractions per 15 minutes was managed by decreasing the oxytocin infusion rate by 6 mU/min. Groups: G1: Active management G2: Traditional management N at enrollment: G1: 351 G2: 354 N at birth: G1: 351 G2: 354 Age, mean yrs \pm SD: G1: 27.3 \pm 5.8 G2: 26.7 \pm 6.1 G1/G2: $P = NS$ Race/ethnicity, n (%): White:* G1: 241 (68.6) G2: 226 (63.8)	Inclusion criteria: <ul style="list-style-type: none"> Nulliparous In spontaneous labor ≥ 37 weeks Exclusion criteria: <ul style="list-style-type: none"> Multiple gestation Noncephalic presentation Previous uterine surgery Amniotomy performed before criteria for labor satisfied Labor augmentation with oxytocin begun before criteria for labor satisfied 	Cervical dilation at admission, mean cm \pm SD: G1: 3.2 \pm 1.5 G2: 3.2 \pm 1.5 G1/G2: $P = NS$ Cervical effacement at admission: NR	Labor progression, mean hours \pm SD: Length of first stage: G1: 5.05 \pm 2.33 G2: 6.72 \pm 3.64 G1/G2: $P < 0.0001$ Length of second stage: G1: 1.44 \pm 0.97 G2: 1.43 \pm 1.08 G1/G2: $P = NS$ Labor augmented, n (%): G1: 250 (71.2) G2: 234 (66.1) G1/G2: $P = NS$ AROM: NR Internal monitoring, n (%): Intrauterine pressure catheter: G1: 191 (54.4) G2: 182 (51.4) G1/G2: $P = NS$ Amnioinfusion: NR Epidural, n (%): G1: 253 (72.1) G2: 255 (72.0) G1/G2: $P = NS$ Maternal infection in labor: NR	Maternal Outcomes Cesarean birth, n (%): G1: 37 (10.5) G2: 50 (14.1) Vaginal, assisted, n (%): G1: 89 (25.3)* G2: 99 (27.9)* Vaginal, spontaneous, n (%): G1: 225 (64.1)* G2: 205 (57.9)* Maternal harms: NR Maternal mortality: NR Infant outcomes Neonatal mortality, n: G1: 0 G2: 0 G1/G2: $P = NS$ Apgar score < 7, 5 minutes, n (%): G1: 1 (0.3) G2: 1 (0.3) G1/G2: $P = NS$ NICU admission, n (%): G1: 14 (4.0) G2: 11 (3.1) G1/G2: $P = NS$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Lopez-Zeno et al., 1992 (continued)	<p>Nonwhite: G1: 110 (31.3) G2: 128 (36.2)</p> <p>Parous, n (%): Nulliparous: G1: 351 (100) G2: 354 (100)</p> <p>Medicaid: NR</p>				

* Calculated by reviewer.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Mahomed et al., 1998 [See Hofmeyr et al., 1998] Country: Zimbabwe Participant source: Academic multisite Intervention setting: Labor and delivery suite Enrollment period: 05/1995 to 04/1996 Funding: South African Medical Research Council University of Witwatersand Author industry relationship disclosure: NR Design: RCT	Intervention: Transcervical amnioinfusion of 500 mL of saline over 30 minutes, then 500 mL at 30 drops/min Groups: G1: Amnioinfusion G2: Routine care/control N at enrollment: G1: 325 G2: 336 N at birth: G1: 319 G2: 324 Age, mean yrs \pm SD: G1: 23.3 \pm 4.9 G2: 23.2 \pm 5.2 Race/ethnicity: NR Parous, n (%): G1: 123 (37.8)* G2: 137 (40.8)* Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • In labor during office hours • ≥ 37 weeks gestation • Singleton • Cephalic presentation • Moderate or heavy meconium staining of amniotic fluid Exclusion criteria: <ul style="list-style-type: none"> • Indication for immediate delivery • Chorioamnionitis • Vaginal bleeding • Serious fetal congenital abnormality • Previous cesarean • Maternal cardiac or pulmonary disease 	Cervical dilation at admission, n (%): < 3 cm: G1: 6 (1.8) G2: 10 (3.0) > 7 cm: G1: 35 (10.8) G2: 30 (8.9) Cervical effacement at admission: NR	Labor progression: NR Labor augmented, n (%): Oxytocin: G1: 122 (38) G2: 155 (46) AROM: NR Internal monitoring, n: G1: 0 G2: 0 Amnioinfusion, n (%): G1: 325 (100) G2: 0 Epidural: NR Maternal infection in labor, n (%): Pyrexia in labor ward: G1: 3 (0.9) G2: 10 (3.0) G1/G2: RR = 0.31 (95% CI: 0.09-1.12)	Maternal outcomes Cesarean birth, n (%): G1: 30/317 (9.5) G2: 37/328 (12.3) G1/G2: RR = 0.84 (95% CI: 0.53-1.32) Vaginal, assisted, n (%): G1: 13/320 (4.1) G2: 11/333 (3.3) G1/G2: RR = 1.23 (95% CI: 0.56-2.7) Vaginal, spontaneous: NR Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 4/324 (1.2) G2: 12/335 (3.6) G1/G2: RR = 0.34 (95% CI: 0.11-1.06) Apgar score < 7, 5 minutes, n (%): G1: 9/324 (2.8) G2: 27/336 (8.0) G1/G2: RR = 0.35 (95% CI: 0.17-0.73) NICU admission, n (%): G1: 41/321 (12.8) G2: 76/332 (22.9) G1/G2: RR = 0.56 (95% CI: 0.39-0.79)

* Calculated by reviewer

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Matsuo et al., 2009 Country: US Participant source: Academic single site Intervention setting: Hospital, labor and delivery suite Enrollment period: 10/2007 to 12/2007 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Use of dental support device (DSD) during active pushing in the second stage of labor Groups: G1: DSD G2: Control/no DSD N at enrollment: G1: 32 G2: 32 N at birth: G1: 32 G2: 32 N at follow-up: (questionnaire completed by patients, timing NR) G1: 27 G2: 0 Age, mean yrs \pm SD: G1: 22.6 \pm 5.7 G2: 22.2 \pm 5.8 Race/ethnicity, n (%): White: G1: 7 (21.9) G2: 6 (18.7) Black: G1: 23 (71.9) G2: 23 (71.9) Asian: G1: 2 (6.3) G2: 3 (9.4) Parous, n: G1: 0 G2: 0 Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> Onset or induction of labor Primipara Term Singleton Cephalic presentation Reactive fetal heart rate pattern Functioning epidural anesthesia Exclusion criteria: <ul style="list-style-type: none"> Medical or obstetrical complications, including intra-uterine growth retardation (IUGR), large for gestational age (LGA), uterine anomaly, uterine myomata, pre-eclampsia, diabetes mellitus, fetal anomaly, and maternal heart disease 	Cervical dilation at admission: NR Cervical effacement at admission: NR Favorable cervix, n (%): G1: 8 (25) G2: 8 (25)	Labor progression: Duration 1 st stage, mean minutes \pm SD: G1: 453.9 \pm 135.3 G2: 472.0 \pm 186.9 G1/G2: $P = 0.20$ Duration 2 nd stage, median (IQR): G1: 19 (9) G2: 31 (23) G1/G2: $P < 0.001$ Labor augmented, n (%): Induction: G1: 15 (46.9) G2: 13 (40.6) G1/G2: RR = 0.8 (95% CI: 0.3-2.1), $P = 0.8$ Oxytocin: G1: 23 (71.9) G2: 19 (59.4) G1/G2: RR = 0.6 (95% CI: 0.2-1.6), $P = 0.71$ AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 32 (100) G2: 32 (100) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 4 (12.5) G2: 8 (25.0) Vaginal, assisted, n (%): G1: 3 (9.4) G2: 2 (6.3) Vaginal, spontaneous, n (%): G1: 25 (78.1) G2: 22 (68.8) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, 1 minute, median (IQR): G1: 9 (1) G2: 9 (1) G1/G2: $P = 0.50$ Apgar score, 5 minutes, median (IQR): G1: 9 (0) G2: 9 (0) G1/G2: $P = 0.33$ NICU admission, n (%): G1: 3 (9.4) G2: 3 (9.4) G1/G2: $P = 1.0$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: McGrath and Kennell, 2008 Country: US Participant source: Community practice (childbirth education classes in the greater Cleveland area) Intervention setting: Labor and delivery suite Enrollment period: 10/1988 to 10/1992 Funding: NICHD Author industry relationship disclosure: NR Design: RCT	Intervention: Doula met couples at hospital as soon as possible after random assignment (typically within an hour of arrival) and remained with them throughout labor and delivery. Groups: G1: Doula support G2: Routine care N at enrollment: G1: 224 G2: 196 N at birth: G1: 224 G2: 196 Age, mean yrs \pm SD: G1: 29.0 \pm 4.8 G2: 28.6 \pm 4.5 Race/ethnicity, n (%): Caucasian: G1: 180 (80.4) G2: 149 (76.0) African American: G1: 37 (16.5) G2: 43 (21.9) Asian: G1: 6 (2.7) G2: 3 (1.5) Hispanic: G1: 1 (0.4) G2: 1 (0.5) Parous, n: G1: 0 G2: 0 Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Ages 18-41 • In the third trimester of an uncomplicated pregnancy • Expected to be accompanied during labor by their male partner • Planned to deliver at University Hospitals in Cleveland • Under the care of a private obstetrician Exclusion criteria: <ul style="list-style-type: none"> • Midwife delivery 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: NR Labor augmented, n (%): Total: 240/420 (57) AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 145 (64.7) G2: 149 (76.0) G1/G2: $P = 0.008$ Elevated temperature, n (%): $\geq 37.5^{\circ}\text{C}$: Total: 73 (17.4) $\geq 38^{\circ}\text{C}$: Total: 29 (7) G1/G2: $P = \text{NS}$ Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 30 (13.4) G2: 49 (25.0) G1/G2: $P = 0.002$ Vaginal, assisted, n (%): Total: 90/420 (21) Vaginal, spontaneous: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 0 G2: 0 Apgar score ≤ 7, 5 minutes, n (%): G1: 4 (1.8) G2: 6 (3.1) NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: McNiven et al., 1998 Country: Canada Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 02/1994 to 01/1995 Funding: The Perinatal Nursing Research Unit, University of Toronto Author industry relationship disclosure: NR Design: RCT	Intervention: Early labor assessment: women found to be in false or latent labor were encouraged to go home or walk before admission Groups: G1: Early labor assessment G2: Direct admission to hospital N at enrollment: G1: 105 G2: 104 N at birth: G1: 105 G2: 104 Age, mean yrs \pm SD: G1: 24.9 \pm 5.5 G2: 25.7 \pm 4.8 Race/ethnicity: NR Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> Nulliparous ≥ 37 weeks gestation Defined as low risk Spontaneous labor Exclusion criteria: <ul style="list-style-type: none"> Booked for labor induction or cesarean section 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: Labor in hospital, mean hours \pm SD: G1: 8.3 \pm 5.6 G2: 13.5 \pm 7.9 G1/G2: $P = 0.001$ 2 nd stage, mean minutes \pm SD: G1: 76.8 \pm 66.7 G2: 95.0 \pm 63.7 G1/G2: $P = 0.045$ Labor augmented, n (%): Oxytocin: G1: 24 (22.9) G2: 42 (40.4) G1/G2: OR = 0.44 (95% CI: 0.24-0.8), $P = 0.001$ AROM, n (%): G1: 49 (46.7) G2: 56 (53.8) G1/G2: OR = 0.75 (95% CI: 0.44-1.29), $P = 0.368$ Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 83 (79) G2: 94 (90.4) G1/G2: OR = 0.40 (95% CI: 0.18-0.90), $P = 0.023$ Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 8 (7.6) G2: 11 (10.6) G1/G2: OR = 0.70 (95% CI: 0.27-1.81), $P = 0.45$ Vaginal, assisted, n (%): Forceps: G1: 10 (9.5) G2: 14 (13.5) G1/G2: OR = 0.68 (95% CI: 0.28-1.60), $P = 0.4992$ Vacuum extraction: G1: 22 (21.0) G2: 23 (22.0) G1/G2: OR = 0.93 (95% CI: 0.48-1.81), $P = 0.838$ Vaginal, spontaneous, n (%): G1: 65 (61.9) G2: 56 (53.8) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, n (%): G1: 1 (1) G2: 0 NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Mehrangiz et al., 2004 Country: Iran Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 1996 to 1999 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Comparison of effectiveness for paracervical block with promethazine versus promethazine only Groups: G1: Paracervical block with promethazine G2: Promethazine only/control N at enrollment: G1: 50 G2: 50 N at birth: G1: 50 G2: 50 Age: NR Race/ethnicity: NR Parous, %: Total: 58 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Full term • Uncomplicated • Stages 4-5 cm dilatation • Having contractions • Pain score 8-10 Exclusion criteria: <ul style="list-style-type: none"> • Uteroplacental insufficiency • Diabetes • Gestational hypertension • Malpresentation • Chronic hypertension 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: 1 st stage, mean minutes: G1: 85 G2: 220 2 nd stage, mean minutes: G1: 15 G2: 17 Mean ratio of cervical dilation, cm/hour: G1: 3/8 G2: 2/1 Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth (with fetal distress), n (%): G1: 1 (2) G2: 2 (4) G1/G2: $P = 0.310$ Vaginal, assisted: NR Vaginal, spontaneous: NR Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 0 G2: 0 Apgar score > 7, 5 minutes, n (%): G1: 50 (100) G2: 50 (100) NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Moodley et al., 1998 Country: South Africa Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 01/1993 to 04/1993 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Amnioinfusion with 0.9% normal saline at room temperature at 15 mL/min until a volume of 1 liter was completed Groups: G1: Amnioinfusion G2: Routine care for MSAF (IV fluids, 40% oxygen by mask, left lateral positioning of mother, and continuous FHR monitoring) N at enrollment: G1: 30 G2: 30 N at birth: G1: 30 G2: 30 Age, mean yrs: G1: 21.6 G2: 22.6 Race/ethnicity: NR Parous, n (%): G1: 9 (30) G2: 12 (40) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Singleton • Cephalic presentation • Term pregnancy • In active phase of labor • MSAF (grade I, II, or III) • Normal CTG Exclusion criteria: <ul style="list-style-type: none"> • Multiple pregnancy • Significant medical or surgical conditions • Chorioamnionitis • Abnormal CTG that necessitated immediate delivery • Previous cesarean 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: NR Labor augmented: NR AROM: NR Internal monitoring, n: G1: 0 G2: 0 Amnioinfusion, n (%): G1: 30 (100) G2: 0 Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 12 (40) G2: 14 (47) Vaginal, assisted, n: G1: 0 G2: 0 Vaginal, spontaneous, n (%): G1: 18 (60) G2: 16 (53.3) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 0 G2: 0 Apgar score, 5 minutes, mean \pm SD: G1: 9.57 \pm 0.67 G2: 9.33 \pm 1.03 Umbilical artery pH, mean \pm SD: G1: 7.0 \pm 0.056 G2: 7.23 \pm 0.114 G1/G2: <i>P</i> = 0.0029 NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Nicholson et al., 2008 Country: US Participant source: Academic multi site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: NIH, First Hospital Foundation, Forest Pharmaceuticals Author industry relationship disclosure: NR Design: RCT	Intervention: Active management of risk in pregnancy at term (AMOR-IPAT): determination of an upper limit of the optimal time of delivery (UL-OTD) based on maternal and fetal characteristics, preventive induction of labor 1-4 days before UL-OTD ± cervical ripening Groups: G1: AMOR-IPAT exposed G2: Not AMOR-IPAT exposed N at enrollment: G1: 136 G2: 134 N at birth: G1: 136 G2: 134 Age, median yrs: G1: 23.4 G2: 23.3 Race/ethnicity, %: African American: G1: 89.7 G2: 86.6 Parous, %: G1: 52.2 G2: 53.0 Medicaid, %: G1: 92.6 G2: 91.8	Inclusion criteria: <ul style="list-style-type: none"> Between 32-37½ weeks gestation Accurate pregnancy dating Fluent in English At least 1 of 6 risk factors for cesarean delivery: (1) maternal age ≥ 35 years at time of delivery; (2) maternal height ≤ 62 in; (3) BMI ≥ 30 kg/m² at conception; (4) blood pressure > 80 mmHg diastolic or > 120 mmHg systolic in 1st trimester; (5) 1st trimester hemoglobin level < 11.0 g/dL; (6) history of fetus > 8 lb 8 oz <ul style="list-style-type: none"> Undelivered at 37 weeks 4 days gestation Exclusion criteria: <ul style="list-style-type: none"> Multiple gestation Previous cesarean delivery Placenta previa Positive HIV antibody titers Previous cervical cone biopsy Any other fetal or maternal issue that would preclude a trial of labor 	Cervical dilation at admission: NR Cervical effacement at admission: NR Initial Bishop's score, median: G1: 3 G2: 5 Initial Bishop's score ≤ 5, %: G1: 79.4 G2: 69.4	Labor progression: Duration of 1 st stage, mean hours: G1: 7.3 G2: 6.4 G1/G2: $P = 0.11$ Duration of 2 nd stage, mean minutes: G1: 41 G2: 48 G1/G2: $P = 0.43$ Labor augmented, after PROM or ineffective spontaneous labor, %: G1: 19.8 G2: 32.8 G1/G2: $RR = 0.62$ (95% CI: 0.40-0.92), $P = 0.02$ AROM, %: G1: 72.1 G2: 64.9 G1/G2: $RR = 1.11$ (95% CI: 0.94-1.31), $P = 0.21$ Internal monitoring: NR Amnioinfusion: NR Epidural, %: G1: 81.6 G2: 84.3 G1/G2: $RR = 0.97$ (95% CI: 0.87-1.08), $P = 0.55$ Maternal infection in labor, %: Maternal fever (> 100.4°F): G1: 4.4 G2: 3.0 G1/G2: $RR = 1.48$ (95% CI: 0.43-5.12), $P = 0.53$	Maternal Outcomes Cesarean birth, %: G1: 10.3 G2: 14.9 G1/G2: $RR = 0.69$ (95% CI: 0.36-1.31), $P = 0.25$ Vaginal, assisted, %: G1: 5.9 G2: 9.7 G1/G2: $RR = 0.61$ (95% CI: 0.26-1.42), $P = 0.24$ Vaginal, spontaneous: NR Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 0 G2: 1 (0.8) Apgar score, 5 minutes, mean: G1: 8.9 G2: 8.9 G1/G2: $P = 0.91$ Apgar score < 7, 5 minutes, n (%): G1: 0 G2: 1 (0.8) G1/G2: $P = 0.31$ NICU admission, n (%): G1: 2 (1.5) G2: 9 (6.7) G1/G2: $RR = 0.22$ (95% CI: 0.05-0.99), $P = 0.03$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Norris et al., 2001 Country: US Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 08/1997 to 07/1998 Funding: Intramural Author industry relationship disclosure: None Design: RCT	Intervention: Combined spinal-epidural analgesia for labor. Early labor: 10 µg intrathecal sufentanil then 45 mg lidocaine and 15 µg epinephrine via epidural catheter. Advanced labor: 10 µg intrathecal sufentanil and 2 mg intrathecal bupivacaine, then 45 mg lidocaine and 15 µg epinephrine via epidural catheter. Groups: G1: Combined spinal-epidural analgesia for labor G2: Epidural analgesia for labor N at enrollment: G1: 1,427 G2: 1,400 N at birth: G1: 1,071 G2: 1,112 Age, mean yrs ± SD: G1: 24.6 ± 6.2 G2: 24.6 ± 6.2 Race/ethnicity: NR Parous, n (%): G1: 630 (58.8) G2: 644 (57.9) Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> • Singleton gestation • In labor or planning a trial of labor Exclusion criteria: <ul style="list-style-type: none"> • See inclusion criteria 	Cervical dilation at admission, mean cm ± SD: G1: 4.0 ± 1.5 G2: 4.0 ± 1.0 Cervical effacement at admission: NR	Labor progression: Duration first stage of labor, median hours (IQR): G1: 10 (8.7) G2: 9.8 (8.5) Time from analgesia to full cervical dilation, median hours (IQR): G1: 3.3 (4.1) G2: 3.4 (4.2) Duration second stage of labor, median minutes (IQR): G1: 29.0 (44) G2: 31.0 (46) Labor augmented, n (%): Oxytocin: G1: 500 (46.7) G2: 522 (47.0) AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 106 (9.8) G2: 1,051 (94.5) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 155 (14.5) G2: 149 (13.4) Vaginal, assisted, n (%): G1: 184 (17.2) G2: 182 (16.4) Vaginal, spontaneous, n (%): G1: 731 (68.3) G2: 780 (70.2) Maternal harms, n (%): Accidental dural puncture: G1: 14 (1.3) G2: 13 (1.2) Intravascular catheter: G1: 64 (6.4) G2: 49 (4.4) Failed epidural: G1: 8 (0.8) G2: 8 (0.7) Positional headache: G1: 17 (1.7) G2: 17 (1.6) Blood patch: G1: 4 (0.4) G2: 6 (0.6) Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, mean: 1 minute: G1: 8 G2: 8 5 minutes: G1: 9

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Norris et al., 2001 (continued)					G2: 9 NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Ojala et al., 2006 Country: Finland Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 01/2003 to 02/2004 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Labor monitored by STAN S21 (ST analysis of fetal electrocardiography), continuous monitoring via scalp electrode Groups: G1: Fetal monitoring by STAN S21 G2: Monitoring by cardiotocography (CTG; Hewlett-Packard 8030A) internal intra-uterine scalp probe or external ultrasonographic signal sensor N at enrollment: G1: 733 G2: 739 N at birth: G1: 714 G2: 722 Age, mean yrs \pm SD: G1: 27.9 \pm 5.4 G2: 27.6 \pm 5.6 Race/ethnicity: NR Parous, n (%): G1: 350 (49) G2: 344 (47.6) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Active labor • Term \geq 36 weeks gestational age • Singleton fetus • Cephalic presentation • Among whom amniotomy had been decided Exclusion criteria: <ul style="list-style-type: none"> • If scalp electrodes contraindicated • Admitted to labor ward in the second phase of labor • Refusal to participate 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression: NR Labor augmented, n (%): G1: 144 (20.2) G2: 126 (17.5) AROM: NR Internal monitoring, n (%): Fetal blood sampling: G1: 51 (7) G2: 115 (15.6) STAN S21: G1: 714 (100) G2: 0 Amnioinfusion: NR Epidural, n (%): G1: 390 (54.6) G2: 390 (54.0) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 47 (6.4) G2: 35 (4.7) G1/G2: RR = 1.35 (95% CI: 0.86-2.07), P = 0.124 Vaginal, assisted, n (%): G1: 70 (9.5) G2: 79 (10.7) G1/G2: RR = 0.89 (95% CI: 0.66-1.21), P = 0.530 Vaginal, spontaneous, n (%): G1: 686 (93.6) G2: 704 (95.3) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, n (%): G1: 9 (1.3) G2: 8 (1.1) G1/G2: RR = 1.14 (95% CI: 0.44-2.93), P = 0.776 NICU admission, n (%): G1: 26 (3.6) G2: 26 (3.6) G1/G2: RR = 1.01 (95% CI: 0.59-1.72), P = 0.967

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Olofsson et al., 1998 Country: Sweden Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: Karolinska Institute, Swedish Medical Research Council, Torsten and Ragnar Soderberg's Foundation Author industry relationship disclosure: NR Design: RCT	Intervention: Epidural anesthesia (EDA); comparison of high dose (HD) versus low dose (LD) Groups: G1: 0.25% bupivacaine with adrenaline G2: 0.125% bupivacaine with sufentanil 10 µg Ga: Primiparous Gb: Multiparous N at enrollment: G1: 435 G2: 422 N at birth: G1: 435 G2: 422 Age, mean yrs: G1: 29 G2: 30 Race/ethnicity: NR Primiparous, n (%): G1: 284 (65.3)* G2: 282 (66.8)* Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • All parturients who requested and were found eligible to receive EDA • Normal and abnormal pregnancies planned for vaginal delivery Exclusion criteria: <ul style="list-style-type: none"> • Refusal to participate 	Cervical dilation at admission, n: 0-3 cm: G1: 70 G2: 58 4-5 cm: G1: 205 G2: 188 6-10 cm: G1: 156 G2: 171 Cervical dilation at admission: NR	Labor progression, (total delivery time), mean hours: G1a: 12.4 G1b: 10.0 G2a: 12.1 G2b: 7.6 Labor augmented, n: Oxytocin, mL: G1a: 338.7 G1b: 251.9 G2a: 279.7 G2b: 111.9 AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 435 (100) G2: 422 (100) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 64 (14.7) G2: 43 (10.2) Instrumental deliveries, %: Vacuum extraction and cesarean: G1: 48.9 G2: 29.7 G1/G2: RR = 1.64 (95% CI: 1.38-1.96), $P < 0.00001$ Vaginal, assisted: NR Vaginal, spontaneous, n:¹ Multiparous: 210/291 Primiparous: 306/566 G1/G2: $P < 0.00001$ Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, %: G1: 4.5 G2: 3.9 NICU admission: NR

* Calculated by reviewer

¹ Adjusting for treatment effect

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: O'Sullivan et al., 2009 Country: UK Participant source: Academic single site Intervention setting: Hospital, labor and delivery suite Enrollment period: 06/2001 to 04/2006 Funding: Obstetric Anaesthetists' Association and Special Trustees of St. Thomas' Hospital Author industry relationship disclosure: None Design: RCT	Intervention: Allowing women to eat during labor- advised a low fat low residue diet during labor Groups: G1: Eating G2: Ice chips and water only N at enrollment: G1: 1227 G2: 1216 N at birth: G1: 1219 G2: 1207 Age, mean yrs \pm SD: G1: 29 \pm 6 G2: 29 \pm 6 Race/ethnicity, n (%): White: G1: 751 (62) G2: 741 (61) African or Caribbean: G1: 285 (23) G2: 281 (23) Other: G1: 183 (15) G2: 185 (15) Parous, n: G1: 4 ¹ G2: 4 ¹ Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> > 18 years old Nulliparous > 36 weeks gestation Singleton Cephalic presentation In labor with cervical dilation < 6 cm Exclusion criteria: <ul style="list-style-type: none"> Diabetes Known obstetric or medical complication that could increase the likelihood of operative delivery Severe pain Intent to use parenteral opioids for analgesia during labor Unable to understand English and no interpreter available 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, (duration), mean minutes: G1: 597 G2: 612 G1/G2: RR = 0.97 (95% CI: 0.93-1.03) Labor augmented, n (%): Prostglandin only: G1: 117 (10) G2: 92 (8) Prostglandin plus oxytocin: G1: 212 (17) G2: 233 (19) AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 804 (66) G2: 813 (67) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 362 (30) G2: 363 (30) G1/G2: RR = 0.99 (95% CI: 0.87-1.12), P = 0.86 Vaginal, assisted, n (%): G1: 324 (27) G2: 310 (26) G1/G2: RR = 1.04 (95% CI: 0.91-1.19), P = 0.64 Vaginal, spontaneous, n (%): G1: 533 (44) G2: 534 (44) G1/G2: RR = 0.99 (95% CI: 0.91-1.09), P = 0.77 Maternal harms, n (%): Vomited: G1: 430 (35) G2: 406 (34) G1/G2: RR = 1.05 (95% CI: 0.94-1.17), P = 0.41 Maternal mortality, n: G1: 0 G2: 1 Neonatal outcomes Neonatal mortality: NR Apgar score \leq 7, 5 minutes, n (%): G1: 16 (1.3) G2: 22 (1.8) G1/G2: RR = 0.72 (95% CI: 0.38-1.36), P = 0.33

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
O'Sullivan et al., 2009 (continued)					<p>Apgar score ≤ 4, 5 minutes, n (%): G1: 4 (0.3) G2: 9 (0.8) G1/G2: RR = 0.44 (95% CI: 0.14-1.42), $P = 0.18$</p> <p>NICU admission, n (%): G1: 61 (5.0) G2: 62 (5.2) G1/G2: RR = 0.96 (95% CI: 0.68-1.35), $P = 0.81$</p>

¹ Excluded

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Palomaki et al., 2006 Country: Finland Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: Medical Research Fund of Tampere University Hospital, Finland Author Industry Relationship Disclosure: NR Design: RCT	Intervention: 2 mg propranolol IV over a 10 minute period. Repeated after 1 hour of cervix remained unchanged. Concurrent infusion of oxytocin 2.5 mIU/min raised by 2.5 mIU/min every 30 min until contractions reached 150 Montevideo units. Groups: G1: Propranolol with oxytocin G2: Placebo with oxytocin N at enrollment: G1: 55 G2: 52 N at birth: G1: 55 G2: 52 Age, mean yrs (range): G1: 27 (20-43) G2: 27 (18-39) Race/ethnicity: NR Parous, %: G1: 29 G2: 29 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Singleton pregnancy with cephalic presentation • Gestational age ≥ 37 weeks • Estimated weight of fetus 2500-4500 g • Normal course of pregnancy • Normal CTG before augmentation • Spontaneous or artificial rupture of membranes • Heart rate of the parturient 60-120 beats per minute • Systolic blood pressure of the parturient > 100 mmHg • Failure to progress in active phase of the first stage of labor Exclusion criteria: <ul style="list-style-type: none"> • Chronic maternal illness including hypertension, heart disease, arrhythmia, bronchial asthma, diabetes mellitus • Acute infectious disease 	Cervical dilation before augmentation, median (range): G1: 4 (2-6) G2: 4 (2-7) Cervical effacement at admission: NR	Labor progression, total duration in minutes, median excluding cesarean births: G1: 810 G2: 768 G1/G2: $P = 0.486$ Duration of augmented part of labor in minutes, median G1: 185 G2: 223 G1/G2: $P = 0.217$ Labor augmented, n (%) G1: 55 (100) G2: 52 (100) AROM: NR Internal monitoring (intrauterine scalp electrode and intrauterine Philips catheter), n (%) G1: 55 (100) G2: 52 (100) Amnioinfusion: NR Epidural, %: G1: 82 G2: 83 Maternal infection in labor: NR	Maternal Outcomes Cesarean birth, n (%) G1: 6 (11) G2: 2 (4) G1/G2: $P = 0.154$ Vaginal, assisted, n (%) G1: 9 (16) G2: 6 (11) G1/G2: $P = 0.331$ Vaginal, spontaneous, n (%) G1: 40 (73) G2: 44 (85) RR = 0.86, 95% CI 0.70-1.05 Maternal harms (transient bradycardia), n (%) G1: 2 (4) G2: 2 (4) Maternal mortality: NR Infant outcomes Neonatal mortality: NR Apgar score, 5 minutes, median (range): G1: 9 (8-9) G2: 9 (6-10) NICU admission, n (%) G1: 6 (11) G2: 5 (10)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Palomaki et al., 2006 (continued)		<ul style="list-style-type: none"> • Suspected or verified fetal abnormality or distress including fetal growth retardation, abnormal presentation, abnormal CTG before augmentation • Fetopelvic disproportion 			

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Pattinson et al., 2003 Country: South Africa Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: South African Medical Research Council Author industry relationship disclosure: NR Design: RCT	Interventions: <ul style="list-style-type: none"> Aggressive management: 1-line partogram with alert line; vaginal exam every 2 hours Expectant management: 2-line partogram with alert line and a parallel action line drawn 4 hours later; vaginal exam every 4 hours. Groups: G1: Aggressive management G2: Expectant management N at enrollment: G1: 344 G2: 352 N at birth: G1: 344 G2: 350 Age, mean yrs \pm SD: G1: 21.9 \pm 4.0 G2: 21.7 \pm 3.4 Race/ethnicity: NR Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> Healthy Nulliparous Active labor Singleton with cephalic presentation Exclusion criteria: <ul style="list-style-type: none"> Obstructed labor Fetal distress on admission Severe maternal disease (e.g., pre-eclampsia, breech, abnormal lie) Cervix > 8 cm dilated Gestational age < 36 weeks or estimated fetal weight < 2.5 kg if gestational age uncertain 	Cervical dilation at admission, mean cm \pm SD: G1: 4.6 \pm 1.1 G2: 4.6 \pm 1.1 Cervical effacement at admission: NR	Labor progression: NR Labor augmented, n (%): Oxytocin: G1: 77 (22.4) G2: 52 (14.9) G1/G2: RR = 1.51 (95% CI: 1.10-2.07) AROM, n (%): G1: 19 (15.3) G2: 29 (20.1) Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 257 (74.7) G2: 256 (73.7) G1/G2: RR = 1.01 (95% CI: 0.93-1.11) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 55 (16) G2: 82 (23.4) G1/G2: RR = 0.68 (95% CI: 0.50-0.93) Vaginal, assisted, n (%): Vacuum and forceps: G1: 70 (20.3) G2: 97 (27.9) Vaginal, spontaneous: NR Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 3 (0.6) G2: 0 G1/G2: RR = 7.12 (95% CI: 0.37-137.37) Apgar score, 1 minute, n (%): 0-3: G1: 14 (4.1) G2: 11 (3.1) 4-7: G1: 69 (20.1) G2: 57 (16.3) 8-9: G1: 261 (75.8) G2: 282 (80.6) G1/G2: <i>P</i> = NS Apgar score < 8, 10 minutes, n (%): G1: 3 (0.9) G2: 0

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Pattinson et al., 2003 (continued)					G1/G2: <i>P</i> = NS NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Phipps et al., 2009 Country: Australia Participant source: Academic single site Intervention setting: Antenatal class Enrollment period: 08/2005 to 07/2006 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Two 15-minute structured education sessions, taught by midwife one week apart: anatomy, physiology, practice pushing with midwife observing perineum then applying digital pressure and biofeedback to the levator ani muscle Groups: G1: Education session G2: Control/no education session N at enrollment: G1: 50 G2: 50 N at birth: G1: 50 G2: 50 N at follow-up: (3 months postnatal) G1: 45 G2: 45 Age, mean yrs \pm SD: G1: 29.04 \pm 3.8 G2: 30.8 \pm 4.3 Race/ethnicity, n (%) : White: G1: 37 (74) G2: 35 (70) Asian: G1: 9 (18) G2: 14 (28) Other: G1: 4 (8) G2: 1 (2) Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • 35-37 weeks gestation • Nulliparous • Singleton • Cephalic presentation • English speaking • Planning a vaginal birth Exclusion criteria: <ul style="list-style-type: none"> • < 18 years • Cognitive impairment • High-risk pregnancy • Contraindication to vaginal examination 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, mean minutes \pm SD: Duration: G1: 484.3 \pm 338.3 G2: 547.9 \pm 443.7 G1/G2: $P = 0.584$ Labor augmented, n (%) : G1: 22 (44) G2: 16 (32) AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%) : G1: 11 (22) G2: 13 (26) G1/G2: $P = 0.789$ Vaginal, assisted, n (%) : G1: 8 (16) G2: 6 (12) Vaginal, spontaneous, n (%) : G1: 31 (62) G2: 31 (62) Maternal harms, perineum, n (%) : Episiotomy: G1: 10 (20) G2: 5 (10) Intact or first degree tear: G1: 29 (58) G2: 28 (56) Second degree tear: G1: 7 (14) G2: 14 (28) Third degree tear: G1: 4 (8) G2: 3 (6) G1/G2: $P = 0.142$ Maternal mortality, n: G1: 0 G2: 0 Neonatal outcomes Neonatal mortality: NR Apgar score: NR NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Rathore et al., 2002 Country: India Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: NR Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Amnioinfusion (8°F nasogastric tube inserted transcervically into uterine cavity just above head, initially 500 ml of normal saline at room temperature infused through tube over 30 minutes, then 500 ml at the rate of 3ml/min for a maximum of 1L.) Groups: G1: Amnioinfusion G2: Control/non-amnioinfusion N at enrollment: G1: 100 G2: 100 N at birth: G1: 100 G2: 100 Age, mean years ± SD: G1: 24.3 ± 3.3 G2: 24.2 ± 3.2 Race/ethnicity: NR Parous: NR Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • ≥ 37 weeks gestation • Singleton • Cephalic presentation • Moderate or thick meconium in amniotic fluid • Meconiumcrit of > 10% Exclusion criteria: <ul style="list-style-type: none"> • Choriomnionitis • Indication for immediate delivery • Fetal congenital anomaly • Antepartum hemorrhage • Polyhydramnios • Maternal cardiac or pulmonary disease 	Cervical dilation at admission, mean cm ± SD: G1: 4.1 ± 0.9 G2: 4.3 ± 0.9 Cervical effacement at admission: NR	Labor progression (AROM to delivery interval), mean hours ± SD: G1: 2.7 ± 1.1 G2: 2.6 ± 0.7 Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion, n (%): G1: 100 (100) G2: 0 Epidural: NR Maternal infection in labor, n: Pyrexia: G1: 6 G2: 12 G1/G2: RR = 0.47 (95% CI: 0.15-1.42)	Maternal outcomes Cesarean birth, n (%): G1: 21 (21) G2: 36 (36) G1/G2: RR = 0.47 (95% CI: 0.24-0.93) Vaginal, assisted, n (%): G1: 5 (5) G2: 14 (14) Vaginal, n (%): G1: 79 (79) G2: 64 (64) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 2 (2) G2: 5 (5) Apgar score < 7, n: 1 minute: G1: 2/94 G2: 8/98 G1/G2: RR = 0.24 (95% CI: 0.03-1.29) 5 minutes: G1: 1/99 G2: 2/96 G1/G2: RR = 0.48 (95% CI: 0.02-6.89) NICU admission, n (%): G1: 3 (3) G2: 11 (11) G1/G2: RR = 0.25 (95% CI: 0.05-1.01)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Regi et al., 2009 Country: India Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 10/2003 to 09/2004 Funding: NR Author industry relationship disclosure: None Design: RCT	Intervention: Transcervical Intrapartum amnioinfusion (AI) 500 mL of warmed saline at 37°C infused over 30 minutes at rate 15-25 mL/min followed by continuous infusion 3 mL/min until delivery. Groups: G1: Amnioinfusion G2: Standard care, no infusion N at enrollment: G1: 75 G2: 75 N at birth: G1: 73 G2: 75 Age: NR Race/ethnicity: NR Parous, n (%): G1: 20 (27.4) G2: 23 (31.5) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> First stage of active labor (cervical dilation < 10 cm) Gestational age > 34 weeks Clear or grade I meconium staining of amniotic fluid Presence of repetitive severe (< 70 beats per minute lasting for > 60 seconds) or moderate (> 5 consecutive or following > 50% of the contractions in a 20 minute period) variable decelerations Exclusion criteria: <ul style="list-style-type: none"> Variable decelerations with poor variability of delayed recovery Baseline bradycardia or tachycardia Repetitive late decelerations Grade II or III meconium-stained amniotic fluid Pervious cesarean delivery Presence of contraindication to vaginal delivery (fetal malpresentation, placenta previa) 	Cervical dilation at admission, n (%): ≤ 3 cm: G1: 38 (52) G2: 35 (46.7) > 3 cm: G1: 35 (48) G2: 10 (53.3) G1/G2: <i>P</i> = 0.512 Cervical effacement at admission: NR	Labor progression: Rupture of membranes until delivery, hours, mean ± SD: G1: 11.14 ± 8.3 G2: 9.52 ± 8.6 Labor augmented, n (%): G1: 46 (63) G2: 36 (48) G1/G2: <i>P</i> = 0.066 Oxytocin augmentation, n (%): G1: 56 (76.7) G2: 53 (70.7) G1/G2: <i>P</i> = 0.315 AROM, n (%): G1: 35 (48) G2: 44 (58.6) G1/G2: <i>P</i> = 0.191 Internal monitoring: NR Amnioinfusion, n (%): G1: 73 (100) G2: 0 Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 28 (38) G2: 28 (37.3) Vaginal, assisted: NR Vaginal, spontaneous: NR Relief of variable decelerations, n (%): G1: 58 (79.5) G2: 2 (2.7) G1/G2: <i>P</i> = .001 Maternal harms, n (%): Intrapartum temp ≥ 38.3°C: G1: 2 (2.7) G2: 0 Postpartum temp ≥ 38.3°C: G1: 2 (2.7) G2: 2 (2.7) Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score ≤ 7, 5 minutes, n: Nulliparous: G1: 0 G2: 0 Multiparous: G1: 0 G2: 0 NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Rogers et al., 1997 Country: US Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 08/1992 to 04/1996 Funding: NIH Author industry relationship disclosure: NR Design: RCT	Intervention: Active management of labor. Labor defined as painful, palpable uterine contractions 2-5 minutes apart, cervical effacement of at least 80%; amniotomy performed within 2 hours of admission and augmentation of labor with oxytocin instituted if cervical dilatation of 1 cm/hr within first stage of labor or descent of 1 cm/hr in second stage failed to occur; a cervical exam every 2 hrs; if augmentation was necessary oxytocin infusion started at 6 mU/min, increased every 15 minutes, titrating to seven contractions in 15 minutes or appropriate cervical change. Maximum dose 36 mU/min. Groups: G1: Active management of labor G2: Usual care N at enrollment: ¹ G1: 200 G2: 205 N at birth: G1: 200 G2: 205 Age, mean yrs \pm SD: G1: 20.7 \pm 4.2 G2: 20.5 \pm 3.7	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Term pregnancy • Examined in antenatal testing unit • Painful, palpable uterine contractions \leq 5 minutes apart • Cervical effacement of at least 80% • Gestational age \geq 37 weeks • Cephalic presentation • No known maternal medical complications • No known fetal anomalies Exclusion criteria: <ul style="list-style-type: none"> • Placenta previa or abruptio placentae • Twin gestations • Prior uterine surgery • Any other obstetric or medical complications of pregnancy 	Cervical dilation at admission, mean cm \pm SD: G1: 2.8 \pm 1.0 G2: 2.9 \pm 1.1 Cervical effacement at admission, mean % (range): G1: 90 (80-100) G2: 80 (80-100)	Labor progression, length of labor, mean hours \pm SD: Total: G1: 9.7 \pm 4.9 G2: 11.2 \pm 5.4 First stage: G1: 8.5 \pm 4.5 G2: 10.1 \pm 5.9 Second stage: G1: 1.0 \pm 1.0 G2: 1.1 \pm 1.4 Labor augmented, n (%): G1: 112 (56) G2: 105 (51) AROM, n (%): G1: 172 (86) G2: 164 (80) Internal monitoring, n (%): G1: 138 (69) G2: 137 (67) Amnioinfusion: NR Epidural, n (%): G1: 118 (59) G2: 105 (51) Maternal infection in labor, n (%): Febrile episodes attributed to chorioamnionitis: G1: 28 (14) G2: 26 (13)	Maternal outcomes Cesarean birth, n (%): G1: 15 (7.5) G2: 24 (11.7) G1/G2: <i>P</i> = NS Vaginal, assisted, n (%): G1: 35 (19) G2: 33 (18) G1/G2: <i>P</i> = NS Vaginal, spontaneous, n (%): G1: 150 (81) G2: 148 (82) G1/G2: <i>P</i> = NS Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, n: G1: 2 G2: 2 NICU admission, n: G1: 1 G2: 4 G1/G2: <i>P</i> = NS

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Rogers et al., 1997 (continued)	Race/ethnicity, n (%) : White: G1: 58 (29) G2: 51 (25) Hispanic: G1: 132 (66) G2: 140 (68) Other: G1: 10 (5) G2: 14 (7) Parous, n: G1: 0 G2: 0 Medicaid: NR				

¹ Two additional multiparous women were erroneously allowed in the study but excluded from analysis

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Sadler et al., 2000 Country: New Zealand Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 06/1993 to 08/1997 Funding: Auckland Health Care, Health Research Council of New Zealand, Evelyn Bond Obstetric Research Fund Author industry relationship disclosure: NR Design: RCT	Intervention: Active management of labor: women encouraged to have amniotomy at diagnosis of labor. Cervical assessment every 2 hours. Oxytocin started for delayed progress (< 1 cm/hour in the 1 st stage of labor and absence of descent of baby's head after 30 minutes of pushing or contractions < one in five minutes and delivery not imminent in 2 nd stage) 6mU per minute and increased by 6mU per minute every 15 minutes to maximum dose of 36 mU per minute. Groups: G1: Active management of labor G2: Usual care N at enrollment: G1: 320 G2: 331 N at birth: G1: 320 G2: 331 N at follow-up (6 weeks post-partum): G1: 243 G2: 225 Age, mean yrs: G1: 25.7 G2: 25.7	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparity • Singleton pregnancy • No severe cardiac disease • No uterine scar • No proven contracted pelvis Exclusion criteria: (at onset of labor prior to randomization) <ul style="list-style-type: none"> • Induced labor • Noncephalic presentation • Withdrawal of consent • Gestation < 37 weeks • Abnormal cardiotocograph or thick meconium suggesting fetal distress • Involvement in study not recognized at admission • Elective CS • Intrauterine death • Multiparity 	Cervical dilation at admission, mean \pm SD: G1: 4.5 \pm 1.8 G2: 4.5 \pm 2.1 Cervical effacement at admission: NR	Labor duration for vaginal deliveries only, median (interquartile range): G1: (n=290) 326 (185-485) G2: (n=299) 376 (212-543) G1/G2: $P = 0.05$ Labor augmented, n (%): Oxytocin: G1: 168 (53) G2: 129 (39) G1/G2: RR = 1.35 (95% CI: 1.14-1.60) AROM, n (%): G1: 231 (72) G2: 209 (63) G1/G2: RR= 1.14 (95% CI: 1.03-1.27) Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 156 (49) G2: 149 (45) Maternal infection in labor, n (%): G1: 37 (12) G2: 34 (10)	Maternal outcomes Cesarean birth, n (%): G1: 30 (9.4) G2: 32 (9.7) G1/G2: $P = 0.5$ for mode of delivery Vaginal, assisted, n (%): G1: 63 (20) G2: 54 (16) Vaginal, spontaneous, n (%): G1: 227 (71) G2: 245 (74) Maternal harms (hemorrhage), n (%): G1: 48 (15) G2: 47 (14) Maternal mortality: NR Infant outcomes Neonatal mortality: NR Apgar score < 6, five minutes, n (%): G1: 1 (0.3) G2: 0 NICU admission, n (%): G1: 17 (5) G2: 16 (5)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Sadler et al., 2000 (continued)	<p>Race/ethnicity, n (%):</p> <p>European: G1: 121 (38) G2: 110 (33)</p> <p>Maori: G1: 41 (13) G2: 51 (16)</p> <p>Pacific Island: G1: 92 (29) G2: 100 (30)</p> <p>Asian/Other: G1: 66 (20) G2: 70 (21)</p> <p>Parous, n: G1: 0 G2: 0</p> <p>Medicaid, n (%): Not applicable</p> <p>Public care giver: G1: 135 (42) G2: 137 (41)</p>				

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Saisto et al., 2001 Country: Finland Participant source: Community Intervention setting: Clinic Enrollment period: 08/1996 to 07/1999 Funding: Signe and Ane Gyllenberg Foundation, Emil Aaltonen Foundation, Helsinki University Central Hospital, Academy of Finland Author industry relationship disclosure: NR Design: RCT	Intervention: Intensive therapy: Written information (pros and cons of vaginal and cesarean births, alternative modes of pain relief), questionnaires (24 and 36 weeks, 3 months post partum); OB appointments for routine check up and cognitive therapy (24, 28, 32, 36, 38 weeks); appointment with midwife at 37 weeks (information on pain relief and possible interventions). Phone access to OB and NM. Discussion of birth plan. Conventional care: Routine OB check-ups (24 and 36 weeks); written information (pros and cons of vaginal and cesarean births, alternative modes of pain relief). Groups: G1: Intensive therapy G2: Conventional care N at enrollment: (at 26 weeks) G1: 85 G2: 91 N at birth: G1: 85 G2: 91 Age, mean yrs \pm SD: G1: 31.2 \pm 5.1 G2: 31.9 \pm 4.8	Inclusion criteria: <ul style="list-style-type: none"> • Women referred for antenatal consultation because of fear of childbirth • Obstetrically low risk • Physically healthy Exclusion criteria: <ul style="list-style-type: none"> • Contraindication to vaginal delivery at the time of randomization (two previous cesareans or vertical incision in previous cesarean) 	Cervical dilation at admission: NR Cervical effacement at admission: NR Previous spontaneous abortions, n (%): G1: 19 (22.4) G2: 7 (7.7) Wish for cesarean (pre-intervention), n (%): G1: 58 (68.2) G2: 59 (64.8) G1/G2: $P = NS$	Labor progression duration, hours \pm SD: G1: 6.8 \pm 3.8 G2: 8.5 \pm 4.8 G1/G2: $P = 0.039$ Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: NR (85) G2: NR (82) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 37 (43.5) G2: 44 (48.3) Cesarean, elective, n (%): G1: 20/85 (23.5*) G2: 26/91 (28.5*) Cesarean, emergency, n (%): All women: G1: 17/85 (20.0*) G2: 18/91 (19.8*) Women choosing vaginal delivery: G1: 17/65 (26.1*) G2: 18/65 (27.7*) Vaginal, assisted: NR Vaginal, spontaneous: NR Vaginal, any, n: G1: 48 G2: 47 Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score: NR NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Saisto et al., 2001 (continued)	Race/ethnicity, n (%) Finnish: G1: 85 (100) G2: 91 (100) Parous, n (%) G1: 41 (48.2) G2: 45 (49.5) Medicaid: Not applicable				

*Calculated by reviewer

Parity was related to request for cesarean: 74% of parous and 59% of nulliparous women requested it in the beginning ($P = 0.003$), and of them 42% of parous and 32% of nulliparous women also finally chose it ($P < 0.05$).

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Sanchez-Ramos et al., 1996 Country: US Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 03/1992 to 02/1994 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: 2 mg IV propranolol, repeated 1 hour later if no change in cervical dilation Continuous IV oxytocin in all patients, started at 1-2 mU/min, increased at 1-2 mU/min in 30 min intervals until ≥ 3 uterine contractions/10 min Groups: G1: Propranolol G2: Placebo N at enrollment: G1: 49 G2: 47 N at birth: G1: 49 G2: 47 Age, mean yrs \pm SD: G1: 24.3 \pm 5.2 G2: 22.5 \pm 4.2 Race/ethnicity, n (%): White: G1: 19 (38.8) G2: 23 (48.9) Non-white: G1: 30 (61.2) G2: 24 (51.1) Parous, n (%): G1: 22 (44.9) G2: 19 (40.4) Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> • Singleton pregnancy • Vertex presentation at term • Active phase of labor (5-9 cm dilation) • Estimated fetal weight of 2500-4500 g • Arrest of dilation (lack of progressive cervical dilation ≥ 2 hours or deceleration phase ≥ 3 hours in nulliparas or 1 hour in multiparas) • Normal maternal heart rate (60-120 bpm) Exclusion criteria: <ul style="list-style-type: none"> • Systolic BP < 100 mm Hg • Hypertensive disorders of pregnancy, asthma, or diabetes 	Cervical dilation at admission: NR Cervical effacement at admission: NR Cervical dilation at arrest, mean cm \pm SD: G1: 6.8 \pm 1.3 G2: 6.8 \pm 1.4	Labor progression, time from administration of study drug to vaginal delivery, mean minutes \pm SD: G1: 239 \pm 148 G2: 237 \pm 106 Labor augmented, n (%): G1: 49 (100) G2: 47 (100) AROM: NR Internal monitoring, n (%): IUPC and scalp electrode: G1: 49 (100) G2: 47 (100) Amnioinfusion: NR Epidural, n (%): G1: 22 (44.9) G2: 20 (42.5) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 13 (26.5) G2: 24 (51.1) G1/G2: RR = 0.58 (95% CI: 0.35-0.93), $P = 0.02$ Vaginal, assisted, n (%): G1: 10 (20.4) G2: 8 (17.0) G1/G2: $P = 0.79$ Vaginal, spontaneous, n (%): G1: 26 (53.1)* G2: 15 (31.9)* Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 5 minutes, n (%): G1: 1 (2.0) G2: 2 (4.2) NICU admission, n (%): G1: 1 (2.0) G2: 1 (2.1)

* Number of spontaneous births calculated by the reviewer, subtracting the number of operative vaginal and cesarean deliveries from the number of participants

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Scheepers et al., 2002 Country: The Netherlands Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 07/1998 to 06/2000 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Carbohydrate solution (per 100 mL, 12.6 g carbohydrates, 9.8% polysaccharides/sodium 50 mg, 280 mOsm/L) consumed by mouth as desired during labor Placebo solution: artificial aroma, aspartame, acesulfame Groups: G1: Carbohydrate solution G2: Placebo N at enrollment: G1: 102 G2: 99 N at birth: G1: 102 G2: 99 Age, mean yrs \pm SD: G1: 26.3 \pm 5.0 G2: 25.7 \pm 5.6 Race/ethnicity: NR Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> Nulliparous In early labor (2-4 cm cervical dilation) Fetus in cephalic position Exclusion criteria: <ul style="list-style-type: none"> Elective cesarean Multiple pregnancy Diabetes Women considered to have direct risk of cesarean 	Cervical dilation at admission, mean \pm SD: G1: 3.1 \pm 1.0 G2: 3.0 \pm 0.9 Cervical effacement at admission: NR	Labor progression, duration, median minutes (range): G1: 370 (29-1500) G2: 300 (50-1210) G1/G2: $P = 0.06$ Labor augmented, n (%): G1: 24 (23.5) G2: 28 (28.3) AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 26 (25.5) G2: 16 (16.2) RR = 1.56 95%CI 0.89-2.73 Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 21 (20.6) G2: 7 (7.1) RR 2.91 95%CI 1.29-6.54 Vaginal, assisted, n (%): G1: 29 (28.4) G2: 36 (36.4) RR = 0.78 95%CI 0.52-1.17 Vaginal, spontaneous, n (%): G1: 52 (51.0) G2: 56 (56.6) RR = 0.90 95%CI 0.68-1.17 Maternal harms: NR Maternal mortality: NR Infant outcomes Neonatal mortality: NR Apgar score, 5 minutes, mean \pm SD: G1: 9.6 \pm 0.8 G2: 9.5 \pm 0.9 G1/G2: $P = 0.18$ NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Skrablin et al., 2011 Country: Croatia Participant source: Academic single site Intervention setting: Labor and deliver suite Enrollment period: 05/2009 to 02/2010 Funding: NR Author industry relationship disclosure: None Design: RCT	Intervention: Before enrollment an initial bolus of 20 ml of lebovupivacaine (0.07% concentration) with 2 mg/ml of fentanyl was given via epidural catheter (equal dose given if baseline pain VAS > 1 cm at 15 minutes after the first one); then randomized between intermittent bolus dose (20 ml of levobupivacaine with 2.5 µg/ml fentanyl given 1 hour after an initial bolus dose, then upon reported discomfort or contractions) and continuous infused epidural analgesia (20 ml levobupivacaine with fentanyl of 2.5 µg/ml at infusion rate up to 14 ml/hour until delivery) Groups: G1: Intermittent epidural G2: Continuous epidural N at enrollment: G1: 101 G2: 104 N at birth: G1: 101 G2: 104 Age, mean yrs: G1: 28 G2: 28 Race/ethnicity: NR	Inclusion criteria: <ul style="list-style-type: none"> • Low risk • Nulliparous • Term pregnancy Exclusion criteria: <ul style="list-style-type: none"> • Pre-term (< 37 weeks) • Cervical dilation ≤ 2 or ≥ 5 cm • Systemic disease (e.g., heart disease, renal disease, asthma, diabetes mellitus, hypertension) • Chronic analgesic use • Contraindications to neuraxial blocks (e.g., coagulopathy, thrombocytopenia) • Multiple pregnancies • Absolute indication for cesarean (e.g., strait pelvis, placenta previa) • Breech presentation or other malpresentation • Failure to achieve adequate analgesia 	Cervical dilation at randomization, mean cm: G1: 4 G2: 4 Cervical effacement at randomization, n (%): Partial: G1: 50 (49.5) G2: 49 (48.5) Full: G1: 51 (50.5) G2: 55 (52.9)	Labor progression, duration from epidural to delivery, mean minutes ± SD: G1: 414 ± 101 G2: 432 ± 94 Labor augmented, n (%): Oxytocin: G1: 101 (100) G2: 104 (100) AROM, n (%): G1: 24 (23.5) G2: 28 (26.9) G2/G1: $P = 0.29$ Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 101 (100) G2: 104 (100) Maternal infection in labor, n (%): Intrapartum fever: G1: 23 (22.8) G2: 21 (20.2) G2/G1: $RR = 1.12$ (95% CI: 0.67-1.91), $P = 0.38$	Maternal outcomes Cesarean birth, n (%): G1: 5 (5.0) G2: 15 (14.4) G2/G1: $RR = 2.91$ (95% CI: 1.09-7.72), $P = 0.03$ Vaginal, assisted: NR Vaginal, spontaneous: NR Maternal harms: Motor blockade, n (%): G1: 1 (1.0) G2: 11 (10.6) G2/G1: $RR = 10.68$ (95% CI: 1.40-81.24), $P = 0.01$ Intrapartum pain, mean VAS score (range): G1: 5.4 (1.7-31.2) G2: 4.3 (1.3-24.5) G2/G1: $P = 0.36$ Hypotension, n (%): G1: 33 (32.7) G2: 22 (21.2) G2/G1: $RR = 1.53$ (95% CI: 0.78-3.78), $P = 0.56$ Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score ≤ 7, 5 minutes, n (%): G1: 3 (3.0) G2: 2 (1.9) G2/G1: $RR = 1.54$ (95% CI: 0.26-9.06), $P = 0.48$

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Skrablin et al., 2011 (continued)	Parous, n: G1: 0 G2: 0 Medicaid: Not applicable				NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Somprasit et al., 2005 Country: Thailand Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 05/2001 to 12/2002 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Active management of labor: artificial rupture of membranes within 1 hour of admission, 2 hourly vaginal assessments, high doses of oxytocin augmentation if cervical dilatation < 1 cm/hour in the first stage of labor Groups: G1: Active management of labor G2: Conventional management of labor N at enrollment: G1: 320 G2: 640 N at birth: G1: 320 G2: 640 Age, mean yrs \pm SD: G1: 24.4 \pm 4.5 G2: 24.2 \pm 4.5 Race/ethnicity: NR Parous, n: G1: 0 G2: 0 Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Nulliparous • Singleton • Normal fetal heart pattern at admission • Cephalic presentation • Gestational age \geq 37 weeks • Spontaneous labor without fetal distress at admission • No contra-indications to vaginal delivery or oxytocin • No medical or surgical complications Exclusion criteria: <ul style="list-style-type: none"> • Diabetes • Cervical incompetence • Pregnancy-induced hypertension 	Cervical dilation at admission, mean cm \pm SD: G1: 3.1 \pm 1.2 G2: 3.1 \pm 1.4 Cervical effacement at admission: NR	Labor progression, mean minutes \pm SD: G1: 539.3 \pm 261.4 G2: 610.3 \pm 264.4 G1/G2: $P < 0.001$ Labor augmented, n (%): Oxytocin: G1: 178 (55.6) G2: 305 (47.7) G1/G2: $P < 0.05$ AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor, n (%): Chorioamnionitis: G1: 0 G2: 6 (0.9) G1/G2: $P = NS$	Maternal outcomes Cesarean birth, n (%): G1: 38 (11.9) G2: 94 (14.7) G1/G2: $P = NS$ Vaginal, assisted, n (%): G1: 38 (11.9) G2: 91 (14.2) G1/G2: $P = NS$ Vaginal, spontaneous, n (%): G1: 244 (76.3) G2: 455 (71.1) G1/G2: $P = NS$ Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, 1 minute, n (%): G1: 6 (1.9) G2: 15 (2.3) G1/G2: $P = NS$ NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Spallici et al., 2007 Country: Brazil Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 01/1999 to 01/2000 Funding: Cientifico e Tecnologic (CNPq); Fundacao de Amparo a Pesquisa do Estado de Sao Paulo (FAPESP), Brazil; Apsen Farmaceutica S.A. Author industry relationship disclosure: NR Design: RCT	Intervention: 5 ml of 20,000 UI lyophilized HAase diluted in distilled water injected at two sites on the cervix (at 6 o'clock and 12 o'clock positions) Groups: G1: Hyaluronic acid G2: Placebo Ga: Nulliparae Gb: Multiparae N at enrollment: G1: 83 G1a: 46 G1b: 37 G2: 85 G2a: 48 G2b: 37 N at birth: G1: 83 G1a: 46 G1b: 36 G2: 85 G2a: 48 G2b: 37 Age, mean yrs \pm SD: G1a: 20.5 \pm 4.7 G1b: 27.4 \pm 5.8 G2a: 22.3 \pm 4.0 G2b: 27.9 \pm 5.0 Race/ethnicity, n (%): Caucasian: G1a: 30 (66) G1b: 17 (46) G2a: 22 (46) G2b: 22 (46) Parous, n (%): G1: 37 (44.6) G2: 37 (43.5) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> Gestational age between 37 weeks complete and 42 weeks incomplete Vertex presentation Bishop score < 5 Normal fetal vitality No uterine contractions Exclusion criteria: <ul style="list-style-type: none"> Elective cesarean Contra-indications to vaginal delivery 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, mean hours \pm SD: Patients admitted before labor: G1a: 6.8 \pm 4.0 G1b: 4.3 \pm 2.1 G2a: 11.0 \pm 4.4 G2b: 7.6 \pm 3.5 G1/G2: $\Delta = 3.8$ (95% CI: 2.2-5.2), $P = 0.0002$ Patients admitted in labor: G1a: 6.5 \pm 1.8 G1b: 4.3 \pm 1.5 G2a: 12.0 \pm 2.6 G2b: 9.5 \pm 3.0 G1/G2: $\Delta = 5.3$ (95% CI: 4.9-5.7), $P = 0.0001$ Labor augmented, n (%): G1: 83 (100) G2: 0 AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural: NR Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 15 (18) G2: 42 (49) G1/G2: ARR = 31 (95% CI: 18-44), $P < 0.0001$ Vaginal, assisted: NR Vaginal, spontaneous, n (%): G1: 68 (82) G2: 43 (51) G1/G2: ARR = 31 (95% CI: 19-44), $P = 0.0007$ Maternal harms: Cramps: G1: NR G2: NR G1/G2: $P = 0.2709$ Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, (%): G1: 2 (2.4) G2: 7 (8.4) Apgar score (1, 5, 10 minutes): G1: NR G2: NR G1/G2: $P > 0.115$ NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Strong et al., 1990 Country: US Participant source: Academic single site Intervention setting: Labor and delivery suite Enrollment period: 10/1988 to 03/1989 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Prophylactic amnioinfusion (250 ml normal saline warmed to 37°C infused through intrauterine pressure catheter at a rate of 10-20 ml/min) to attain an amniotic fluid index \geq 8 cm Groups: G1: Prophylactic amnioinfusion G2: No amnioinfusion N at enrollment: G1: 30 G2: 30 N at birth: G1: 30 G2: 30 Age, mean yrs \pm SD: G1: 23.9 \pm 5.6 G2: 24 \pm 5.8 Race/ethnicity: NR Parous, n (%): G1: 15 (50) G2: 11 (37) Medicaid: NR	Inclusion criteria: <ul style="list-style-type: none"> • Oligohydramnios (amniotic fluid index \leq 5 cm) • Singleton • Vertex presentation • Cervical dilation \leq 4 cm • Gestation \geq 37 weeks • Normal baseline fetal heart rate (FHR) variability • Estimated fetal weight $>$ 2500 g Exclusion criteria: <ul style="list-style-type: none"> • Late decelerations • Moderate or severe variable decelerations • Vaginal bleeding • Chorioamnionitis • Meconium-stained amniotic fluid • Fetal anomalies • Uterine anomalies 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, duration from membrane rupture to delivery, mean hours \pm SD: G1: 16.8 \pm 12.1 G2: 10.1 \pm 6.5 G1/G2: $P = 0.01$ Labor augmented: NR AROM: NR Internal monitoring: NR Amnioinfusion, n (%): G1: 30 (100) G2: 0 Epidural: NR Maternal infection in labor, n (%): Maternal temperature $>$ 100.4°F: G1: 6 (20) G2: 2 (7) G1/G2: $P = 0.06$	Maternal outcomes Cesarean birth, n (%): G1: 4 (13.3) G2: 6 (20) Vaginal, assisted, n (%): Forceps: G1: 5 (16.7) G2: 8 (26.7) Vaginal, spontaneous, n (%): G1: 21 (70)* G2: 16 (53.3)* Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, 5 minutes, mean \pm SD: G1: 8.9 \pm 0.6 G2: 8.9 \pm 0.2 G1/G2: $P = NS$ Apgar score $<$ 7, 5 minutes, n: G1: 0 G2: 0 G1/G2: $P = NS$ NICU admission: NR

* Calculated by reviewer.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Trueba et al., 2000 Country: Mexico Participant source: Community practice Intervention setting: Labor and delivery suite Enrollment period: 03/1997 to 02/1998 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Support of a childbirth educator also trained as a doula Groups: G1: Doula support G2: Standard care (no doula support) N at enrollment: G1: 50 G2: 50 N at birth: G1: 50 G2: 50 Age: NR Race/ethnicity: NR Parous, n (%): Nulliparous: G1: 50 (100) G2: 50 (100) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • Term • Active labor • ≥ 3 cm dilation • Nulliparous • Adequate pelvis • No previous uterine incision Exclusion criteria: <ul style="list-style-type: none"> • See inclusion criteria 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, labor length, mean hours \pm SD: G1: 14.5 \pm 5.36 G2: 19.38 \pm 7.3 G1/G2: $P = NS$ Labor augmented, n (%): Pitocin: G1: 21 (42) G2: 48 (96) G1/G2: $P = 0.001$ AROM: NR Internal monitoring: NR Amnioinfusion: NR Epidural, n (%): G1: 4 (8) G2: 16 (32) G1/G2: $P = NS$ Maternal infection in labor: NR	<u>Maternal outcomes</u> Cesarean birth, n (%): G1: 1 (2) G2: 12 (24) G1/G2: $P = 0.003$ Vaginal, assisted: NR Vaginal, spontaneous: NR Maternal harms: NR Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar score: NR NICU admission: NR

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Vayssiere et al., 2007 Country: France Participant source: Academic multi site Intervention setting: Labor and delivery suite Enrollment period: 02/2004 to 05/2006 Funding: Strasbourg Regional Project in Clinical Research Author industry relationship disclosure: NR Design: RCT	Intervention: Fetal ST-segment analysis using a STAN S21 device, monitoring for nonreassuring fetal status (NRFS) Groups: G1: Cardiotocography with STAN G2: Cardiotocography only N at enrollment: G1: 399 G2: 400 N at birth: G1: 399 G2: 400 Age, median yrs \pm SD: G1: 29.8 \pm 5.7 G2: 30.1 \pm 5.7 Race/ethnicity: NR Parous, n (%): G1: 111 (27.8) G2: 113 (28.2) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> • In labor • ≥ 36 gestational weeks • Singleton fetus • Cephalic presentation • Abnormal cardiotocography (defined according to the International Federation of Gynecology and Obstetrics classification) or thick meconium-stained amniotic fluid (7%) during labor Exclusion criteria: <ul style="list-style-type: none"> • Normal cardiotocography without deceleration during labor • Maternal infection contraindicating placement of scalp electrodes (seropositive for HIV or hepatitis B or C) • Cardiac malformation • Severe decelerations with variability reduced immediately on entry into the delivery room • Refusal to participate 	Cervical dilation at randomization, median \pm SD: G1: 5.8 \pm 2.4 G2: 5.5 \pm 2.3 Cervical effacement at admission: NR Prior cesarean, n (%): G1: 25 (6.3) G2: 24 (6.0)	Labor progression: NR Labor augmented: NR AROM: NR Internal monitoring (fetal scalp electrode), n (%): G1: 399 (100) G2: 0 Amnioinfusion: NR Epidural, n (%): G1: 364 (91.2) G2: 361 (90.3) Maternal infection in labor: NR	Maternal outcomes Cesarean birth (for NRFS), n (%): G1: 54 (13.5) G2: 65 (16.3) Vaginal, assisted (for NRFS), n (%): G1: 80 (20.1) G2: 83 (20.8) Operative delivery, total, n (%): G1: 216 (54.1) G2: 221 (55.3) G1/G2: RR = 0.98 (95%CI: 0.86-1.11) Vaginal, spontaneous, n (%): G1: 183 (45.9) G2: 179 (44.7) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n: G1: 0 G2: 1 Apgar score < 7, 5 minutes, n: G1: 6 G2: 6 NICU admission, n: G1: 5 G2: 6

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Waldenstrom et al., 2001 Country: Australia and Sweden Participant source: Academic single site Intervention setting: Clinic Labor and delivery suite Enrollment period: 02/1996 to 11/1997 Funding: NR Author industry relationship disclosure: NR Design: RCT	Intervention: Team midwife care (8 midwives providing antenatal and intrapartum care) vs. usual care by patient preference (care mostly doctors; mostly by midwives in collaboration with medical staff; birth center care; shared care between local GP and hospital doctors) Groups: G1: Team midwife care G2: Standard care N at enrollment: G1: 495 G2: 505 N at birth: G1: 464 G2: 471 N at follow-up: (2 months) G1: 361 G2: 323 Age, mean yrs \pm SD: G1: 27.9 \pm 5.2 G2: 27.9 \pm 5.2 Race/ethnicity: NR Parous, n (%)¹: G1: 202/494 (40.9) G2: 198/504 (39.3) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> Medical low-risk Exclusion criteria: <ul style="list-style-type: none"> Non-English speaking Gestation > 25 weeks Previous obstetric complications, including: cesarean, difficult forceps delivery, shoulder dystocia, anal sphincter tear, severe postpartum hemorrhage (> 100 ml), preterm delivery (< 34 weeks), intrauterine growth retardation, severe preeclampsia/eclampsia, perinatal loss (habitual abortion \geq 3 consecutively) Significant medical disorder (e.g., cardiovascular disease, diabetes mellitus, chronic renal disease, autoimmune disease) Drug addition Abuse of alcohol Long standing infertility (> 5 years) 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, duration: 1 st stage, mean hours \pm SD: G1: 5.8 \pm 4.4 G2: 6.2 \pm 4.8 G1/G2: $P = 0.17$ 2 nd stage, mean minutes \pm SD: G1: 49.5 \pm 51.8 G2: 53.9 \pm 57.6 G1/G2: $P = 0.21$ 3 rd stage, mean minutes \pm SD: G1: 8.1 \pm 15.2 G2: 9.4 \pm 21.2 G1/G2: $P = 0.90$ Labor augmented, n (%): G1: 122 (26.3) G2: 130 (27.6) G1/G2: OR = 0.94 (95% CI: 0.69-1.26) AROM: NR Internal monitoring, n (%): Fetal monitoring, scalp pH: G1: 14 (3.0) G2: 18 (3.8) G1/G2: OR = 0.78 (95% CI: 0.36-1.68) Amnioinfusion: NR Epidural, n (%): G1: 141 (30.4) G2: 150 (31.8) G1/G2: OR = 0.93 (95% CI: 0.7-1.24) Maternal infection in labor: NR	Maternal outcomes Cesarean birth, n (%): G1: 55 (11.9) G2: 56 (11.9) G1/G2: OR = 1.0 (95% CI: 0.66-1.51) Vaginal, assisted, n (%): Forceps: G1: 66 (14.2) G2: 73 (15.5) G1/G2: OR = 0.9 (95% CI: 0.62-1.32) Vacuum: G1: 12 (2.6) G2: 16 (3.4) G1/G2: OR = 0.75 (95% CI: 0.33-1.71) Vaginal, spontaneous, n (%):¹ G1: 331 (71.3) G2: 326 (69.2.1) Maternal harms: NR Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): G1: 5/466 (1.1) G2: 7/475 (1.5) Apgar score < 7, 5 minutes, n (%): G1: 9/461 (1.9) G2: 7/470 (1.5) G1/G2: OR = 1.32 (95% CI: 0.45-3.95) NICU admission, n (%): G1: 48/461 (10.4)

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Waldenstrom et al., 2001 (continued)					G2: 36/470 (7.7) G1/G2: OR = 1.4 (95% CI: 0.87-2.26)

¹ The proportion of spontaneous vaginal delivery was calculated by the reviewer, subtracting operative deliveries from N at birth.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Waldenstrom et al., 1997 Country: Sweden Participant source: Non-academic single site Intervention setting: Birthing center for study group and community hospitals for control group Enrollment period: 10/1989 to 06/1993 Funding: Swedish National Delegation for Social Research; Swedish Medical Research Council; Karolinska Institute; Sodersjukhuset, Stockholm Author industry relationship disclosure: NR Design: RCT	Intervention: Birth center: comprehensive and integrated antenatal, intrapartum and postpartum care with the same team of midwives, restricted use of medical technology and 24 hours postpartum discharge. Groups: G1: Birth center care G2: Standard maternity care N at enrollment: G1: 928 G2: 932 N at birth: ¹ G1: 912 G2: 916 Age, mean yrs ± SD: G1: 29.9 ± 4.5 G2: 29.9 ± 4.3 Race/ethnicity, n (%): Native Swedes: G1: 785 (86.9) G2: 767 (87.4) Primiparous, n (%): G1: 544 (58.6) G2: 522 (56.0) Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> Residents of Greater Stockholm One partner in couple had to be Swedish-speaking If previous cesarean, last delivery was vaginal Low risk Willingness to participate At least one antenatal visit Exclusion criteria: <ul style="list-style-type: none"> Diabetes Hypertension Drug abusers Current smoker Previous cesarean unless last delivery was vaginal 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, (contractions to birth), mean hours (median): G1: 15.0 (12.1) G2: 14.0 (11.7) G1/G2: $P = 0.05$ Labor augmented, n (%): Amniotomy: G1: 209 (23.3) G2: 351 (39.9) G1/G2: $P < 0.001$ Oxytocin 1 st stage: G1: 140 (15.6) G2: 223 (24.9) G1/G2: $P < 0.001$ Oxytocin 2 nd stage: G1: 160 (17.9) G2: 264 (29.5) G1/G2: $P < 0.001$ AROM, n (%): G1: 209 (23.3) G2: 351 (39.3) G1/G2: $P < 0.001$ Internal monitoring, n (%): Internal monitoring: G1: 165 (18.4) G2: 283 (31.7) G1/G2: $P < 0.001$ Fetal scalp blood sampling: G1: 20 (2.2) G2: 37 (4.1) G1/G2: $P = 0.03$ Intrauterine pressure catheter: G1: 55 (6.1) G2: 51 (5.7) G1/G2: $P = 0.77$ Amnioinfusion: NR Epidural, n (%): G1: 108 (12.1) G2: 135 (15.1)	Maternal outcomes Cesarean birth, n (%): G1: 65 (7.1) G2: 82 (8.9) G1/G2: $P = 0.18$ Vaginal, assisted, n (%): G1: 36 (3.9) G2: 41 (4.5) G1/G2: $P = 0.74$ Vaginal, spontaneous, n (%): G1: 811 (88) G2: 793 (86) Maternal harms: NR Maternal mortality, n: G1: 0 G2: 0 Neonatal outcomes Neonatal mortality, n (%): G1: 8 (0.9) G2: 2 (0.2) G1/G2: OR = 4.04 (95% CI: 0.80-39.17), $P = 0.11$ Apgar score < 7, 5 minutes, n (%): G1: 11 (1.29) G2: 10 (1.1) G1/G2: $P = 0.99$ NICU admission (within first week after birth), n (%): G1: 102 (11.1) G2: 83 (9.0) G1/G2: $P = 0.13$ NICU length of stay, mean days: G1: 9.6 G2: 10.2 G1/G2: $P = 0.78$ Serious neonatal morbidity not

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Waldenstrom et al., 1997 (continued)				G1/G2: $P = 0.07$ Maternal infection in labor: NR	caused by malformations or preterm birth, n: G1: 6 ² G2: 2

¹ Excluding miscarriages and two women lost to follow up.

² Three cases in G1 identified as possibly avoidable and related to the care at the birth center.

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Author: Windrim et al., 2007 Country: Canada Participant source: Academic multi site Intervention setting: Labor and delivery suite Enrollment period: 07/1997 to 12/1999 Funding: Physicians' Services Incorporated Foundation, Canada Author industry relationship disclosure: NR Design: RCT	Intervention: Labor progress recorded using a bedside graphical partogram with a 2-hour alert line and no action line. Groups: G1: Partogram and written notes G2: Written notes only N at enrollment: G1: 970 G2: 962 N at birth: G1: 970 G2: 962 Age, mean yrs \pm SD: G1: 30.1 \pm 5 G2: 30.0 \pm 5 Race/ethnicity: NR Parous: NR Medicaid: Not applicable	Inclusion criteria: <ul style="list-style-type: none"> Nulliparous 36 to 42 weeks gestation Singleton pregnancy with a cephalic presentation Exclusion criteria: <ul style="list-style-type: none"> Known major fetal structural anomaly Non-cephalic presentation Previous uterine surgery Acute obstetric complication, such as antepartum hemorrhage or severe hypertension 	Cervical dilation at admission: NR Cervical effacement at admission: NR	Labor progression, mean hours \pm SD: 1 st stage spontaneous: G1: 16.8 \pm 7.3 G2: 16.0 \pm 7.6 1 st stage induced: G1: 14.0 \pm 6.8 G2: 13.9 \pm 7.0 2 nd stage spontaneous: G1: 2.4 \pm 1.8 G2: 2.4 \pm 1.9 2 nd stage induced: G1: 2.7 \pm 1.9 G2: 2.5 \pm 1.9 Labor augmented, n (%): Oxytocin augmentation: G1: 757 (78) G2: 755 (78) AROM, n (%): G1: 521 (53.7) G2: 520 (54.1) Internal monitoring, non reassuring fetal heart tracing, n (%): G1: 399 (41) G2: 391 (41) Amnioinfusion: NR Epidural, n (%): G1: 902 (93) G2: 879 (91) Maternal infection in labor, n (%): Intrapartum temperature > 38°C: G1: 114 (12) G2: 78 (8) G1/G2: <i>P</i> = NS	Maternal outcomes Cesarean birth, n (%): G1: 240 (24) G2: 244 (25) G1/G2: <i>P</i> = NS Vaginal, assisted, n (%): Spontaneous labor: G1: 173 (30) G2: 178 (31) G1/G2: <i>P</i> = NS Induced labor: G1: 121 (31) G2: 89 (23) G1/G2: <i>P</i> = NS Vaginal, spontaneous, n (%): Spontaneous labor: G1: 282 (49) G2: 277 (48) G1/G2: <i>P</i> = NS Induced labor: G1: 154 (40) G2: 174 (45) G1/G2: <i>P</i> = NS Maternal harms, n (%): Postpartum temperature > 38°C: G1: 32 (3) G2: 24 (2) G1/G2: <i>P</i> = NS Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score < 7, n (%): 1 minute: G1: 113 (11.6) G2: 99 (10.2) G1/G2: <i>P</i> = NS

Evidence Table C1: Strategies to reduce cesarean birth (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Factors	Clinical Events	Outcomes
Windrim et al., 2007 (continued)					5 minutes: G1: 12 (1.2) G2: 10 (1.0) G1/G2: <i>P</i> = NS NICU admission, n (%): G1: 33 (3.4) G2: 37 (3.9) G1/G2: <i>P</i> = NS

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: World Health Organization, 1994</p> <p>Country: Indonesia, Thailand, and Malaysia</p> <p>System: Eight maternity hospitals</p> <p>Baseline period: 01/1990 to 06/1990</p> <p>Evaluation period: 06/1990 to 04/1991</p> <p>Routine use period: 04/1991 to 09/1991</p> <p>Funding: World Health Organization (WHO) and ministries of health of Indonesia, Thailand, and Malaysia</p> <p>Author industry relationship disclosure: NR</p> <p>Design: Cluster randomized trial (4 matched pairs of hospitals selected; one of each randomly selected to implement use of partogram)</p>	<p>Cesarean reduction intervention: Use of the WHO partogram to inform active management of labor and decisions about need for cesarean</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> District general hospitals in urban settings Current use of active management of labor <p>Exclusion criteria:</p> <ul style="list-style-type: none"> See inclusion criteria 	<p>Births, n: Baseline period: 18,254 Evaluation period: 17,230</p> <p>Births to normal¹ women, n: Baseline period: 10,049 Evaluation period: 9,130</p> <p>Births to normal¹ nulliparous women: Baseline period: 4,212 Evaluation period: 3,924</p> <p>Age, mean yrs ± SD: Baseline period: 27.23 ± 5.72 Evaluation period: 27.17 ± 5.75 EP/BL: <i>P</i> = 0.55</p> <p>Parous, %: Baseline period: 61.0 Evaluation period: 60.8 EP/BL: <i>P</i> = 0.87</p> <p>Medicaid: Not applicable</p> <p>Private insurance coverage: Not applicable</p> <p>Multiple gestations, n (%): Baseline period: 239 (1.3) Evaluation period: 247 (1.4)</p>	<p>Total providers/staff: NR</p> <p>Total providers/staff formally trained: NR</p> <p>Specialty: NR</p>	<p>Mode of birth</p> <p>Vaginal, spontaneous, n (%): Total singleton births: Baseline period: 13,186 (72.4) Evaluation period: 12,704 (73.9) EP/BL: <i>P</i> = 0.201</p> <p>Normal¹ women: Baseline period: 8,428 (83.9) Evaluation period: 7,869 (86.3) EP/BL: <i>P</i> < 0.001</p> <p>Normal¹ nulliparous women: Baseline period: 3,129 (74.3) Evaluation period: 3,069 (78.3) EP/BL: <i>P</i> < 0.001</p> <p>Vaginal, assisted, n (%): Total singleton births: Baseline period: 1,793 (9.8) Evaluation period: 1,649 (9.6) EP/BL: <i>P</i> = 0.110</p> <p>Normal¹ women: Baseline period: 995 (9.9) Evaluation period: 841 (9.2) EP/BL: <i>P</i> = NR</p> <p>Normal¹ nulliparous women: Baseline period: 668 (15.9) Evaluation period: 578 (14.7) EP/BL: <i>P</i> = NR</p> <p>Cesarean birth, n (%): Total singleton births: Baseline period: 2,278 (12.5) Evaluation period:</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
World Health Organization, 1994 (continued)					<p>1,926 (11.2) EP/BL: $P = 0.841$</p> <p>Normal¹ women: Baseline period: 621 (6.2) Evaluation period: 409 (4.5) EP/BL: $P = 0.056$</p> <p>Normal¹ nulliparous women: Baseline period: 414 (9.8) Evaluation period: 271 (6.9) EP/BL: $P = 0.060$</p> <p><u>Maternal outcomes</u> Maternal mortality, n: Baseline period: 23 Evaluation period: 24</p> <p><u>Neonatal outcomes</u> Neonatal mortality: NR</p> <p>Apgar score: NR</p> <p>NICU admission, %: Baseline period: 6.3 Evaluation period: 5.0 EP/BL: $P = 0.49$</p> <p>Stillbirths, n (%): Baseline period: 516 (2.8) Evaluation period: 43 (2.4)</p>

¹ A normal woman is a woman who is less likely to require intervention.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: Althabe et al., 2004</p> <p>Country: Argentina, Brazil, Cuba, Guatemala, and Mexico</p> <p>System: 36 hospitals Argentina (18) Brazil (8) Cuba (4) Mexico (4) Guatemala (2)</p> <p>Baseline period: 6 months baseline data; followed by 1 month staff training and implementation practice in intervention sites</p> <p>Evaluation period: 6 months use of the intervention in intervention sites</p> <p>Funding: European Union, Pan American Health Organization, WHO and World Bank Special Programme of Research, multiple national contributions.</p> <p>Author industry relationship disclosure: None</p> <p>Design: Cluster randomized trial (hospitals matched by country, type of hospital, and baseline rates)</p>	<p>Cesarean reduction intervention: Implementation of policy of mandatory second opinion from person of equal or higher clinical qualifications to the attending physician. Consultations informed by use of evidence-based guidelines for reviewing cesarean birth indications.</p> <p>Groups: G1: Intervention G2: Control</p> <p>N (hospitals) at randomization: G1: 18 G2: 18</p> <p>N at baseline: G1: 17 G2: 17</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> Hospital baseline cesarean rate $\geq 15\%$ Hospitals with $> 1,000$ births per year Able to implement protocol Successful completion of run-in period <p>Exclusion criteria:</p> <ul style="list-style-type: none"> See inclusion criteria 	<p>Births per year, n:</p> <p>Baseline: G1: 34,735 G2: 39,175</p> <p>Evaluation: G1: 35,675 G2: 39,638</p> <p>Parous, %: Baseline: G1: 62.2 G2: 66.5</p> <p>Medicaid: Not applicable</p> <p>Private insurance coverage: Not applicable</p> <p>Prior cesarean, %: Baseline period: G1: 13.5 G2: 13.8</p>	<p>Total providers/staff: NR</p> <p>Total providers/staff formally trained: Not applicable</p> <p>Specialty: NR</p> <p>Compliance with second opinion, non-emergent cesarean, %: 88</p>	<p>Mode of birth Vaginal, spontaneous: NR</p> <p>Vaginal, assisted, %: Baseline period: G1: 4.4 G2: 2.8</p> <p>Evaluation period: G1: 4.9 G2: 3.4 G1/G2: $P = 0.85$</p> <p>Total cesarean births, %: Baseline period: G1: 26.3 G2: 24.6</p> <p>Evaluation period: G1: 24.7 G2: 24.9 G1/G2: $P = 0.044$</p> <p>Maternal outcomes Maternal mortality, rate per 10,000 live births: Baseline period: G1: 3.2 G2: 5.9</p> <p>Evaluation period: G1: 4.3 G2: 7.5</p> <p>Neonatal outcomes Neonatal mortality, mean rate: Baseline period: G1: 1.1 G2: 1.1</p> <p>Evaluation period: G1: 0.9 G2: 1.0 G1/G2: $P = 0.756$</p> <p>Perinatal mortality, mean rate: Baseline period: G1: 2.6 G2: 2.8</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Althabe et al., 2004 (continued)					<p>Evaluation period: G1: 2.4 G2: 2.9 G1/G2: $P = 0.273$</p> <p>Apgar score: NR</p> <p>NICU admission, mean rate: Baseline period: G1: 8.4 G2: 8.1</p> <p>Evaluation period: G1: 8.0 G2: 8.3 G1/G2: $P = 0.340$</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Berglund et al., 2010 Country: Ukraine System: Three maternity units. ¹ S1: Donetsk S2: Lutsk S3: Lviv Baseline period: S1: 4 months prior to training S2: 4 months prior S3: 2 months prior Evaluation period: S1: 05/2004 to 12/2006 S2: 05/2004 to 12/2006 S3: 05/2004 to 11/2006 Funding: WHO, national and university Author industry relationship disclosure: None Design: Pre-post assessment	Cesarean reduction intervention: National Mothers and Infant Health Project to train maternity staff and providers implemented in nine provinces. Detailed data collected at selected maternity sites. Training provided by a non-governmental organization (NGO) based on the WHO Making Pregnancy Safer tools and framework focused on implementation of evidence-based routines as standard care. Topics included: <ul style="list-style-type: none"> • Avoiding Induction • Use of partograms • Augmentation • AROM • Labor pain management • Labor support 	Inclusion criteria: NR Exclusion criteria: NR	Births per year, n: Baseline period: S1: 652 S2: 742 S3: 302 2004: S1: 1,021 S2: 2,283 S3: 1,756 2005: S1: 1,720 S2: 3,578 S3: 2,881 2006: S1: 1,820 S2: 4,004 S3: 2,590 Last three month period: S1: 425 S2: 998 S3: 1,016 Age, median yrs (range): Baseline period: S1: 24 (16-42) S2: 25 (14-44) S3: 22 (14-46) Evaluation period: S1: 25 (15-45) S2: 25 (15-48) S3: 23 (16-40) Parous, %: Primiparae: Baseline period: S1: 52.0 S2: 47.4 S3: 49.7 Evaluation period: S1: 65.0 S2: 51.8 S3: 58.6 Medicaid: Not applicable Private insurance coverage: Not applicable	Total providers/staff, n: S1: 108 S2: 171 S3: 90 Total providers/staff formally trained, n (%): S1: 108 (100) S2: NR (36) S3: NR (49) Specialty: NR ²	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted, %: Baseline period: S1: 3.7 S2: 2.0 S3: 0.0 Evaluation period: S1: 0.0 S2: 2.0 S3: 0.0 Cesarean birth, %: Baseline: S1: 30.0 S2: 33.0 S3: 22.0 Total: 29.9* Evaluation period: S1: 17.0 S2: 12.3 S3: 19.6 Last three month period: S1: 18.4 S2: 12.7 S3: 16.9 Total: 15.4* S1/BL: $P < 0.0001$ S2/BL: $P < 0.0001$ S3/BL: $P < 0.0606$ <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Early neonatal death, %: Baseline period: S1: 13.6 S2: 4.6 S3: 6.4 Evaluation period: S1: 10.9 S2: 2.4 S3: 1

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Berglund et al., 2010 (continued)					Apgar score: NR NICU admission, %: Baseline period: S1: 11.2 S2: 7.3 S3: 6.4 Evaluation period: S1: 10.7 S2: 4.3 S3: 3.3 S1/BL: $P = 0.4153$ S2/BL: $P = 0.0015$ S3/BL: $P = 0.0015$

* Calculated by reviewer.

¹ Three sites selected from among 20, method not reported.

² Those trained included obstetricians, neonatologists, midwives, pediatricians, pediatric nurses, and anesthesiologists.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: Bickell et al., 1996 Dillon et al., 1992†</p> <p>Country: US</p> <p>System: New York State hospitals</p> <p>S1: 45 reviewed hospitals S2: 120 non-reviewed hospitals</p> <p>Baseline period: 1988</p> <p>Evaluation period: 1989 to 1990† 1989 to 1993</p> <p>Funding: NR</p> <p>Author industry relationship disclosure: NR</p> <p>Design: Pre-post assessment</p>	<p>Cesarean reduction intervention:</p> <p>Task force developed guidelines for in-house peer review of obstetric care. Presented educational programs across the state to assist hospitals in implementation. Included a Dictionary of Terms to standardize terminology.</p> <p>External peer reviews by ACOG trained teams of 3-4 physicians and nurse. Reviewed 100 labor and delivery records to assess quality of care.</p> <p>Teams provided summary report to hospital for distribution to staff. Reviewed hospital was requested to provide implementation changes to Task Force 6-12 months later.</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Participation was voluntary • First 24 hospitals selected for geographic diversity by strata of cesarean section rates† • Second set of hospitals randomly selected from those with high cesarean rates <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • See inclusion criteria 	<p>Births per year, mean (SE):</p> <p>Baseline period: S1: 1,430 (141.4) S2: 1,720 (125.9)</p> <p>Evaluation period: S1: 1,503 (152.8) S2: 1,720 (119.2)</p> <p>Hospitals by 1988 cesarean rate, n:</p> <p>< 20: S1: 8 S2: 25</p> <p>20-24: S1: 3 S2: 30</p> <p>25-29: S1: 11 S2: 43</p> <p>≥ 30: S1: 23 S2: 22</p> <p>Medicaid: NR</p> <p>Private insurance coverage: NR</p>	<p>Total providers/staff: NR</p> <p>Total providers/staff formally trained: NR</p> <p>Specialty: NR</p>	<p>Mode of birth</p> <p>Vaginal, spontaneous: NR</p> <p>Vaginal, assisted: NR</p> <p>Cesarean birth, mean rate (SE):</p> <p>Total: 1988: S1: 29.1 (1.2) S2: 25.1 (0.5) S1/S2: $P < 0.01$</p> <p>1993: S1: 25.8 (0.9) S2: 24.0 (0.4) S1/S2: $P = \text{NS}^1$</p> <p>Change in total cesarean rate, by 1988 cesarean rate:</p> <p>< 20: S1: 2.5 (1.0) S2: 2.3 (0.7)</p> <p>20-24: S1: -1.0 (2.5) S2: 0.0 (0.6)</p> <p>25-29: S1: -2.4 (1.6) S2: -2.5 (0.6)</p> <p>≥ 30: S1: -6.2 (0.9) S2: -3.8 (0.9)</p> <p>Repeat cesarean:</p> <p>1988: S1: 10.9 (0.5) S2: 9.8 (0.3) S1/S2: $P = \text{NS}$</p> <p>1993: S1: 24.8 (2.0) S2: 24.8 (1.1) S1/S2: $P = \text{NS}$</p> <p>Maternal outcomes</p> <p>Maternal mortality: NR</p> <p>Neonatal outcomes</p> <p>Neonatal mortality: NR</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Bickell et al., 1996 Dillon et al., 1992† (continued)					Apgar score: NR NICU admission: NR

¹ Although there was a significant crude difference in overall cesarean rate ($P < 0.01$), when 1988 cesarean rates were controlled for, there was no statistically significant impact of the intervention.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: Boylan et al., 1991</p> <p>Country: US</p> <p>System: Hermann Hospital in Houston, TX (affiliated with the University of Texas)</p> <p>Baseline period: 07/1/1984 to 06/30/1985</p> <p>Evaluation period: 07/1/1985 to 06/30/1986</p> <p>Funding: NR</p> <p>Author industry relationship disclosure: NR</p> <p>Design: Pre-post assessment</p>	<p>Cesarean reduction intervention: Introduction of active management of labor (AML), including: AROM if laboring without SROM for more than two hours. IV oxytocin augmentation if dilation < 1 cm per hour.</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Nulliparous women • Singleton • Vertex pregnancy • Presenting in labor without fetal distress • Labor defined by painful contraction at least every ten minutes with 80% effacement and 1 cm dilation. <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • See inclusion criteria 	<p>Births, n: Baseline period: 1,843 Evaluation period: 2,057</p> <p>Age, mean yrs \pm SD: Baseline period: First six months: 23.9 \pm 5.1 Last six months: 24.3 \pm 5.1 Evaluation period: First six months: 24.1 \pm 5.3 Last six months: 23.6 \pm 5.4</p> <p>Race/ethnicity, %: Baseline period: First six months: White: 44.8 Black: 36.6 Hispanic: 13.1 Other: 5.5 Second six months: White: 47.8 Black: 34.7 Hispanic: 12.9 Other: 4.5 Evaluation period: First six months: White: 42.7 Black: 39.7 Hispanic: 14.1 Other: 3.5 Second six months: White: 39.3 Black: 42.1 Hispanic: 14.0 Other: 4.6</p> <p>Parous, n: Total: 0</p> <p>Medicaid: NR</p>	<p>Total providers/staff: 10 obstetricians 11 University of Texas faculty members 5 autonomous private practitioners 6 residents per year supervised by faculty</p> <p>Total providers/staff formally trained: NR</p> <p>Specialty: NR (those trained included obstetricians, neonatologists, midwives, pediatricians, pediatric nurses, and anesthesiologists)</p>	<p>Mode of birth Vaginal, spontaneous, n (%): Baseline period: 735 (39.9) Evaluation period: 1,049 (51.0)</p> <p>Vaginal, assisted, n (%): Baseline period: 660 (35.8) Evaluation period: 621 (30.2)</p> <p>Cesarean birth, n (%): Baseline period: 448 (24.3) Evaluation period: 387 (18.8) EP/BL: Δ = 5.5 (95% CI: 2.9-8.1), P < 0.05</p> <p>Maternal outcomes Maternal mortality: NR</p> <p>Neonatal outcomes Neonatal mortality, n (%): Asphyxia: Baseline period: 1 (1.1) Evaluation period: 0</p> <p>Apgar score: NR</p> <p>NICU admissions, for asphyxia, n: Baseline period: 36 Evaluation period: 37</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Boylan et al., 1991 (continued)			Private insurance coverage: NR Prior cesarean, n: Total: 0		

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Calvo et al., 2009 Country: Spain System: Two public maternity hospitals: S1: Son Llàtzer S2: Menorca Baseline period: 01/2006 to 06/2006 Evaluation period: 11/2006 to 04/2007 Funding: NR Author industry relationship disclosure: None Design: Pre-post assessment	Cesarean reduction intervention: Using a consensus policy for cesarean indications in a multifaceted feedback program. Program included: weekly “debate” of cesareans performed in clinical meetings; appropriateness review of all cesareans every two months; dissemination of results, and introduction of methods for improvement by the units.	Inclusion criteria: NR ¹ Exclusion criteria: NR	Births: NR Medicaid: All public patients Private insurance coverage: Not applicable	Total providers/staff: NR Total provider/staff formally trained: NR Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean birth, %: Baseline period: S1: 17.5 S2: 29.0 Evaluation period: S1: 15.8 S2: 22.0 S1/BL: <i>P</i> = NS S2/BL: <i>P</i> = NS Appropriate by study criteria, %: Baseline period: S1: 68.3 S2: 80.0 Evaluation period: S1: 84.3 S2: 92.0 S1/BL: <i>P</i> < 0.05 S2/BL: <i>P</i> < 0.05 <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar score: NR NICU admission: NR

¹ Voluntary participation based on positive results at similar regional hospitals.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: Elferink-Stinkens et al., 2004</p> <p>Country: Netherlands</p> <p>System: 85 of 116 Dutch obstetric departments participating in national database</p> <p>Baseline period: 1994</p> <p>Evaluation period: 04/1995 to 09/1998</p> <p>Funding: Praeventiefonds Nederland</p> <p>Author industry relationship disclosure: NR</p> <p>Design: RCT with hospitals stratified by size of department, academic vs. non-academic status, and initial cesarean rates</p>	<p>Cesarean reduction intervention: Report contextualizing departmental data in tabular and graphic form including:</p> <ul style="list-style-type: none"> No spontaneous onset (induction or planned cesarean) Planned cesarean No spontaneous birth (vacuum, forceps, or cesarean) Cesarean <p>Data also subdivided by very preterm, preterm, term, and postterm.</p> <p>1995 sent to department contacts for distribution; 1996 through 1998 sent to individual obstetricians within the intervention departments.</p> <p>Mailing followed up with repeat report and brief questionnaire shortly after first mailing.</p> <p>Groups: G1: Intervention G2: Control</p>	<p>Hospitals Inclusion criteria:</p> <ul style="list-style-type: none"> Participation in national perinatal database Medical ethics committee approval for newborn follow-up exams <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Data excluded in a case of merger of intervention and control departments <p>Infants 1% random sample of births obtained by contacting four randomly selected hospitals per day and sampling as below for newborn neurological exam</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> All 32 - < 37 week births 50% of term births All ≥ 42 weeks Maternal consent <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Less than 32 weeks at birth 	<p>Births: NR</p> <p>Neonatal examinations, n: Baseline period: 32 - < 37 weeks: G1: 78 G2: 116 37 - < 42 weeks: G1: 406 G2: 425 ≥ 42 weeks: G1: 59 G2: 47</p> <p>Evaluation period: 32 - < 37 weeks: G1: 130 G2: 130 37 - < 42 weeks: G1: 575 G2: 554 ≥ 42 weeks: G1: 85 G2: 88</p> <p>Medicaid: Not applicable</p> <p>Private insurance coverage: Not applicable</p>	<p>Total providers/staff: NR</p> <p>Total providers/staff formally trained: NR</p> <p>Specialty: NR</p>	<p>Mode of birth Vaginal, spontaneous: NR</p> <p>Vaginal, assisted: NR</p> <p>Total cesarean births, % range: Total: 10 to 31 G1/G2: $P = NS$</p> <p>Maternal outcomes Maternal mortality: NR</p> <p>Neonatal outcomes Neonatal mortality: NR</p> <p>Apgar score: NR</p> <p>NICU admission: NR</p> <p>Abnormal neurological exam, %: Baseline period: 32 - < 37 weeks: G1: 17.9 G2: 23.3 37 - < 42 weeks: G1: 13.1 G2: 19.8 ≥ 42 weeks: G1: 22.0 G2: 6.4</p> <p>Evaluation period: 32 - < 37 weeks: G1: 26.9 G2: 24.6 37 - < 42 weeks: G1: 13.2 G2: 10.3 ≥ 42 weeks: G1: 5.9 G2: 19.3</p> <p>G1/G2: OR = 1.3 (95% CI: 0.89-2.00)</p>

The spread of the cesarean rates between hospitals (as measured by the mean distance of the percentiles to the median) was significantly (7%) lower in the intervention group for term births (37 to 42 weeks). The difference in the spread was not significant for other gestational ages.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Gilstrap et al., 1984 Country: US System: Wilford Hall Medical Center Baseline period: 1974 to 1977 Evaluation period: 1978 to 1981 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Preliminary review of cesarean section policy in 1976, with special regard to the most common indications. Informal criteria and policies were established and directed toward assuring an adequate trial of labor, or ensuring fetal distress was persistent and ominous, and toward using established criteria to allow selected term frank breech presentations a trial at vaginal delivery. Assessment included mandatory intrauterine pressure monitoring with oxytocin usage and selected usage of scalp pH determinations.	Inclusion criteria: NR Exclusion criteria: NR	Total births, n: Baseline period: 6,693 Evaluation period: 6,162 Parity, women delivered by cesarean section, n (%): Primigravidas: Baseline period: 633/1,125 (56) Evaluation period: 469/940 (50) Medicaid: NR Private insurance coverage: NR	Total providers/staff: NR Total providers/staff formally trained: NR Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted, %: Baseline period: 6.7 Evaluation period: 6.1 Cesarean birth, n (%):* Total: Baseline period: 1,125 (16.8) Evaluation period: 940 (15.2) EP/BL: $P < 0.02$ Primary: Baseline period: 855** (12.8) Evaluation period: 592** (9.6) EP/BL: $P < 0.0001$ Repeat: Baseline period: 270 (4.0) Evaluation period: 348 (5.6) EP/BL: $P < 0.0001$ <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar score: NR NICU admissions: NR

* The total, primary, and repeat cesarean rates by year from 1970 to 1981 are only displayed graphically.

** Calculated by reviewer.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Gregory et al., 1999 Country: US System: Cedars Sinai Medical Center Baseline period: 04/1993 to 12/1993 Evaluation period: 1994 to 1998 Funding: NR Author industry relationship disclosure: NR Design: Prospective observational	Cesarean reduction intervention: 17 sequential interventions at the administrative, clinical education, and clinical protocol/guidelines levels	Inclusion criteria: NR Exclusion criteria: NR	Births per year, n: Baseline: 5,134 1994: 6,960 1995: 6,987 1996: 6,528 1997: 6,595 1998: 6,427 Age, mean yrs \pm SD: Baseline: 29.6 ¹ \pm 6.2 1994: 29.4 \pm 6.3 1995: 29.4 \pm 6.3 1996: 29.7 \pm 6.2 1997: 29.9 \pm 6.3 1998: 30.1 \pm 6.3 Race/ethnicity, %: Caucasian: Baseline: 47 1994: 45 1995: 43 1996: 45 1997: 46 1998: 46 Latina: Baseline: 19 1994: 19 1995: 19 1996: 20 1997: 20 1998: 21 African American: Baseline: 25 1994: 27 1995: 26 1996: 27 1997: 25 1998: 24 Other: Baseline: 9 1994: 8 1995: 12 1996: 9 1997: 9 1998: 9 Medicaid, %: Baseline: 15 1994: 17 1995: 18 1996: 17	Total providers/staff: 9 full-time faculty 100 private physicians with obstetrical privileges Total providers/staff formally trained: NR Specialty: NR	Mode of birth Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean birth, %: Baseline: 26.0 1994: NR 1995: NR 1996: NR 1997: 20.5 1998: NR Post evaluation: 23.5 Maternal outcomes Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score: NR NICU admission: NR

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Gregory et al., 1999 (continued)			1997: 16 1998: 16 Private insurance coverage: Baseline: 10 1994: 6 1995: 3 1996: 3 1997: 2 1998: 2		

¹ Mean age reported as 19.6 at baseline, apparently in error as the change in mean age was not mentioned among those that were statistically significant.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Hamilton et al., 2004 Country: US and Canada System: Seven university hospitals Baseline period: 12/1/1998 to 01/30/1999 Evaluation period: 02/1/1999 to 03/31/2001 Funding: NR Author industry relationship disclosure: NR Design: RCT and Pre-post assessment	Cesarean reduction intervention: Computer assistance in evaluation of labor progress. Output given to providers in the intervention group of the RCT displayed individual labor curve plotted with addition of reference ranges (95 th , 50 th , and 5 th percentile) that take into account contraction frequency, parity, and epidural use. Groups: G1: Intervention G2: Control N at randomization: G1: 2,478 G2: 2,515	Inclusion criteria: • Nulliparous Exclusion criteria: • See inclusion criteria	Births, n: Baseline period: Total: 5,753 Evaluation period: Total: 4,993 (RCT participants) Parous, %: Primiparous: Total: 100 Medicaid: NR Private insurance coverage: NR	Total providers/staff: NR Total providers/staff formally trained: NR Specialty: NR	Mode of birth Vaginal, n (%): Evaluation period: G1: 2,038 (82.3) G2: 2,089 (83.1) G1/G2: $P = 0.53$ Vaginal, assisted: NR Cesarean birth, n (%): Evaluation period: G1: 436 (17.6) G2: 425 (16.9) G1/G2: $P = 0.53$ Cesarean rates, eligible women at all hospitals, n (%): Baseline period: Total: 1,124/5,753 (19.5) Evaluation period, 6 th month: Total: 551/3,234 (17.0) EP/BL: $P = 0.004$ Evaluation period, 12 th month: Total: 923/5,554 (16.6) EP/BL: $P = 0.0006$ Maternal outcomes Maternal mortality: NR Neonatal outcomes Neonatal mortality: NR Apgar score, 5 minutes, n (%): Evaluation period: 0-2: G1: 7 (0.3) G2: 8 (0.3) 3-4: G1: 5 (0.2) G2: 4 (0.2) 5-6: G1: 37 (1.5)

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Hamilton et al., 2004 (continued)					G2: 35 (1.4) 7-8: G1: 186 (7.5) G2: 201 (8.0) 9-10: G1: 2,239 (90.5) G2: 2,261 (90.1) NICU admission: NR

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Iglesias et al., 1991 Country: Canada System: Hinton General Hospital, Alberta (44 bed community hospital) Baseline period: 01/1985 Evaluation period: 01/01/1985 to 12/31/1989 Funding: Hinton General Hospital, George Cedric Metcalf Charitable Foundation Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Guidelines from National Consensus Conference on Aspects of Cesarean Birth (NCCACB) for VBAC, management of breech presentation and diagnosis of dystocia requiring cesarean introduced at hospital in 1985. Cesarean section rate discussed annually at grand rounds. Consultation mandatory before primary cesarean section but not before a repeat section.	Inclusion criteria: <ul style="list-style-type: none"> All births at the hospital from 01/01/1985-12/31/1989 Exclusion criteria: <ul style="list-style-type: none"> See inclusion criteria 	Births, n: Nulliparous: 1985: 237 1986: 227 1987: 218 1988: 237 1989: 242 Parous, n (%): Nulliparous: 1985: 102 (43.0) 1986: 91 (40.1) 1987: 90 (41.3) 1988: 84 (35.4) 1989: 89 (36.8) Medicaid: Not applicable Private insurance coverage: NR Prior cesarean, n (%):¹ 1985: 27 (11.3) 1986: 28 (12.3) 1987: 24 (11.0) 1988: 25 (10.5) 1989: 33 (13.6)	Total providers/staff: ² Total: 12 (4 performed cesareans) Total providers/staff formally trained: NR Specialty: Family physicians that all practice obstetrics, and several that are trained in anesthesia and surgery	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean birth, n (%): Total: 1985: 55 (23) 1986: 43 (19) 1987: 38 (17) 1988: 37 (16) 1989: 31 (13) EP/BL: $P = 0.001$ Nulliparous: 1985: 23 (23) 1986: 19 (21) 1987: 21 (23) 1988: 14 (17) 1989: 11 (12) EP/BL: $P = 0.069^3$ <u>Maternal outcomes</u> Maternal mortality n: Total: 0 <u>Neonatal outcomes</u> Neonatal mortality, n (%): Total: 1 (0.09) Apgar score: NR Neonatal transfer, n: Total: 1985: 3 (1.3) 1986: 5 (2.2) 1987: 4 (1.8) 1988: 6 (2.5) 1989: 2 (0.8)

¹ Includes only the women who were eligible for VBAC.

² Medical staff started with nine physicians. During the study period two physicians left and three joined the staff.

³ The decreased cesarean rate for nulliparous women was due to a drop in the number that were dystocia-related.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: Kazandjian and Lied, 1998</p> <p>Country: US, Canada, UK, and Japan</p> <p>System: Maryland's Quality Indicator (QI) Project member hospitals</p> <p>S1: 110 hospitals (continuously reporting)</p> <p>S2: 957 hospitals (non-continuous reporting)</p> <p>Baseline period: 1991</p> <p>Evaluation period: 1992 to 1996</p> <p>Funding: NR</p> <p>Author industry relationship disclosure: NR</p> <p>Design: Pre-post assessment</p>	<p>Cesarean reduction intervention:</p> <p>QI Project: continuous reporting of total, primary, and repeat cesarean section rates.</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> Hospitals participating in the QI Project Continuous reporting of cesarean measures for 24 quarters of 6 years <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Joining QI Project late in the evaluation period Failure to report cesarean measures continuously 	<p>Births per year, most recent fiscal year, mean \pm SD:</p> <p>S1: 1,427 \pm 1,287</p> <p>S2: 1,238 \pm 1,311</p> <p>S1/S2: $P = 0.16$</p> <p>Medicaid: NR</p> <p>Private insurance coverage: NR</p>	<p>Total providers/staff: NR</p> <p>Total providers/staff formally trained: NR</p> <p>Specialty: NR</p>	<p>Mode of birth</p> <p>Vaginal, spontaneous: NR</p> <p>Vaginal, assisted: NR</p> <p>Cesarean birth, mean % \pm SD:</p> <p>Total:</p> <p>1991: S1: 22.5 \pm 7.1 S2: 21.2 \pm 7.8</p> <p>1992: S1: 21.7 \pm 6.0 S2: 21.2 \pm 7.4</p> <p>1993: S1: 20.9 \pm 6.0 S2: 21.3 \pm 7.4</p> <p>1994: S1: 20.0 \pm 5.5 S2: 21.2 \pm 6.7</p> <p>1995: S1: 19.3 \pm 5.4 S2: 21.0 \pm 6.9</p> <p>1996: S1: 19.4 \pm 5.2 S2: 20.7 \pm 6.6</p> <p>ANOVA: Year S1: $P < 0.001$ S2: $P = NS$</p> <p>Primary:</p> <p>1991: S1: 15.8 \pm 6.2 S2: 15 \pm 7.2</p> <p>1992: S1: 15.3 \pm 4.8 S2: 15.1 \pm 6.6</p> <p>1993: S1: 14.6 \pm 4.9 S2: 15.1 \pm 6.7</p> <p>1994: S1: 14.2 \pm 4.4 S2: 14.7 \pm 5.5</p> <p>1995: S1: 14.1 \pm 5.9 S2: 14.8 \pm 5.7</p> <p>1996: S1: 13.9 \pm 4.2 S2: 14.6 \pm 5.5</p> <p>ANOVA: Year S1: $P < 0.001$ S2: $P = NS$</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Kazandjian and Lied, 1998 (continued)					<p><u>Maternal outcomes</u> Maternal mortality: NR</p> <p><u>Neonatal outcomes</u> Neonatal mortality: NR</p> <p>Apgar score: NR</p> <p>NICU admission: NR</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: Kiwanuka and Moore, 1993</p> <p>Country: UK</p> <p>System: Central Manchester Health District</p> <p>S1: Saint Mary's Hospital</p> <p>S2: Other hospital in district or home confinement</p> <p>Baseline period: 1982</p> <p>Evaluation period: 1986</p> <p>Funding: NR</p> <p>Author industry relationship disclosure: NR</p> <p>Design: Pre-post assessment</p>	<p>Cesarean reduction intervention:</p> <p>Audit and feedback of specific information, imparted in a non-directive way to resident obstetricians at Saint Mary's Hospital responsible for performing cesarean sections.</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> Women resident in the Central Manchester Health District who delivered in 1986 <p>Exclusion criteria:</p> <ul style="list-style-type: none"> See inclusion criteria 	<p>Births per year, n:</p> <p>1982: Total: 1,895</p> <p>1986: S1: 1,881 S2: 327 Total: 2,216</p> <p>Parous, n: Primigravidas at term: 1986: S1: 703 S2: 219</p> <p>Medicaid: Not applicable</p> <p>Private insurance coverage: Not applicable</p> <p>Prior cesarean, n: 1986: 128</p>	<p>Total providers/staff: Resident obstetricians</p> <p>Total providers/staff formally trained: NR</p> <p>Specialty: NR</p>	<p><u>Mode of birth</u></p> <p>Vaginal, spontaneous: NR</p> <p>Vaginal, assisted: NR</p> <p>Cesarean birth, n (%): 1982: Total: 302 (15.9)</p> <p>1986: S1: 230 (12.2) S2: 51 (15.6) Total: 281 (12.7) EP/BL: $P < 0.005$</p> <p>Primigravidas at term: 1986: S1: 82 (11.7) S2: 19 (14.7)</p> <p><u>Maternal outcomes</u></p> <p>Maternal mortality: NR</p> <p><u>Neonatal outcomes</u></p> <p>Neonatal mortality: NR</p> <p>Apgar scores: NR</p> <p>NICU admissions: NR</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Lagrew and Morgan, 1996 Country: US System: Saddleback Memorial Medical Center Baseline period: Evaluation began in 1988 Evaluation period: 05/15/1988 to 06/30/1994 Funding: NR Author industry relationship disclosure: NR Design: Pre-post analysis	Cesarean reduction intervention: Clinic guideline changes including oxytocin administration for induction and augmentation of labor, cervical ripening protocols, education of nursing staff in active labor management and evaluation of fetal monitoring. Prenatal VBAC class.	Inclusion criteria: NR Exclusion criteria: NR	Births, n: 1988: 705 ¹ 1989: 1,600 1990: 2,254 1991: 2,273 1992: 2,248 1993: 1,934 1994: 1,005 ¹ Age, n (%): ≤ 19 years: 1988: 16 (2.3) 1989: 51 (3.2)* 1990: 83 (3.5)* 1991: 88 (3.9)* 1992: 67 (3.0)* 1993: 61 (3.1)* 1994: 50 (4.9) ≥ 35 years: 1988: 103 (14.6) 1989: 251 (15.7)* 1990: 346 (14.7)* 1991: 353 (15.5)* 1992: 367 (16.3)* 1993: 277 (14.3)* 1994: 162 (16.1) Nulliparous, n (%): 1988: 328 (46.6) 1989: 778 (48.6)* 1990: 1,186 (50)* 1991: 1,111 (48.9)** 1992: 1,048 (46.6)** 1993: 961 (49.7)* 1994: 485 (48.3) Medicaid: Low incidence of Medicaid deliveries Private insurance coverage: NR Multiple gestations, n (%): 1988: 11 (1.6) 1989: 26 (1.6)* 1990: 38 (1.6)* 1991: 39 (1.7)* 1992: 47 (2.1)*	Total providers/staff: NR Total providers/staff formally trained: Nurses Physicians Specialty: NR	Mode of birth Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean birth, %: Total: 1988: 31.1 1989-1993: NR** 1994: 15.4 EP/BL: $P < 0.000001$ Primary: 1988: 17.9 1989-1993: NR** 1994: 9.8 EP/BL: $P < 0.000001$ Repeat: 1988: 13.2 1989-1993: NR** 1994: 5.7 EP/BL: $P < 0.000001$ Nulliparous: 1988: 28.1 1989-1993: NR** 1994: 16.9 EP/BL: $P < 0.00001$ Maternal outcomes Maternal mortality: NR Neonatal outcomes Neonatal mortality, deaths per 1000 live births, n (%): 1988: 3 (4.26) 1989: 1 (0.63) 1990: 3 (1.34) 1991: 5 (2.20) 1992: 6 (2.67) 1993: 4 (2.07) 1994: 2 (2.0) Apgar score < 7, 5 minutes, n: 1988: 15 (2.1) 1989: 27 (1.7)*

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Lagrew and Morgan, 1996 (continued)			1993: 34 (2.3)* 1994: 15 (1.5)		1990: 53 (2.3)* 1991: 37 (1.6)* 1992: 46 (2.1)* 1993: 48 (2.5)* 1994: 21 (2.1) NICU admission: NR Stillbirths, n (%): (deaths per 1000 births) > 500 gm: 1988: 2 (1.42) 1989: 2 (1.25) 1990: 9 (3.11) 1991: 3 (1.32) 1992: 5 (1.78) 1993: 6 (2.07) 1994: 6 (2.99)

* Calculated by reviewer.

** Results only displayed graphically.

¹ The evaluation period included 7.5 months in 1988 and 6 months in 1994.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Liang et al, 2004 Country: Taiwan System: Taipei Veterans General Hospital ¹ Baseline period: 1993 to 1996 Evaluation period: 1997 to 2000 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Established a cesarean surveillance system, held weekly departmental cesarean indication conferences to review data for all cesarean sections. Required second opinion from consultant obstetrician for all cesarean sections. Physician's section rates presented at conference. Guidelines for dystocia, fetal distress and breech were unchanged from 1993-2000.	Inclusion criteria: <ul style="list-style-type: none"> • One low transverse uterine scar • Singleton pregnancy • Vertex presentation • No medical or surgical illness • Patient consent Exclusion criteria: <ul style="list-style-type: none"> • No food or drink was allowed until the baby was born 	Births, n: Baseline period: 9,864 Evaluation period: 7,937 1997: 2,082 1998: 1,776 1999: 1,928 2000: 2,151 Medicaid: NR Private insurance coverage: NR Prior cesarean, n: Evaluation period: 1,169 1997: 328 1998: 280 1999: 264 2000: 297	Total providers/ staff: NR Total providers/ staff formally trained: 2 board certified-obstetricians Specialty: Obstetrics Pediatricians	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean births, n (%): ² Total: Baseline period: 3,647 (37) Evaluation period: 2,436 (30.7) EP/BL: $P < 0.001$ Primary: Baseline period: 2,099 (21.3) Evaluation period: 1,412 (17.8) EP/BL: $P < 0.001$ Repeat: Baseline period: 1,548 (15.7) Evaluation period: 1,024 (12.9) EP/BL: $P < 0.001$ <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar scores: NR NICU admissions: NR

¹ Authors also present data for the entire country.

² Total, primary, and repeat cesarean rates are reported for each year from 1993 to 2000.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Maher et al., 1994 Country: Australia System: Toowoomba Base Hospital Baseline period: 1991 to 1992 Evaluation period: 1992 to 1993 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: In July 1992, active management of labor protocol and systematically incorporating VBAC into the management of previous-cesarean patients in the resident service. Rigorous peer review.	Inclusion criteria: NR Exclusion criteria: NR	Births, n: Baseline period: 1,112 Evaluation period: 1,167 Medicaid: NR Private insurance coverage: NR	Total providers/staff: NR Total providers/staff formally trained: NR Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean birth, n (%): Total: Baseline period: 228 (20.6) Evaluation period: 129 (11.0) EP/BL: OR = 0.48 (95% CI: 0.37-0.59), $P < 0.0001$ Elective: Baseline period: 107 (9.6) Evaluation period: 59 (5.0) EP/BL: OR = 0.50 (95% CI: 0.34-0.66), $P < 0.0001$ Emergency: Baseline period: 121 (10.9) Evaluation period: 70 (6.0) EP/BL: OR = 0.52 (95% CI: 0.36-0.68), $P < 0.0001$ <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality, n (%): Baseline period: 5 (0.4) Evaluation period: 8 (0.7) Apgar score ≤ 7, 5 minutes, n: Baseline period: 93 Evaluation period: 61

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Maher et al., 1994 (continued)					NICU admissions: NR Stillbirths, n (%): Baseline period: 8 (0.7) Evaluation period: 8 (0.7)

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: Main, 1999</p> <p>Country: US</p> <p>System: S1: Children's Hospital of San Francisco (1980-1995) S2:¹ Pacific Presbyterian Medical Center; (control group from 1989-1992; intervention from 1992-1995)</p> <p>Baseline period: 1980 to 1988</p> <p>Evaluation period: 1989 to 1995</p> <p>Funding: NR</p> <p>Author industry relationship disclosure: NR</p> <p>Design: Pre-post assessment</p>	<p>Cesarean reduction intervention: Intensive outcomes feedback using a computerized information system. First 3 years: daily reports and coded group comparison statistics at department meetings. Those in worst quartile were bolded, and guidance provided on how to "be like" the best quartile.</p> <p>Starting in 1993, "open label" feedback: intra-departmental release of everyone's key statistics with names. Computer algorithm introduced to review the electronic portion of cesarean births records. Standardized nuliparous and multiparous cesarean birth rates reported to facilitate comparisons between individual providers.</p>	<p>Inclusion criteria: NR</p> <p>Exclusion criteria: NR</p>	<p>Births per year, 1980s, range: S1: 3,200 to 3,600 S2: NR</p> <p>Medicaid: NR</p> <p>Private insurance coverage: NR</p>	<p>Total providers/staff: NR</p> <p>Total providers/staff formally trained: NR</p> <p>Specialty: Obstetrics</p>	<p><u>Mode of birth</u> Vaginal, spontaneous: NR</p> <p>Vaginal, assisted: NR</p> <p>Cesarean birth, %: Baseline period: Total:[*] 23 to 25 1989: S1: NR[*] S2: NR[*] 1990: S1: NR[*] S2: NR[*] 1991: S1: 20.7 S2: 25.1 1992: S1: NR[*] S2: 24.6 1993: S1: NR[*] S2: 20.3 1994: Total: 18.3 1995: Total: 18.1</p> <p>Primary cesarean: Baseline period: S1: 15.6 to 16.9 S2: 15.2 to 17.8 Post evaluation: Total: 13.6</p> <p>Repeat cesarean: Baseline period: S1: 8.0 to 8.6 S2: 6.8 to 8.1 Post evaluation: Total: 4.4</p> <p><u>Maternal outcomes</u> Maternal mortality: NR</p> <p><u>Neonatal outcomes</u> Neonatal mortality: NR</p> <p>Apgar score: NR</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Main, 1999 (continued)					NICU admissions: NR

¹ In 1987, three groups of obstetricians left the Children's Hospital of San Francisco and opened a new obstetric service at Pacific Presbyterian Medical Center. In 1993, the two hospitals rejoined with a single obstetric unit.

* Data only presented graphically.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Myers and Gleicher, 1988 Myers and Gleicher, 1993† Country: US System: Mount Sinai Hospital Medical Center Baseline period: 1985 Evaluation period: 1986-1987 1987-1991† Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Stringent implementation of existing departmental guidelines and implementation of new ones, including (1) a second opinion, (2) philosophy that vaginal delivery was preferred for those who had prior cesarean, (3) diagnosis of dystocia required no progress of labor with contractions of appropriate strength by intrauterine pressure catheter, (4) fetal distress, based on monitoring of the fetal heart rate, had to be corroborated by sampling of blood from the fetal scalp when feasible, (5) vaginal birth recommended for most breech fetuses, (6) comprehensive peer review of adherence to guidelines. All attending physicians were informed of their personal cesarean rates at quarterly intervals, and were told whether they were within two SD of the departmental rate.	Inclusion criteria: NR Exclusion criteria: NR	Births per year, n: 1985: 1,697 1986: 2,101 1987: 2,301 1988: 2,340† 1989: 2,688† 1990: 2,817† 1991: 3,218† Parous, n (%): Primigravidae: 1985: 399 (22.9) 1986: 606 (28.8) 1987: 683 (29.7) 1988: 761 (31.3)† 1989: 806 (29.9)† 1990: 785 (27.8)† 1991: 941 (29.2)† Medicaid: NR Private insurance coverage: NR	Total providers/staff: Teaching service supervised by full-time faculty and private attending physicians Total providers/staff formally trained: NR Specialty: Obstetricians and perinatology staff	Mode of birth Vaginal, spontaneous, n (%): 1985: 1,223 (72.1) 1986: 1,685 (80.2) 1987: 1,937 (82.1) EP/BL: $P < 0.05$ 1988: 1,997 (82.1)† 1989: 2,262 (84.1)† 1990: 2,431 (84.8)† 1991: 2,756 (85.6)† Vaginal, assisted, n (%): 1985: 177 (10.4) 1986: 154 (7.3) 1987: 99 (4.3) EP/BL: $P < 0.05$ 1988: 78 (3.1)† 1989: 73 (2.6)† 1990: 79 (2.7)† 1991: 76 (2.4)† Cesarean birth, n (%): Total: 1985: 297 (17.5) 1986: 262 (12.5) 1987: 265 (11.5) EP/BL: $P < 0.05$ 1988: 298 (12.2)† 1989: 279 (10.3)† 1990: 293 (10.4)† 1991: 382 (11.9)† Primary: 1985: 204 (12) 1986: 175 (8.3) 1987: 156 (6.8) EP/BL: $P < 0.05$ Repeat: 1985: 93 (5.5) 1986: 87 (4.1) 1987: 109 (4.7) EP/BL: $P < 0.05$ Cesarean birth, teaching staff, %: 1985: 15.0 1986: 11.0 1987: 11.7 EP/BL: $P < 0.05$

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Meyers and Gleicher, 1988 Meyers and Gleicher, 1993 (continued)					<p>Cesarean birth, private staff, %:1985: 20.0 1986: 15.0 1987: 12.4 EP/BL: $P < 0.05$</p> <p><u>Maternal outcomes</u> Maternal mortality: A single maternal death occurred in 1986</p> <p><u>Neonatal outcomes</u> Neonatal mortality, n (%):² 1985: 22 (12.8) 1986: 23 (10.7) 1987: 26 (11.2) 1988: 18 (10.7)† 1989: 29 (14.5)† 1990: 46 (16.0)† 1991: 29 (9.0)†</p> <p>Apgar score, 5 minutes, n (%): < 7: 1985: 50 1986: 82 (3.8) 1987: 116 (4.9) 1988: 70 (2.8)† 1989: 54 (1.9)† 1990: 62 (2.1)† 1991: 57 (1.7)† < 3: 1985: NR 1986: 8 (0.5) 1987: 17 (0.7) 1988: 12 (0.4)† 1989: 10 (0.3)† 1990: 12 (0.4)† 1991: 13 (0.4)†</p> <p>NICU admission: NR</p>

¹ 1985 data based on total deliveries; 1986 and 1987 data based on mothers giving birth

² An analysis of birth weight specific neonatal mortality fails to demonstrate any statistical benefit from cesarean delivery.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Oleske et al., 1992 Country: US System: Illinois hospitals 1986 to 1987: 198 hospitals 1988: 187 hospitals Baseline period: 1985 Evaluation period: 1986 to 1988 Funding: Partial from Illinois Health Care Cost Containment Council Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Illinois Health Care Cost Containment Council (IHCCCC) distributed information to patients and providers on average hospital charge, average length of stay and cesarean birth rate in each hospital. Over 50,000 informational brochures distributed annually. Also annual press releases to media on state-wide cesarean birth patterns.	Inclusion criteria: <ul style="list-style-type: none"> Non-federal, short-stay hospital deliveries in Illinois (from hospital discharge abstract form for uniform billing) ICD9 codes 650-699, V27 or procedure codes 72-74 Aged 10-50 Exclusion criteria: <ul style="list-style-type: none"> See inclusion criteria 	Births per year, n: 1986: 130,249 1987: 147,257 1988: 167,654 Age, mean yrs: 1988: 26.4	Total providers/staff: NR Total providers/staff formally trained: Council of Teaching Hospitals member Specialty: NR	Mode of birth Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean birth, %: Baseline period: 21.2 Evaluation period: 22.4 EP/BL: P = NS Cesarean birth rate by age, %: < 20: 1986: 16.6 1987: 17.7 1988: 17.3 20-24: 1986: 20.5 1987: 20.9 1988: 20.6 25-29: 1986: 23.0 1987: 23.9 1988: 22.5 30-34: 1986: 25.1 1987: 25.2 1988: 24.8 > 35: 1986: 27.7 1987: 28.8 1988: 28.7 Cesarean birth rate by expected primary payer, %: Medicaid: 1986: 20.6 1987: 20.9 1988: 20.6 Self-pay: 1986: 16.8 1987: 17.2 1988: 16.7 Commercial: 1986: 23.8 1987: 24.3 1988: 23.9

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Oleske et al., 1992 (continued)					<p>HMO: 1986: 25.1 1987: 23.7 1988: 22.5</p> <p><u>Maternal outcomes</u> Maternal mortality: NR</p> <p><u>Neonatal outcomes</u> Neonatal mortality: NR</p> <p>Apgar score: NR</p> <p>NICU admissions: NR</p>

Subgroup analysis showed that the cesarean rate declined for women with a history of uterine scar or dystocia ($P < 0.05$), and increased for breech or fetal distress ($P < 0.05$).

The VBAC rate increased by 58.4% from 10.1 to 16.0 during the study ($P < 0.001$).

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Poma, 1998 Country: US System: Ravenswood Hospital (Loyola University affiliated community hospital) Baseline period: 1991 to 1993 Evaluation period: 1994 to 1996 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Departmental goal of 15% total cesarean rate supported by case review of cesareans using ACOG guidelines with feedback to individual providers. During this timeframe the departmental also implemented 24-hour in-hospital attending coverage.	Inclusion criteria: NR Exclusion criteria: NR	Births, n: 1991: 2,231 1992: 2,259 1993: 2,372 1994: 2,239 1995: 2,028 1996: 1,783 Age, n (%): < 15: Baseline period: 6 (0.1) Evaluation period: 12 (0.2) 15-19: Baseline period: 1,109 (16.2) Evaluation period: 983 (16.2) 20-35: Baseline period: 5,298 (77.2) Evaluation period: 4,619 (76.4) 36-40: Baseline period: 402 (5.8) Evaluation period: 379 (6.3) > 40: Baseline period: 47 (0.7) Evaluation period: 57 (0.9) Race/ethnicity, n (%): Hispanic: Baseline period: 3,430 (50.0) Evaluation period: 3,086 (51.0) Parous, n (%): Baseline period: 4,770 (69.5) Evaluation period: 4,142 (68.5) Medicaid, n (%): Baseline period: 3,280 (47.8) Evaluation period: 2,638 (43.6)	Total providers/staff: NR Total providers/staff formally trained: NR Specialty: NR	Mode of birth Vaginal, spontaneous: NR Vaginal, assisted, n (%): Forceps: ¹ Baseline period: 147 (2.1) Evaluation period: 104 (1.7) Vacuum: Baseline period: 103 (1.5) Evaluation period: 212 (3.5) EP/BL: $P < 0.001$ Cesarean, n (%): Total: 1991: 518 (23.2) 1992: 492 (21.8) 1993: 535 (22.5) 1994: 460 (20.5) 1995: 379 (18.7) 1996: 285 (16) EP/BL: $P < 0.001^2$ Total cesarean, %: Baseline period: 22.5 Evaluation period: 18.6 EP/BL: $P = 0.001$ Primary cesarean, %: 1991: 13.8 1992: 13.4 1993: 13.4 1994: 11.2 1995: 10.8 1996: 9.7 EP/BL: $P < 0.001^2$ Baseline period: 13.5 Evaluation period: 10.6 EP/BL: $P = 0.001$ Repeat cesarean, %: 1991: 9.4 1992: 8.4 1993: 9.1

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Poma, 1998 (continued)			EP/BL: $P = 0.0001$ Private insurance coverage, n (%): Baseline period: 1,277 (18.6) Evaluation period: 1,162 (19.2) EP/BL: $P = 0.016$ HMO, n (%): Baseline period: 1,866 (27.2) Evaluation period: 1,791 (29.6) EP/BL: $P = 0.002$ Prior cesarean, n (%): Baseline period: 617 (39.9) Evaluation period: 481 (42.8)		1994: 9.3 1995: 7.9 1996: 6.3 EP/BL: $P < 0.001^2$ Baseline period: 9.0 Evaluation period: 7.9 EP/BL: $P = 0.03$ Maternal outcomes Maternal mortality: NR Neonatal outcomes Neonatal mortality, n (%): Baseline period: 25 (3.6) Evaluation period: 14 (2.3) Apgar score < 7, %: 1 minute: Baseline period: 4.3 Evaluation period: 5.0 EP/BL: $P = 0.08$ 5 minutes: Baseline period: 1.5 Evaluation period: 1.2 EP/BL: $P = 0.12$ Neonatal admissions, n (%): Baseline period: 106 (1.5) Evaluation period: 85 (1.4)

¹ One mid-forceps delivery² First compared to last year

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Porreco, 1990 Country: US System: Eight hospitals in the Denver metropolitan area Baseline period: Intervention began in 1982 Earliest data: 1984 Evaluation period: 1986 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Five year community education strategy initiated in 1982 designed to reach: physicians, nurses, and interested lay group with educational presentations about: 1) management of patients with prior cesarean; 2) diagnosis and management of fetal distress in labor, 3) indications and strategies for labor induction, 4) approach to failed progress in labor; 5) alternative management of breech and twin births; 6) increasing risk-free interval for women with genital herpes	Inclusion criteria: <ul style="list-style-type: none"> Hospitals with ≥ 1,500 births per year Exclusion criteria: <ul style="list-style-type: none"> See inclusion criteria 	Births, n: 1984: 22,624 1986: 23,642 Medicaid: NR Private insurance coverage: NR	Total providers/staff: NR Total providers/staff formally trained: NR ¹ Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean, %: Total: 1984: 17.3 1986: 19.3 Primary: 1984: 11.8 1986: 13.7 Repeat: 1984: 5.5 1986: 5.6 <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar score: NR NICU admission: NR

¹ 30 presentations to physicians, 22 presentations to nurses and health professionals, and 15 presentations to community organizations.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Pridjian et al., 1991 Country: US System: Chicago Lying-In Hospital Baseline period: 1982 Evaluation period: 1983 to 1988 Funding: Mother's Aid Research Fund, Chicago Lying-In Hospital Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Systematically incorporating VBAC into the management of previous-cesarean patients in the resident service.	Inclusion criteria: NR Exclusion criteria: NR	Births per year, n: 1982: 2,827 1983: 3,009 1984: 2,919 1985: 2,612 1986: 2,555 1987: 2,840 1988: 3,049 Age ≥ 35 years, %: 1982: 5.6 1983: 5.7 1984: 5.3 1985: 6.2 1986: 6.3 1987: 5.6 1988: 6.4 $\chi^2: P = 0.515$ Race/ethnicity, %: Black: 1982: 91.0 1983: 93.0 1984: 90.0 1985: 87.7 1986: 89.3 1987: 89.9 1988: 86.6 $\chi^2: P < 0.001$ Parous, %: Primiparous: 1982: 34.2 1983: 38.4 1984: 38.8 1985: 39.1 1986: 38.7 1987: 39.2 1988: 39.9 $\chi^2: P < 0.001$ Medicaid: NR Private insurance coverage: NR	Total providers/staff: 20 residents, 6 faculty members and 2 fellows Total providers/staff formally trained: NR Specialty: Maternal-fetal medicine	Mode of birth <u>Vaginal, spontaneous:</u> NR Vaginal, operative, %: 1982: 15.7 1983: 14.5 1984: 14.7 1985: 13.1 1986: 14.2 1987: 11.9 1988: 10.2 Cesarean birth, %: Total: 1982: 12.5 1983: 14.7 1984: 16.1 1985: 17.1 1986: 17.6 1987: 17.0 1988: 15.9 EP/BL: $P < 0.001^*$ Primary: 1982: 7.5 1983: 8.8 1984: 9.9 1985: 10.2 1986: 11.9 1987: 11.5 1988: 10.6 EP/BL: $P < 0.001^*$ Repeat: 1982: 5.0 1983: 5.9 1984: 6.2 1985: 6.9 1986: 5.7 1987: 5.5 1988: 5.3 EP/BL: $P = 0.776^*$ Maternal outcomes <u>Maternal mortality:</u> NR Neonatal outcomes <u>Neonatal mortality:</u> NR Apgar scores: NR

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Pridjian et al., 1991 (continued)					NICU admission: NR

* Logistic regression, with year as the independent variable.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Robson et al., 1996 Country: UK System: Pembury Hospital Baseline period: 1984 to 1988 Evaluation period: 09/1989 to 08/1992 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Introduction and completion of the medical audit cycle.	Inclusion criteria: NR Exclusion criteria: NR	Births, n: Baseline period: 12,628 Evaluation period: 8,497 Parous: Nulliparous: Baseline period: 5,622 Evaluation period: 3,585 Multiparous: Baseline period: 7,006 Evaluation period: 4,912 Medicaid: NR Private insurance coverage: NR Multiple gestations, n: Baseline period: 157 Evaluation period: 127	Total providers/staff: NR Total providers/staff formally trained: NR Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean birth, n (%): Baseline period: 1,518 (12.0) Evaluation period: 1810 (9.5) Nulliparous: Baseline period: 744 (13.2) Evaluation period: 344 (9.6) Multiparous: Baseline period: 774 (11.0) Evaluation period: 466 (9.5) <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar score: NR Admission rate to special care baby unit, spontaneously laboring nulliparous women with singleton, cephalic, n (%): Baseline period: 169/3,977 (4.2) Evaluation period: 88/2,589 (3.4)

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Rust et al., 1993 Country: US System: 93 rd Strategic Hospital at Castle Air Force Base, California Baseline period: 07/1987 to 06/1988 Evaluation period: 07/1988 to 06/1989 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Implemented protocols including: 1) policy for VBAC, including counseling and encouraging trial of labor 2) policy for management of non-vertex presentation by external cephalic version 3) protocol to document an adequate trial of labor 4) established criteria for diagnosis and documentation of fetal distress	Inclusion criteria: <ul style="list-style-type: none"> • Delivery after 24 weeks gestation Exclusion criteria: <ul style="list-style-type: none"> • See inclusion criteria 	Births per year, n: Baseline period: 472 Evaluation period: 430 Parous, n (%): 1985: 1309 (77.1) 1986: 1495 (71.2) 1987: 1618 (70.3) Medicaid: NR Private insurance coverage: NR	Total providers/staff: NR Total providers/staff formally trained: NR Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted, n (%): Baseline period: 27 (5.8) Evaluation period: 20 (4.7) Cesarean birth, n (%): Total: Baseline period: 99 (21.2) Evaluation period: 44 (10.3) EP/BL: $P < 0.0001$ Primary: Baseline period: 59 (12.5)* Evaluation period: 19 (4.4)* EP/BL: $P < 0.0001$ <u>Maternal outcomes:</u> Maternal mortality: NR Postpartum hemorrhage, n (%): Baseline period: 10 (2.1) Evaluation period: 14 (3.3) <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar score: NR NICU admission: NR

* Calculated by reviewer.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Sanchez-Ramos et al., 1990 Country: US System: University Medical Center, Jacksonville FL Baseline period: 1986 Evaluation period: 1987 to 1989 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: New guidelines focused on intrapartum management of women with prior cesarean section. New guidelines were also introduced for: <ul style="list-style-type: none"> • Primary cesarean • Induction • Fetal scalp pH sampling • Breech • Twins 	Inclusion criteria: NR Exclusion criteria: NR	Births, n: 1986: 4,336 1987: 4,270 1988: 4,470 1989: 5,157 Medicaid: NR Private insurance coverage: NR	Total providers/staff: Resident physicians and nurse midwives, supervised by faculty members Total providers/staff formally trained: NR Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted %: 1986: 16.2 1989: 18.5 Cesarean birth, n (%): Total: 1986: 1,198 (27.5) 1987: 952 (22.4) 1988: 598 (13.3) 1989: 542 (10.5) EP/BL: $P < 0.0001$ Primary: 1986: 849 (19.5) 1987: 643 (15.0) 1988: 424 (9.4) 1989: 374 (7.2) EP/BL: $P < 0.0001$ Repeat: 1986: 349 (8.0) 1987: 319 (7.4) 1988: 174 (3.9) 1989: 168 (3.3) EP/BL: $P < 0.0001$ Trial of labor, women with prior cesarean, n (%): 1986: 139 (31.7) 1987: 193 (41.9) 1988: 381 (76.5) 1989: 487 (83.9) EP/BL: $P < 0.0001$ VBAC, women with prior cesarean, n (%): 1986: 90 (20.5) 1987: 142 (30.8) 1988: 342 (65.1) 1989: 403 (69.4) EP/BL: $P < 0.0001$ <u>Maternal outcomes</u> Maternal mortality: NR

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Sanchez-Ramos et al., 1990 (continued)					<p><u>Neonatal outcomes</u></p> <p>Neonatal mortality, per 1000 births, n (%): 1986: 71 (16.4) 1987: 41 (9.6) 1988: 35 (7.8) 1989: 33 (6.4) EP/BL: $P < 0.001$</p> <p>Perinatal mortality rate per 1000 births: 1986: 31.8 1987: 19.7 1988: 17.4 1989: 14.9 EP/BL: $P < 0.0001$</p> <p>Apgar score < 7, n (%): 1 minute: 1986: 457 (10.5) 1987: 357 (8.4) 1988: 476 (10.6) 1989: 571 (11.0) 5 minutes: 1986: 79 (1.8) 1987: 65 (1.5) 1988: 83 (1.9) 1989: 90 (1.7)</p> <p>NICU admission, n (%): 1986: 447 (10.3) 1987: 420 (9.8) 1988: 432 (9.7) 1989: 453 (8.8)</p> <p>NICU length of stay, days, mean: 1986: 19 1987: 15 1988: 15 1989: 16</p> <p>Neonatal seizures, n (%): 1986: 108 (2.5) 1987: 120 (2.8) 1988: 116 (2.6) 1989: 114 (2.2)</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
<p>Author: Sloan et al., 2000</p> <p>Country: Ecuador</p> <p>System: Maternidad Isidro Ayora (public hospital serving lower to middle income women)¹</p> <p>Baseline period: 1995 to 04/1996</p> <p>Evaluation period: 05/15/1996 to 12/15/1996</p> <p>Funding: NR</p> <p>Author industry relationship disclosure: NR</p> <p>Design: Pre-post assessment</p>	<p>Cesarean reduction intervention: Implemented policy requiring “second opinion” from supervising obstetrician or resident for all cesarean candidates (excluding mandatory situations). Consultant obstetrician trained two senior physicians one of whom subsequently trained two more physicians.</p> <p>Groups: (among women for whom detailed data was collected²)</p> <p>G1: Co-managed</p> <p>G2: Not co-managed</p> <p>Ga: Vaginal delivery</p> <p>Gb: Cesarean delivery</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> Co-managed deliveries <p>Exclusion criteria:</p> <ul style="list-style-type: none"> See inclusion criteria 	<p>Births, n: Evaluation period: Total: 7,381 G1: 1,217 G1a: 503 G1b: 714 G2: 367 G2a: 1 G2b: 366</p> <p>Age, mean \pm SD: Evaluation period: Total: NR G1a: 22.6 \pm 6.1 G1b: 25.0 \pm 6.3 G2b: 25.4 \pm 5.7 G1a/G1b: $P < 0.001$ G1a/G2b: $P < 0.001$</p> <p>Parity, mean \pm SD: Evaluation period: Total: NR G1a: 0.75 \pm 1.21 G1b: 0.85 \pm 1.25 G2b: 1.01 \pm 1.06 G1a/G2b: $P < 0.05$</p> <p>Medicaid: NR</p> <p>Private insurance coverage: NR</p> <p>Prior cesarean, %: Evaluation period: Total: NR G1a: 10.7 G1b: 29.3 G2b: 55.2 G1a/G1b: $P < 0.001$ G1a/G2b: $P < 0.001$ G1b/G2b: $P < 0.001$</p> <p>Multiple gestations, %: Evaluation period: Total: NR G1a: 0</p>	<p>Total providers/staff: NR</p> <p>Total providers/staff formally trained: NR</p> <p>Three trained obstetricians provided the mandatory second opinion during a six week period.</p> <p>Specialty: Obstetrics</p>	<p>Mode of birth Vaginal, spontaneous: NR</p> <p>Vaginal, assisted: NR</p> <p>Cesarean births, mean % \pm SD: Baseline period: 26.6 \pm 4.4 Evaluation period: 22.1 \pm 4.2 EP/BL: $P < 0.001$</p> <p>Maternal outcomes Maternal mortality: NR</p> <p>Maternal postpartum infection/fever, %: G1a: 1.0 G1b: 5.2 G2b: 4.6 G1a/G1b: $P < 0.001$ G1a/G2b: $P < 0.001$</p> <p>Neonatal outcomes Neonatal mortality, %: Total: 24 G1a: 1.0 (n=501) G1b: 2.0 (n=712) G2b: 1.4 (n=363)</p> <p>Apgar score < 7, 5 minutes, %: G1a: 1.4 (n=501) G1b: 2.5 (n=712) G2b: 2.5 (n=362)</p> <p>NICU admissions, %: G1a: 10.4 (n=501) G1b: 20.8 (n=712) G2b: 18.2 (n=363) G1a/G1b: $P < 0.001$ G1a/G2b: $P < 0.001$</p> <p>Neonatal length of stay, mean days \pm SD: G1a: 3.37 \pm 2.69 (n=499)</p>

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Sloan et al, 2000 (continued)			G1b: 0.4 G2b: 0		G1b: 4.57 ± 3.39 (n=709) G2b: 4.68 ± 4.07 (n=360) Stillbirth, %: G1a: 0.4 G1b: 0.3 G2b: 0.8

¹ The paper also reports cesarean rates for other major maternity hospitals in Ecuador without the intervention.

² 2111 women were identified as candidates for cesarean sections. Data were not collected on 506 women for whom cesarean was considered mandatory, and on 21 women eligible for co-management but accidentally not included.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Smith et al., 2000 Country: US System: BryanLGH Medical Center, Lincoln, NE Baseline period: 01/1998 to 06/1998 Evaluation period: 07/1998 to 01/1999 Post-evaluation period: 01/1999 to 03/1999 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Interdisciplinary team focused on educating nurses, physicians, and community about labor support measures. Electronic data performance measurement system adopted as part of hospital quality improvement activities Quality improvement team charged with decreasing total and primary cesarean rates Feedback of individual cesarean data to physicians	Inclusion criteria: NR Exclusion criteria: NR	Births: NR Medicaid: NR Private insurance coverage: NR	Total providers/staff: NR Total providers/staff formally trained: NR Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean birth, %: Baseline period: 27.0 Evaluation period: 19.0 Post-evaluation: 24.5 EP/BL: <i>P</i> = NR <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality: NR Apgar score: NR NICU admission: NR

* Quarterly total and primary cesarean birth rates only presented graphically.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Socol et al., 1993 Country: US System: Northwestern Memorial Hospital Baseline period: 1986 Evaluation period: 1987 to 1991 ¹ Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: 1987 to 1988 vaginal birth after prior low transverse cesarean encouraged; 1988 forward cesarean birth rate of each obstetrician circulated annually to attending obstetricians; RCT of active management of labor completed and protocol recommended for routine practice.	Inclusion criteria: <ul style="list-style-type: none"> All providers and births included Exclusion criteria: <ul style="list-style-type: none"> See inclusion criteria 	Births, n: 1986: 4,240 1987: 4,219 1988: 4,271 1989: 4,391 1990: 4,829 1991: 4,669 Race/ethnicity, n (%): White: 1986: 2,718 (64.1) 1987: 2,799 (66.3) 1988: 2,759 (64.6) 1989: 2,849 (64.9) 1990: 3,031 (62.8) 1991: 2,942 (63.0) Black: 1986: 894 (21.1) 1987: 850 (20.2) 1988: 932 (21.8) 1989: 916 (20.9) 1990: 1,009 (20.9) 1991: 888 (19.0) Other: 1986: 628 (14.8) 1987: 570 (13.5) 1988: 580 (13.6) 1989: 626 (14.2) 1990: 789 (16.3) 1991: 839 (18.0) Parous, n (%): 1986: 2,231 (52.6) 1987: 2,250 (53.3) 1988: 2,234 (52.3) 1989: 2,310 (52.6) 1990: 2,502 (51.8) 1991: 2,426 (52.0) Medicaid/Indigent, n (%): 1986: 1,330 (31.4) 1987: 1,269 (30.1) 1988: 1,235 (28.9) 1989: 1,356 (30.9) 1990: 1,446 (29.9) 1991: 1,305 (28.0) Private insurance coverage, n (%): 1986: 2,910 (68.6) 1987: 2,950 (69.9) 1988: 3,036 (71.1) 1989: 3,035 (69.1) 1990: 3,383 (70.1)	Total providers/staff: Private practice and academic obstetricians attending on labor and delivery Total providers/staff formally trained: NR Specialty: NR	Mode of birth <u>Vaginal, spontaneous:</u> NR Vaginal, assisted: NR Cesarean birth, %: Total: 1986: 27.3 1987-1990: NR* 1991: 16.9 EP/BL: $P < 0.0001$ Primary: 1986: 18.2 1987-1990: NR* 1991: 10.6 EP/BL: $P < 0.0001$ Repeat: 1986: 9.1 1987-1990: NR* 1991: 6.4 EP/BL: $P < 0.0001$ Maternal outcomes <u>Maternal mortality:</u> NR Neonatal outcomes <u>Neonatal mortality, n (%):</u> 1986: 44 (1.0) 1987: 29 (0.7) 1988: 28 (0.6) 1989: 24 (0.5) 1990: 16 (0.3) 1991: 18 (0.4) Apgar score, 5 minutes, n (%): ≤ 3: 1986: 20 (0.4) 1987: 23 (0.5) 1988: 18 (0.4) 1989: 21 (0.5) 1990: 19 (0.4) 1991: 15 (0.3) < 7: 1986: 98 (2.2) 1987: 107 (2.5) 1988: 93 (2.1) 1989: 73 (1.6) 1990: 75 (1.5)

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Socol et al., 1993 (continued)			1991: 3,364 (72.0)		1991: 84 (1.8) NICU admission, n (%) 1986: 441 (10.3) 1987: 373 (8.7) 1988: 417 (9.6) 1989: 497 (11.2) 1990: 454 (9.3) 1991: 457 (9.7)

¹ Data provided for all years, statistical comparisons between 1986 and 1991.

* Results only displayed graphically.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Studnicki et al., 1997 Country: US System: Florida Baseline period: 1990 to 1992 Evaluation period: 1990 to 1993 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: State passed a law in 1991 requiring the Department of Health and Rehabilitative Services to adopt rules to establish practice parameters in provider hospitals. Provider hospitals (defined as having 30 or more births per year fully paid by state or federal funds) required to provide copies of guidelines to staff credentialed to perform cesarean section deliveries, establish peer review board to review cesareans, incorporate peer review into hospital quality assurance monitoring. Guidelines comprised of fetal evaluation, definitions of labor and labor diagnosis.	Inclusion criteria: <ul style="list-style-type: none"> Medical discharge data DRG codes 370-375 obtained from nonfederal acute care hospitals in Florida Exclusion criteria: <ul style="list-style-type: none"> See inclusion criteria 	Births, n: 1990: 187,054 1991: 182,896 1992: 182,385 Baseline period: 552,335 1993: 183,291 Medicaid: NR Private insurance coverage: NR Prior cesarean, n (%): 1990: 22,064 (11.8) 1991: 21,655 (11.8) 1992: 22,938 (12.6) Baseline period: 66,657 (12.1) 1993: 23,127 (12.6)	Total providers/staff: NR Total providers/staff formally trained: Obstetricians Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous: NR Vaginal, assisted: NR Cesarean births, n (%): ¹ Total: 1990: 49,543 (26.5) 1991: 46,176 (25.2) 1992: 45,793 (25.1) Baseline period: 141,512 (25.6) 1993: 44,082 (24.1) Primary: 1990: 32,295 (17.3) 1991: 30,061 (16.4) 1992: 28,988 (15.9) Baseline period: 91,344 (16.5) 1993: 28,106 (15.3) Repeat: 1990: 17,248 (9.2) 1991: 16,115 (8.8) 1992: 16,805 (9.2) Baseline period: 50,168 (9.1) 1993: 15,976 (8.7) <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Neonatal mortality, NR Apgar scores: NR NICU admissions: NR

¹ The authors report cesarean rates among all women, women with a prior cesarean, and women without a prior cesarean for each quarter in the study.

Evidence Table C2. Strategies to reduce cesarean birth—systems-level interventions (continued)

Study Description	Intervention & Population	Inclusion & Exclusion Criteria	Clinical Population	Provider Population	Outcomes
Author: Tay et al., 1992 Country: Singapore System: Singapore General Hospital Baseline period: 1987 Evaluation period: 1988 to 1990 Funding: NR Author industry relationship disclosure: NR Design: Pre-post assessment	Cesarean reduction intervention: Critical review of indications for cesarean delivery. Departmental audit of all cesareans.	Inclusion criteria: NR Exclusion criteria: NR	Births, n: 1987: 3,156 1988: 4,658 1989: 3,823 1990: 5,238 Parous, %: Primiparae: 1987: NR 1988: NR 1989: 52 1990: NR Medicaid: Not applicable Private insurance coverage: Not applicable	Total providers/staff: NR Total providers/staff formally trained: NR Specialty: NR	<u>Mode of birth</u> Vaginal, spontaneous, n (%): 1987: 2,244 (71.1) 1988: 3,667 (78.7) 1989: 2,759 (72.2) 1990: 3,787 (72.5) Vaginal, assisted, n (%) 1987: 525 (16.6) 1988: 473 (10.2) 1989: 634 (16.6) 1990: 835 (15.9) Cesarean birth, n (%) 1987: 387 (12.3) 1988: 518 (11.1) 1989: 430 (11.2) 1990: 616 (11.7) <u>Maternal outcomes</u> Maternal mortality: NR <u>Neonatal outcomes</u> Perinatal mortality, rate per 1000 births: > 500 grams: 1987: 8.25 1988: 7.05 1989: 9.39 1990: 5.83 > 1000 grams: 1987: 7.58 1988: 5.77 1989: 6.25 1990: 4.89 Apgar scores: NR NICU admission: NR

Appendix D. Sample Data Abstraction Forms

Strategies to Reduce Cesarean Birth CER Abstract Review Form

First Author, Year: _____

Endnote Reference ID #: _____

Abstractor Initials: ____

Primary Inclusion/Exclusion Criteria			
1. Eligible Study Type? a. ___ RCT/System Intervention	Yes	No	Cannot Determine
2. Original research (exclude reviews, editorials, commentaries, letters to editor, etc.)	Yes	No	Cannot Determine
3. Pregnant women in labor	Yes	No	Cannot Determine
4. Relevant to CER topic If "No", select at least one of the following reasons: a. ___ Exclusively related to labor b. ___ Elective or prior cesarean c. ___ Breech delivery only d. ___ Other _____	Yes	No	Cannot Determine

Retain for:

___ BACKGROUND/DISCUSSION

___ REVIEW OF REFERENCES

___ Other _____

COMMENTS:

Strategies to Reduce Cesarean Birth CER Full Text Review Form

First Author, Year: _____

Endnote Reference ID #: _____

Abstractor Initials: ____

Retain for:

Primary Inclusion/Exclusion Criteria		
1. Eligible Study Type? RCT/System Intervention	Yes	No
2. Original research (exclude reviews, editorials, commentaries, letters to editor, etc.)	Yes	No
3. Pregnant women intending a vaginal birth	Yes	No
4. Relevant to CER topic If "No", select at least one of the following reasons: a. ___ Exclusively related to labor (does not include route of birth data) b. ___ Elective or prior cesarean c. ___ Breech delivery only d. ___ Comparison of two or more agents of induction e. ___ Other _____	Yes	No
5. Do the authors state that the intent is to improve/reduce cesarean rates?	Yes	No
6. If "Yes" to all, select which of the following describes the intent: ___ Introduction includes literature review of improving or reducing cesarean risk/rate OR influencing route of birth as an outcome that would be influenced by the intervention ___ Stated primary and secondary aims indicate intention to examine influence of the intervention on cesarean risk/rate or route of birth ___ Analytic models indicate they conducted data analysis of the effect of the intervention as it relates to cesarean risk/rate or route of birth ___ 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 ___ Tables in the results section feature data about the relationship of the intervention to cesarean risk/rate or route of birth as reporting of a primary or secondary aim ___ Discussion interprets the intervention as potentially having value for modifying cesarean risk/rates or influencing route of delivery ___ Authors express dismay that did not find it had value for modifying cesarean risk/rates or influencing route of delivery		

___ **BACKGROUND/DISCUSSION**

___ **REVIEW OF REFERENCES**

_____ Other _____

COMMENTS:

Appendix E. Quality of the Literature

The Cochrane Risk of Bias Tool for Randomized Controlled Trials

RANDOM SEQUENCE GENERATION Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.	
Criteria for a judgment of 'Low risk' of bias.	<p>The investigators describe a random component in the sequence generation process such as:</p> <ul style="list-style-type: none"> • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. <p>*Minimization may be implemented without a random element, and this is considered to be equivalent to being random.</p>
Criteria for the judgment of 'High risk' of bias.	<p>The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:</p> <ul style="list-style-type: none"> • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. <p>Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example:</p> <ul style="list-style-type: none"> • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
Criteria for the judgment of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.

ALLOCATION CONCEALMENT Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.	
Criteria for a judgment of 'Low risk' of bias.	<p>Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:</p> <ul style="list-style-type: none"> • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgment of 'High risk' of bias.	<p>Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:</p> <ul style="list-style-type: none"> • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgment of 'Unclear risk' of bias.	<p>Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.</p>
SELECTIVE REPORTING Reporting bias due to selective outcome reporting.	
Criteria for a judgment of 'Low risk' of bias.	<p>Any of the following:</p> <ul style="list-style-type: none"> • The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgment of 'High risk' of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • Not all of the study's pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgment of 'Unclear risk' of bias.	<p>Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.</p>

OTHER BIAS Bias due to problems not covered elsewhere in the table.	
Criteria for a judgment of 'Low risk' of bias.	The study appears to be free of other sources of bias.
Criteria for the judgment of 'High risk' of bias.	There is at least one important risk of bias. For example, the study: <ul style="list-style-type: none"> • Had a potential source of bias related to the specific study design used; or • Has been claimed to have been fraudulent; or • Had some other problem.
Criteria for the judgment of 'Unclear risk' of bias.	There may be a risk of bias, but there is either: <ul style="list-style-type: none"> • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.
BLINDING OF PARTICIPANTS AND PERSONNEL Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgment of 'High risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgment of 'Unclear risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • Insufficient information to permit judgment of 'Low risk' or 'High risk'; • The study did not address this outcome.

BLINDING OF OUTCOME ASSESSMENT Detection bias due to knowledge of the allocated interventions by outcome assessors.	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgment of 'High risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgment of 'Unclear risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • Insufficient information to permit judgment of 'Low risk' or 'High risk'; • The study did not address this outcome.
INCOMPLETE OUTCOME DATA Attrition bias due to amount, nature or handling of incomplete outcome data.	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
Criteria for the judgment of 'High risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
Criteria for the judgment of 'Unclear risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.

Thresholds for converting the Cochrane Risk of Bias tool to AHRQ standards (good, fair, and poor):

Good quality: All criteria met (i.e. low for each domain)

Using the Cochrane ROB tool, it is possible for a criterion to be met even when the element was technically not part of the method. For instance, a judgment that knowledge of the allocated interventions was adequately prevented can be made even if the study was not blinded, if EPC team members judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.

Fair quality: One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was **unlikely** to have biased the outcome, and there is no known important limitation that could invalidate the results

Poor quality: One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was **likely** to have biased the outcome, and there are important limitations that could invalidate the results

Poor quality: Two or more criteria listed as high or unclear risk of bias

Newcastle-Ottawa Quality Assessment Form for Cohort Studies

Note: A study can be given a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

Selection

- 1) Representativeness of the exposed cohort
 - a) Truly representative **(one star)**
 - b) Somewhat representative **(one star)**
 - c) Selected group
 - d) No description of the derivation of the cohort
- 2) Selection of the non-exposed cohort
 - a) Drawn from the same community as the exposed cohort **(one star)**
 - b) Drawn from a different source
 - c) No description of the derivation of the non exposed cohort
- 3) Ascertainment of exposure
 - a) Secure record/institutional documentation of the intervention (e.g., surgical record) **(one star)**
 - b) Structured interview **(one star)**
 - c) Written self report
 - d) No description
 - e) Other
- 4) Demonstration that outcome of interest was not present at start of study
 - a) Yes **(one star)**
 - b) No

Comparability

- 1) Comparability of cohorts on the basis of the design or analysis controlled for confounders
 - a) The study controls for vaginal parity and prior cesarean status **(one star)**
 - b) Study controls for other factors (list) _____ **(one star)**
 - c) Cohorts are not comparable on the basis of the design or analysis controlled for confounders
 - d) No comparison group*
 - e) N/A*

Outcome

- 1) Assessment of outcome
 - a) Independent blind assessment **(one star)**
 - b) Record linkage **(one star)**
 - c) Self report
 - d) No description
 - e) Other
- 2) Was follow-up long enough for outcomes to occur
 - a) Yes **(one star)**
 - b) No

Indicate the median duration of follow-up and a brief rationale for the assessment above: _____

- 3) Adequacy of follow-up of cohorts
 - a) Complete follow up- all subject accounted for **(one star)**
 - b) Subjects lost to follow up unlikely to introduce bias- number lost less than or equal to 20% or description of those lost suggested no different from those followed. **(one star)**
 - c) Follow up rate greater than 80% and no description of those lost
 - d) No statement

**Added by Vanderbilt EPC*

Thresholds for converting the Newcastle-Ottawa scales to AHRQ standards (good, fair, and poor):

Good quality: 3 or 4 stars in selection domain AND 1 or 2 stars in comparability domain AND 2 or 3 stars in outcome/exposure domain

Fair quality: 2 stars in selection domain AND 1 or 2 stars in comparability domain AND 2 or 3 stars in outcome/exposure domain

Poor quality: 0 or 1 star in selection domain OR 0 stars in comparability domain OR 0 or 1 stars in outcome/exposure domain

The Vanderbilt EPC included two additional options in the comparability domain not generally included in the Newcastle-Ottawa scales: “no comparison group” and “not applicable”. This was necessary because the review included single-arm studies for both the effectiveness and harms assessments.

Studies of the effectiveness of strategies to reduce cesarean birth that included only one study arm were marked as “no comparison group”, which equates to receiving no stars and an automatic rating of poor quality.

Cross sectional studies used to identify potential harms and measures of environmental exposure could appropriately have no comparison group, and were marked for comparability as “not applicable.” The quality scores for these studies were downgraded to account for their non-comparative study designs. For example, a study with three or four stars in the selection domain and two or three stars in the outcome/exposure domain, which would normally equate to a “good” quality rating, would be deemed “fair” quality if the comparability domain response was “not applicable”.

Quality Tables

Table E1. Risk of bias of RCTs of strategies to reduce cesarean births

Author, Year	Adequate sequence generation	Allocation concealment	Blinding of (Route of delivery)	Blinding (Maternal morbidity/mortality)	Blinding (Neonatal morbidity/mortality)	Incomplete outcome data (Route of delivery)	Incomplete outcome data (Maternal morbidity/mortality)	Incomplete outcome data (Neonatal morbidity/mortality)	Free of selective reporting	Free of other bias	Quality
World Health Organization, 1994 ¹	+	?	-	+	+	+	+	+	+	+	Fair
Abdel-Aleem et al., 2005 ²	+	+	?	+	+	+	+	+	+	+	Fair
Adamsons et al., 1999 ³	?	?	-	+	+	+	+	+	+	?	Poor
Ajadi et al., 2006 ⁴	+	+	?	+	+	+	+	+	?	+	Fair
Althabe et al., ⁵	+	+	-	+	+	?	?	?	+	?	Poor
Asher et al., 2009 ⁶	+	+	?	+	+	+	+	+	+	+	Fair
Barakat et al., 2009 ⁷	?	+	+	+	+	+	+	+	+	-	Fair
Bernitz et al., 2011 ⁸	+	+	?	?	?	+	+	+	+	?	Poor
Bidgood et al., 1987 ⁹	+	+	-	+	+	+	+	+	+	+	Fair
Bloom et al., 2006 ¹⁰	+	+	+	+	+	+	+	+	+	+	Good
Bloom et al., 1998 ¹¹	?	?	-	+	+	+	+	+	+	?	Poor
Campbell et al., 2006 ¹²	+	+	?	+	+	+	+	+	-	+	Poor
Choudhary et al., 2010 ¹³	+	+	-	-	-	+	+	+	+	+	Poor
Cohen et al., 1987 ¹⁴	-	-	-	+	+	+	+	+	+	+	Poor
Cox et al., 1999 ¹⁵	+	+	+	+	+	+	+	+	+	+	Good
East et al., 2006 ¹⁶	+	+	+	+	+	?	+	+	+	+	Fair
Elferink-Stinkens et al., 2004 ¹⁷	?	?	+	+	+	+	+	+	+	+	Poor
Frigoletto et al., 1995 ¹⁸	+	+	-	-	?	+	+	+	+	?	Poor
Gagnon, 1997 ¹⁹	+	+	?	+	+	+	+	+	+	+	Poor
Gambling et al., 1998 ²⁰	+	+	+	+	+	+	+	+	+	-	Fair
Garite et al., 2000 ²¹	+	+	-	+	+	+	+	+	+	?	Fair
Garite et al., 2000 ²²	+	+	+	+	+	+	+	+	+	+	Good
Hamilton et al., 2004 ²³	+	?	?	+	+	+	+	+	+	?	Poor
Harper et al., 2006 ²⁴	+	+	+	+	+	+	+	+	+	?	Fair
Harvey et al., 1996 ²⁵	+	?	+	+	+	+	+	+	+	+	Fair
Hemminki et al., 1990 ²⁶	?	+	-	+	+	+	+	?	+	?	Poor
Hinshaw et al., 2008 ²⁷	+	+	-	+	+	+	+	+	+	+	Poor
Hodnett et al., 2002 ²⁸	+	+	?	+	+	+	+	+	+	+	Fair

+ = Low risk of bias; - = High risk of bias; ? = Unclear risk of bias

Table E1. Risk of bias of RCTs of strategies to reduce cesarean births (continued)

Author, Year	Adequate sequence generation	Allocation concealment	Blinding of (Route of delivery)	Blinding (Maternal morbidity/mortality)	Blinding (Neonatal morbidity/mortality)	Incomplete outcome data (Route of delivery)	Incomplete outcome data (Maternal morbidity/mortality)	Incomplete outcome data (Neonatal morbidity/mortality)	Free of selective reporting	Free of other bias	Quality
Hofmeyr et al., 1998 ²⁹	+	+	-	+	+	+	+	+	+	?	Poor
Homer et al., 2011 ³⁰	+	?	-	-	+	+	+	+	+	?	Poor
Jalil et al., 2009 ³¹	?	+	-	+	+	+	+	+	+	+	Fair
Janssen et al., 2006 ³²	+	+	-	+	+	+	+	+	+	+	Fair
Karraz, 2003 ³³	?	?	-	+	+	+	+	+	+	+	Poor
Kennell et al., 1991 ³⁴	?	?	-	+	+	+	+	+	+	+	Poor
Kuhnert et al., 2004 ³⁵	?	?	+	+	+	+	+	+	+	+	Fair
Lavender et al., 1998 ³⁶	+	+	+	+	+	+	+	+	+	+	Good
Lavender et al., 2006 ³⁷	+	+	+	+	+	+	+	+	+	+	Good
Lopez-Zeno et al., 1992 ³⁸	+	+	-	+	+	+	+	+	+	+	Poor
Mahomed et al., 1998 ³⁹	+	+	?	+	+	+	+	+	+	+	Fair
Matsuo et al., 2009 ⁴⁰	?	+	-	-	+	+	+	+	+	+	Poor
McGrath and Kennell, 2008 ⁴¹	?	+	+	+	+	+	+	+	+	-	Poor
McNiven et al., 1998 ⁴²	?	+	+	+	+	+	+	+	+	+	Fair
Mehrangiz et al., 2004 ⁴³	?	?	-	+	+	+	+	+	+	?	Poor
Moodley et al., 1998 ⁴⁴	+	+	-	+	+	+	+	+	+	?	Poor
Nicholson et al., 2008 ⁴⁵	+	+	+	+	+	+	+	+	+	-	Fair
Norris et al., 2001 ⁴⁶	-	-	?	+	+	-	+	+	+	+	Poor
Ojala et al., 2006 ⁴⁷	+	+	-	+	+	+	+	+	+	+	Fair
Olofsson et al., 1998 ⁴⁸	+	+	-	+	+	+	+	+	+	+	Poor
O'Sullivan et al., 2009 ⁴⁹	+	+	+	+	+	+	+	+	+	+	Good
Palomäki et al., 2006 ⁵⁰	+	?	+	+	+	+	+	+	+	+	Fair
Pattinson et al., 2003 ⁵¹	+	+	+	+	+	+	+	+	+	+	Good
Phipps et al., 2009 ⁵²	+	+	-	+	+	+	+	+	+	+	Fair
Rathor et al., 2002 ⁵³	+	+	-	+	+	+	+	+	+	+	Fair
Regi et al., 2009 ⁵⁴	+	+	-	?	?	+	+	+	+	-	Poor
Rogers et al., 1997 ⁵⁵	+	+	+	+	+	+	+	+	+	+	Good

+ = Low risk of bias; - = High risk of bias; ? = Unclear risk of bias

Table E1. Risk of bias of RCTs of strategies to reduce cesarean births (continued)

Author, Year	Adequate sequence generation	Allocation concealment	Blinding of (Route of delivery)	Blinding (Maternal morbidity/mortality)	Blinding (Neonatal morbidity/mortality)	Incomplete outcome data (Route of delivery)	Incomplete outcome data (Maternal morbidity/mortality)	Incomplete outcome data (Neonatal morbidity/mortality)	Free of selective reporting	Free of other bias	Quality
Sadler et al., 2000 ⁵⁶	+	+	?	?	?	+	+	+	+	?	Poor
Saisto et al., 2001 ⁵⁷	?	+	-	+	+	+	+	?	+	?	Poor
Sanchez-Ramos et al., 1996 ⁵⁸	+	+	+	+	+	+	+	+	+	+	Good
Scheepers et al., 2002 ⁵⁹	+	+	+	+	+	+	+	+	+	-	Fair
Skrablin et al., 2011 ⁶⁰	-	-	+	+	+	+	+	+	+	?	Poor
Somprasit et al., 2005 ⁶¹	+	+	-	+	+	+	+	+	+	+	Poor
Spallicci et al., 2007 ⁶²	+	+	+	+	+	+	+	+	+	-	Fair
Strong et al., 1990 ⁶³	+	+	-	+	+	+	+	+	+	+	Poor
Trueba et al., 2000 ⁶⁴	?	?	-	+	+	+	+	+	+	+	Poor
Vayssiere et al., 2007 ⁶⁵	?	+	?	+	+	+	+	+	+	+	Fair
Waldenstrom et al., 1997 ⁶⁶	+	+	+	-	+	+	+	+	+	+	Fair
Waldenstrom et al., 2001 ⁶⁷	?	+	-	+	+	+	+	+	+	+	Fair
Windrim et al., 2007 ⁶⁸	+	+	?	+	+	+	+	+	+	+	Fair

+ = Low risk of bias; - = High risk of bias; ? = Unclear risk of bias

Table E2. Newcastle-Ottawa quality rating systems-level strategies to reduce cesarean births

Author, Year	Selection (0-4)				Comparability	Outcome (0-3)			Quality
	Representativeness of the exposed cohort	Selection of the non exposed cohort	Ascertainment of exposure	Outcome of interest was not present at start of study		Assessment of outcome	Follow-up long enough for outcomes to occur	Adequacy of follow up of cohorts	
Berglund et al., 2010 ⁶⁹	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Bickell et al., 1996 ⁷⁰	★	★	★	★	★	★	★	★	Good (4+1+3)
Boylan et al., 1991 ⁷¹	★	★	★	★	★	★	★	★	Good (4+1+3)
Calvo et al., 2009 ⁷²	★	★	★	★	N/A	★	★	No statement	Poor (4+0+2)
Dillon et al., 1992 ⁷³	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Gilstrap et al., 1984 ⁷⁴	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Gregory et al., 1999 ⁷⁵	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Iglesias et al., 1991 ⁷⁶	★	★	★	★	★	★	★	★	Good (4+1+3)
Kazandjian and Lied, 1998 ⁷⁷	★	★	★	★	★	★	★	★	Good (4+1+3)
Kim et al., 2005 ⁷⁸	★	★	★	★	★	★	★	★	Good (4+1+3)
Kiwanuka and Moore, 1993 ⁷⁹	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Langrew et al., 1996 ⁸⁰	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Liang et al., 2004 ⁸¹	★	★	★	★	N/A	★	★	No statement	Poor (4+0+2)
Maher et al., 1994 ⁸²	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Main et al., 1999 ⁸³	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Meyers and Gleicher, 1988, 1993 ⁸⁴⁻⁸⁵	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Oleske et al., 1992 ⁸⁶	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Poma, 1998 ⁸⁷	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Porreco, 1990 ⁸⁸	★	★	★	★	N/A	★	★	No statement	Poor (4+0+2)
Pridjian et al., 1991 ⁸⁹	★	★	★	★	N/A	★	★	★	Poor (4+0+3)

N/A=Not applicable

Table E2. Newcastle Ottawa Quality Rating Systems-level strategies to reduce cesarean births (continued)

Author, Year	Selection (0-4)				Comparability	Outcome (0-3)			
	Representativeness of the exposed cohort	Selection of the non exposed cohort	Ascertainment of exposure	Outcome of interest was not present at start of study		Assessment of outcome	Follow-up long enough for outcomes to occur	Adequacy of follow up of cohorts	Quality
Robson et al., 1996 ⁹⁰	★	★	★	★	★	★	★	★	Good (4+1+3)
Rust et al., 1993 ⁹¹	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Sanchez-Ramos et al., 1990 ⁹²	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Sloan et al., 2000 ⁹³	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Smith et al., 2000 ⁹⁴	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Socol et al., 1993 ⁹⁵	★	★	★	★	★	★	★	★	Good (4+1+3)
Studnicki et al., 1997 ⁹⁶	★	★	★	★	N/A	★	★	★	Poor (4+0+3)
Tay et al., 1992 ⁹⁷	★	★	★	★	N/A	★	★	No statement	Poor (4+0+2)

N/A=Not applicable

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Appendix F. Applicability Summary Tables

Table F1. Key Question 1—Applicability for Antenatal Care

Table F2. Key Question 2—Applicability for Management of Labor

Table F3. Key Question 2—Applicability for Psychosocial Support

Table F4. Key Question 2—Applicability for Pain Management

Table F5. Key Question 2—Applicability for Fetal Assessments

Table F6. Key Question 2—Applicability for Amnioinfusion

Table F7. Key Question 2—Applicability for Other Interventions

Table F1. Key Question 1—applicability for antenatal care

Domain	Description of applicability of evidence compared to question
Population	<p>The populations of patients from which the study participants were selected varied considerably across the studies. The control group CS rate (surrogate for baseline event rate) ranged from 9-49% - the rate was high in women with fear of vaginal birth (48%) and in women with a low Bishop score (49%); the control group rate in 5 studies of women with a low risk pregnancy ranged from 9-26%. The control group rate in a study of women at high risk for CS was 15%.</p> <p>Only one of the eight studies conducted in USA.</p> <p>The target population is likely to differ in many characteristics, including baseline risk of Cesarean, willingness to accept risk, pregnancy complications, and demographics.</p>
Intervention	<p>The interventions differed considerably. The antenatal care model studies were conducted in Australia and Sweden; the intervention in the antenatal care model studies might be unavailable to difficult to implement in U.S. settings because of the requirements for trained experienced midwives who are integrated into a system of care.</p> <p>The other interventions could be replicated in the U.S. in many target populations and settings.</p>
Comparators	<p>The antenatal care model studies were conducted in Australia and Sweden, where the standard care model differs from the standard care model at many U.S. centers.</p> <p>The comparator in the other intervention studies was consistent with usual care in U.S. settings.</p>
Outcomes	<p>The outcome of interest was the Cesarean section procedure. The definition and validation of this outcome would apply to any target population. However, the classification of indications for Cesarean may differ considerably in different countries and different regions and centers.</p>
Setting	<p>The studies were international; only one of eight studies conducted in USA.</p> <p>All of the antenatal care model studies were conducted 12-20 years ago, and standards may have changed. The other studies were conducted within the last 5-12 years.</p>

Table F2. Key Question 2—applicability for management of labor

Domain	Description of applicability of evidence compared to question
Population	Most of the studies (15 of 17) only included nulliparous women. Five of the studies focused on women whose labors had become abnormal. The control group cesarean rate (surrogate for baseline event rate) ranged from 1.6% to 51.1%.
Intervention	The interventions differed considerably and were categorized as early labor assessment, measurement of labor progress, active management of labor, management of abnormal labor, amniotomy, and increased intravenous fluids. Even within categories, interventions were not consistent. For example, what constituted active management of labor varied across studies. All of the interventions could be replicated in the United States in many target populations and settings.
Comparators	Partograms are not commonly used in the United States and were used as the comparator in some studies. The comparators in the other studies were consistent with usual care in U.S. settings.
Outcomes	The outcome of interest was cesarean. The definition and validation of this outcome would apply to any target population. However, the classification of indications for cesarean may differ considerably in different countries and different regions and centers.
Setting	Many of the studies were international; only 6 of 17 studies were conducted in the United States. The most recent U.S. study, which also included study sites in Canada, was conducted 7 years ago. The other U.S. studies were conducted 11-24 years ago. Seven of the 11 international studies were conducted in the past 8 years.

Table F3. Key Question 2—applicability for psychosocial support

Domain	Description of applicability of evidence compared to question
Population	<p>The baseline cesarean rates for the population from which participants were selected varied across studies. The baseline cesarean rate in three of the doula support studies ranged from 18 to 40 percent. The baseline cesarean rate in the nursing support studies ranged from 9.8 to 20 percent.</p> <p>There was some variation in the countries in which studies were conducted. Three of the four doula studies were conducted in the US and one in Mexico. The nursing labor support studies were held in Canada, Canada and the US and in Finland.</p> <p>All participants in the doula support studies were nullips. Two of the nursing support studies included both nullips and multips.</p> <p>The mean age for one doula support study was higher than mean age for the other studies. The mean age for the nursing support studies were similar.</p> <p>The race/ethnicity and socio-economic backgrounds of study populations varied significantly across studies.</p>
Intervention	The type of training and experience levels of labor support persons varied considerably across studies.
Comparators	The comparator groups received usual labor care. The studies did not uniformly describe usual labor care. Usual labor care may differ considerably by country.
Outcomes	The outcome of interest was cesarean births, which is defined uniformly across studies.
Setting	Study settings varied somewhat. Two doula support studies were conducted at academic hospitals and two at community hospitals. Two hospitals served were tertiary care facilities. Two of the nursing support studies were conducted at academic hospitals and one at 9 academic and 4 community hospitals. Some of these sites were reported to be tertiary care facilities.

Table F4. Key Question 2—applicability for pain management

Domain	Description of applicability of evidence compared to question
Population	The populations of patients varied considerably in the seven studies. The percent of nulliparous women ranged from 0 to 100%. The rates of Cesarean sections in these studies ranged from 2 to 16 percent Only two of the seven studies were conducted in the USA. The target population is likely to differ in many characteristics, including baseline risk of Cesarean, willingness to accept risk, pregnancy complications, and demographics.
Intervention	Six studies used epidural analgesia but the medications and dosages were unique in each study. Drugs, dosages and methods of administration have changed over time. There are regional differences in analgesia use (i.e. meperidine is widely used worldwide but not popular in the US).
Comparators	The comparators used in these studies was another form of analgesia (either different medication or dose). Drugs and dosages, as well as method of administration have changed over time (i.e meperidine is now less popular in the US)
Outcomes	The outcome of interest was the Cesarean section procedure. The definition and validation of this outcome would apply to any target population. However, the classification of indications for Cesarean may differ considerably in different countries and different regions and centers.
Setting	The studies were international; only two of seven studies were conducted in the USA. All of the studies were conducted within the past 2 decades.

Table F5. Key Question 2—applicability for fetal assessments

Domain	Description of applicability of evidence compared to question
Population	<p>The populations of patients from which the study participants were selected varied considerably across the studies. The control group CS rate (surrogate for baseline event rate) ranged from 4.7- 48.1%.</p> <p>Two of six studies conducted in USA.</p> <p>The target population is likely to differ from the remaining studies in baseline risk of Cesarean, demographics, willingness to accept risk, and pregnancy complications.</p>
Intervention	<p>The interventions using fetal pulse oximetry were similar among studies. Although the fetal pulse oximetry intervention has been utilized in 2 multi-center U.S. trials, and could be replicated in the U.S. in many target populations and settings, it might prove challenging to implement for routine use in U.S. settings because of the requirements for trained experienced hospital personnel.</p> <p>The interventions using STAN monitoring were similar among studies. The use of STAN might also be difficult to implement in U.S. settings because of the requirements for trained experienced hospital personnel.</p>
Comparators	<p>Two of the studies were conducted in the U.S. The remaining four studies were conducted in Germany, France, Australia, and Finland, where the standard care model does not appear consistent with usual care in U.S. settings.</p>
Outcomes	<p>The outcome of interest was the Cesarean section procedure. The definition and validation of this outcome would apply to any target population. However, the classification of indications for Cesarean may differ considerably in different countries and different regions and centers.</p>
Setting	<p>Four studies were international; only two of six studies conducted in USA.</p> <p>All of the fetal monitoring studies were conducted within the last 4-11 years.</p>

Table F6. Key Question 2—applicability for amnioinfusion

Domain	Description of applicability of evidence compared to question
Population	<p>The populations of patients from which the study participants were selected varied considerably across the studies. The control group CS rate (surrogate for baseline event rate) ranged from 12.3-68%.</p> <p>Only one of the eight studies was conducted in USA. The remaining seven studies were conducted in India, Egypt, South Africa and Zimbabwe.</p> <p>The actual target population is likely to differ in many characteristics, including baseline risk of cesarean, demographics, access to standard care, willingness to accept risk, and pregnancy complications.</p>
Intervention	<p>The intervention differed slightly between studies in terms of rates of infusion and total fluid goals of the transcervical amnioinfusion. The amnioinfusion studies appear easy to implement in the U.S. in many target populations and settings because the materials needed are tend to be readily available and the intervention appears simple and relatively easy to perform.</p>
Comparators	<p>Three of the amnioinfusion studies were conducted in India (2) and Zimbabwe (1), where the standard care model differs from the standard care model at many U.S. centers. The comparator in the remaining five intervention studies were consistent with usual care in U.S. settings.</p>
Outcomes	<p>The outcome of interest was the Cesarean section procedure. The definition and validation of this outcome would apply to any target population. However, the classification of indications for Cesarean may differ considerably in different countries and different regions and centers.</p>
Setting	<p>The studies were international; only one of eight studies conducted in USA. Seven of the amnioinfusion studies were conducted within the last 1-13 years. The remaining study, performed in the U.S. was conducted 21 years ago during which time standards may have changed.</p>

Table F7. Key Question 2—applicability for other interventions

Domain	Description of applicability of evidence compared to question
Population	Six of the studies were limited to nulliparous women, with only the walking study including both parous and nulliparous women. The control group cesarean rate (surrogate for baseline event rate) varied widely, ranging from 6-57%. Four of the seven studies were conducted in USA.
Intervention	The interventions differed considerably, including devices, activities, acupuncture, and one medical intervention. With the exception of the obstetric belt tested in a UK study which may not be available commercially in the US, the other interventions could likely be replicated in the United States
Comparators	Four studies were conducted in the United States, two in the United Kingdom, and one in Puerto Rico. The comparators in the other intervention studies were consistent with usual care in U.S. settings. The studies were published within the last fifteen years, with four published in the last five years.
Outcomes	The outcome of interest was the cesarean section procedure. The definition and validation of this outcome would apply to any target population. However, the classification of indications for cesarean may differ considerably in different countries and different regions and centers.
Setting	Three of the studies were international and four were conducted in the United States. Five studies focused on an academic health care setting and two included nonacademic centers.

Appendix G. Strength of the Evidence Calculator

Table G1. Strength of the evidence calculator

Domain:	Risk of Bias judgment (aggregate quality of studies)			Consistency			Directness			Precision		Subtotal numeric
Category						NA (single study)		Indirect				
Subcategory								Surrogate outcome	Indirect comparator			
Subcategory	Low	Mod	High	Consistent	Inconsistent		Direct			Precise	Imprecise	
Numeric rating	4	3	2	0	-1	-0.5 or -1	0	-1	-1	0	-0.5 or -1	
Study A												

Table G2. Interpretation of results

Numeric Score	Strength of Evidence	Interpretation
3.5-4	High	Highly confident of true effect, further research unlikely to change confidence
2.5-3.5	Moderate	Moderately confident of true effect, further research may change confidence and may change effect estimate
1-2.5	Low	Not confident of true effect, further research likely to change confidence and estimate of effect
1-2.5 or NA	Insufficient	Available evidence inadequate for conclusion: too weak, too sparse, too inconsistent

Appendix H. Summary PICOTS Table

Table H1. Summary of PICOTS (population, intervention, comparator, timing and setting) of cesarean reduction strategies in RCTs

Author, Year Country	Population	Intervention/ Comparator (n)	Timing	Setting
World Health Organization, 1994 ¹ Indonesia, Thailand, Malaysia	NR	Baseline (10,049) Use of WHO partogram to guide active management of labor and decisions about cesarean (9,130)	During Labor	NR
Abdel-Aleem et al., 2005 ² Egypt	Academic single site	Standard obstetric care without amnioinfusion (219) Transcervical amnioinfusion (219)	During Labor	Labor and delivery suite
Adamsons et al., 1999 ³ Puerto Rico	Academic single site	Usual care (23) Propanolol labor (34)	During Labor	Labor and delivery suite
Ajadi et al., 2006 ⁴ Nigeria	Academic single site	No amniotomy on admission (64) Amniotomy on admission (64)	During Labor	Labor and delivery suite
Althabe et al., 2004 ⁵ South America	NR	Usual care (39,175) Mandatory second opinion by evidence-based guidelines for indications (34,735)	During Labor	NR
Asher et al., 2009 ⁶ US	Academic single site	Acupuncture (30) Usual care (no acupuncture) (30) Sham acupuncture (29)	During Labor	Clinic
Barakat et al., 2009 ⁷ Spain	Academic single site	No exercise training (80) Exercise training (80)	During Pregnancy	Other
Bernitz et al., 2011 ⁸ Norway	Academic single site	Special unit (282) Normal unit (417) Midwife-led unit (412)	During Labor	Labor and delivery suite
Bidgood et al., 1987 ⁹ UK	Academic single site	Observation (20) High-dose oxytocin (19) Low-dose oxytocin (21)	During Labor	Antenatal clinic Labor and delivery suite
Bloom et al., 1998 ¹⁰ US	Non-academic single site Community	Usual care (531) Walking during 1 st stage of labor (536)	During Labor	Labor and delivery suite
Bloom et al., 2006 ¹¹ US	Academic multisite	Fetal pulse oximetry with oxygen saturation not displayed to clinician (2,712) Fetal pulse oximetry with oxygen saturation displayed to clinician (2,629)	During Labor	Labor and delivery suite

Table H1. Summary of PICOTS (population, intervention, comparator, timing and setting) of cesarean reduction strategies in RCTs (continued)

Author, Year Country	Population	Intervention/ Comparator (n)	Timing	Setting
Campbell et al., 2006 ¹² US	Academic single site	Standard Care (300) Lay doula support (298)	During Labor	Ambulatory care center, diner, homes, various locations
Choudhary et al., 2010 ¹³ India	Academic single site	Standard obstetric care without amnioinfusion (146) Transcervical amnioinfusion (146)	During Labor	Hospital, labor and delivery suite
Cohen et al., 1987 ¹⁴ US	Community Practice	Control (75) Early aggressive management (75)	During Labor	Labor and delivery suite
Cox et al., 1999 ¹⁵ UK	Non-academic single site	Usual Care (240) Inflatable obstetric belt (260)	During Labor	Labor and delivery suite
East et al., 2006 ¹⁶ Australia	Academic multisite	Fetal monitoring with cardioocography only (295) Fetal monitoring without cardiotocography and fetal pulse oximetry (306)	During Labor	Labor and delivery suite
Elferink-Stinkens et al., 2004 ¹⁷ Netherlands	NR	Unusual care (>130,000) Report of departmental data with table and graph form with follow-up (130,000)	During Labor	NR
Frigoletto et al., 1995 ¹⁸ US	Academic single site	Active management (1,009) Usual care (906)	During Labor	Labor and delivery suite
Gagnon et al., 1997 ¹⁹ Canada	Academic single site	Usual nursing care (204) One-to-one nursing care (209)	During Labor	Labor and delivery suite
Gambling et al., 1998 ²⁰ US	Academic single site	Intravenous meperidine analgesia (607) Combined spinal-epidural anesthesia (616)	During Labor	Labor and delivery suite
Garite et al., 2000 ²¹ US	Academic single site	Standard intravenous fluids of 125 ml/hr (94) Increased intravenous fluids (101)	During Labor	Labor and delivery suite
Garite et al., 2000 ²² US	Academic multisite	Fetal monitoring with cardiotocography only (502) Fetal monitoring with cardiotocography and fetal pulse oximetry (508)	During Labor	Labor and delivery suite

Table H1. Summary of PICOTS (population, intervention, comparator, timing and setting) of cesarean reduction strategies in RCTs (continued)

Author, Year Country	Population	Intervention/ Comparator (n)	Timing	Setting
Hamilton et al., 2004 ²³ US & Canada	NR	Labor progress evaluated by plotting cervical dilatation against time (2,514) Computerized reference range used to evaluate labor progress (2,474)	During Labor	NR
Harper et al., 2006 ²⁴ US	Academic single site	Usual care (26) Acupuncture sessions (30)	During Labor	Clinic
Harvey et al., 1996 ²⁵ Canada	Non-academic multi site	Physician care (93) Nurse-midwife care (101)	During Labor	Clinic, labor and delivery suite
Hemminki et al., 1990 ²⁶ Finland	Academic single site	Usual care (118) Midwifery student support (122)	During Labor	Labor and delivery suite
Hinshaw et al., 2008 ²⁷ UK	Non-academic multi site	Delayed oxytocin (204) Early oxytocin (208)	During Labor	Clinic
Hodnett et al., 2002 ²⁸ US & Canada	Multi-site (9 academic and 4 non-academic)	Usual care (3,461) Nurse support (3,454)	During Labor	Labor and delivery suite
Hofmeyr et al., 1998 ²⁹ South Africa	Academic multisite	Standard obstetric care without amnioinfusion (176) Transcervical amnioinfusion (176)	During Labor	Labor and delivery suite
Homer et al., 2001 ³⁰ Australia	NR	Standard hospital-based care (539) Community-based model care (550)	During Pregnancy	Antenatal clinics, public hospital labor and delivery suite
Jalil et al., 2009 ³¹ Malaysia	Academic single site	IM pethidine analgesia (98) Epidural ropivacaine 0.2% with fentanyl 2 µg/ml (94)	During Labor	Labor and delivery suite
Janssen et al., 2006 ³² Canada	Multi site	Telephone triage (731) Home-based triage (728)	During Labor	Other

Table H1. Summary of PICOTS (population, intervention, comparator, timing and setting) of cesarean reduction strategies in RCTs (continued)

Author, Year Country	Population	Intervention/ Comparator (n)	Timing	Setting
Karraz, 2003 ³³ France	Non-academic single site	Intermittent epidural bolus injections of 0.1% ropivacaine with 0.6 µg/ml sufentanil, non-ambulatory (74)	During Labor	Labor and delivery suite
		Intermittent epidural bolus injections of 0.1% ropivacaine with 0.6 µg/ml sufentanil, ambulatory (141)		
Kennell et al., 1991 ³⁴ US	Community practice	Control group assigned after birth (204)	During Labor	Labor and delivery suite
		Received support of a doula (212)		
		Observed by an inconspicuous observer (200)		
Kuhnert et al., 2004 ³⁵ Germany	NR	Fetal monitoring with cardiotocography and fetal scalp blood sampling only (73)	During Labor	NR
		Fetal monitoring with cardiotocography and fetal pulse oximetry and fetal scalp blood sampling (73)		
Lavender et al., 1998 ³⁶ UK	Academic single site	3-hour partogram (302)	During Labor	Labor and delivery suite
		4-hour partogram (311)		
		2-hour partogram (315)		
Lavender et al., 2006 ³⁷ UK	Academic single site	4-hour partogram (1,485)	During Labor	Labor and delivery suite, birthing center
		2-hour partogram (1,490)		
Lopez-Zeno et al., 1992 ³⁸ US	Community practice	Traditional management (354)	During Labor	Labor and delivery suite
		Active management (351)		
Mahomed et al., 1998 ³⁹ Zimbabwe	Academic multisite	Standard obstetric care without amnioinfusion (336)	During Labor	Labor and delivery suite
		Transcervical amnioinfusion (325)		
Matsuo et al., 2009 ⁴⁰ US	Academic single site	Usual care (32)	During Labor	Hospital, labor and delivery suite
		Dental support device during active pushing (32)		
McGrath and Kennell, 2008 ⁴¹ US	Community practice (childbirth education classes in the greater Cleveland area)	Routine care (196)	During Labor	Labor and delivery suite
		Doula support (224)		
McNiven et al., 1998 ⁴² Canada	Academic single site	Direct admission (104)	During Labor	Labor and delivery suite
		Early labor assessment (105)		

Table H1. Summary of PICOTS (population, intervention, comparator, timing and setting) of cesarean reduction strategies in RCTs (continued)

Author, Year Country	Population	Intervention/ Comparator (n)	Timing	Setting
Mehrangiz et al., 2004 ⁴³ Iran	Academic single site	Promethazine only (50)	During Labor	Labor and delivery suite
		Paracervical block with promethazine (50)		
Moodley et al., 1998 ⁴⁴ South Africa	Academic single site	Standard obstetric care without amnioinfusion (30)	During Labor	Labor and delivery suite
		Transcervical amnioinfusion (30)		
Nicholson et al., 2008 ⁴⁵ US	Academic multisite	Standard care (134)	During Pregnancy	Labor and delivery suite
		Induction of labor (136)		
Norris et al., 2001 ⁴⁶ US	Academic single site	Epidural analgesia (1112)	During Labor	Labor and delivery suite
		Combined spinal-epidural anesthesia (1071)		
Ojala et al., 2006 ⁴⁷ Finland	Academic single site	Fetal monitoring with cardiotocography only (739)	During Labor	Labor and delivery suite
		Fetal monitoring with STAN (733)		
Olofsson et al., 1998 ⁴⁸ Sweden	Academic single site	Epidural anesthesia with high dose local anesthetic (0.25% bupivacaine with adrenaline) (435)	During Labor	Labor and delivery suite
		Epidural anesthesia with low dose (0.125% bupivacaine with sufentanil 10 µg) (422)		
O'Sullivan et al., 2009 ⁴⁹ UK	Academic single site	Usual care (1,216)	During Labor	Hospital, labor and delivery suite
		Allowed to eat during labor (1,227)		
Palomäki et al., 2006 ⁵⁰ Finland	Academic single site	Oxytocin plus placebo (55)	During Labor	Labor and delivery suite
		Oxytocin plus propranolol (55)		
Pattinson et al., 2003 ⁵⁰ South Africa	Academic single site	Expectant management (350)	During Labor	Labor and delivery suite
		Aggressive management (344)		
Phipps et al., 2009 ⁵¹ Australia	Academic single site	Standard care (50)	During Pregnancy	Antenatal Class
		Structured education for pushing (50)		
Rathor et al., 2002 ⁵³ India	Academic single site	Standard obstetric care without amnioinfusion (100)	During Labor	Labor and delivery suite
		Transcervical amnioinfusion (100)		

Table H1. Summary of PICOTS (population, intervention, comparator, timing and setting) of cesarean reduction strategies in RCTs (continued)

Author, Year Country	Population	Intervention/ Comparator (n)	Timing	Setting
Regi et al., 2009 ⁵⁴ India	Academic single site	Standard obstetric care without amnioinfusion (75)	During Labor	Labor and delivery suite
		Transcervical amnioinfusion (75)		
Rogers et al., 1997 ⁵⁵ US	Academic single site	Usual care (205)	During Labor	Labor and delivery suite
		Active management (200)		
Sadler et al., 2000 ⁵⁶ New Zealand	Academic single site	Routine management (331)	During Labor	Labor and delivery suite
		Active management (320)		
		Usual care (906)		
Saisto et al., 2001 ⁵⁷ Finland	Community	Conventional therapy (91)	During Pregnancy	Clinic
		Intensive therapy (85)		
Sanchez-Ramos et al., 1996 ⁵⁸ US	Academic single site	Oxytocin plus placebo (47)	During Labor	Labor and delivery suite
		Oxytocin plus propranolol (49)		
Scheepers et al., 2002 ⁵⁹ Netherlands	Academic single site	Placebo (99)	During Labor	Labor and delivery suite
		Oral carbohydrate solution (102)		
Skrablin et al., 2011 ⁶⁰ Croatia	Academic single site	Continuous epidural (104)	During Labor	Labor and delivery suite
		Intermittent epidural (101)		
Somprasit et al., 2005 ⁶¹ Thailand	Academic single site	Conventional management (640)	During Labor	Labor and delivery suite
		Active management (320)		
Spallicci et al., 2007 ⁶² Brazil	Academic single site	Placebo cervical injection (85)	During Pregnancy	Labor and delivery suite
		Hyaluronidase injection in cervix (83)		
Strong et al., 1990 ⁶³ US	Academic single site	Standard care (30)	During Labor	Labor and delivery suite
		Amnioinfusion (30)		
Trueba et al., 2000 ⁶⁴ Mexico	Community Practice	Standard care (50)	During Labor	Labor and delivery suite
		Childbirth educator trained as doula (50)		

Table H1. Summary of PICOTS (population, intervention, comparator, timing and setting) of cesarean reduction strategies in RCTs (continued)

Author, Year Country	Population	Intervention/ Comparator (n)	Timing	Setting
Vayssiere et al., 2007 ⁶⁵ France	Academic multisite	Fetal monitoring with cardiotocography only (400) Fetal monitoring with cardiotocography and STAN (399)	During Labor	Labor and delivery suite
Waldenstrom et al., 1997 ⁶⁶ Sweden	Non-academic single site	Standard maternity care (932) Birth center care (928)	During Pregnancy	Labor and delivery suite
Waldenstrom et al., 2001 ⁶⁷ Sweden	Non-academic single site	Standard care (505) Team midwife care (495)	During Pregnancy	Clinic, labor and delivery suite
Windrim et al., 2007 ⁶⁸ Canada	Academic multisite	Labor progress documented by standard sequential notes (962) Partogram added to standard written labor progress notes (970)	During Labor	Labor and delivery suite

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