Comparative Effectiveness Review
Number 80

Effective Health Care Program

Strategies To Reduce Cesarean Birth in Low-Risk Women

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

Effective Health Care Program

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

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Effective Health Care

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 cesarean[17]
- Amplified perception of the risk of medicolegal liability claims for less than perfect infant outcomes or for failing to intervene[18]
- Shifts in consumer attitude that include less fear of or regret about cesarean[19]
- Lower psychosocial or emotional value placed on the experience of vaginal birth[20]
- 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 cesarean[24]

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)	**Admissible designs** Randomized controlled trials of interventions (KQs 1–4) Pre- and post-studies related to large-scale health systems changes (KQ2 only) **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

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.

Methods

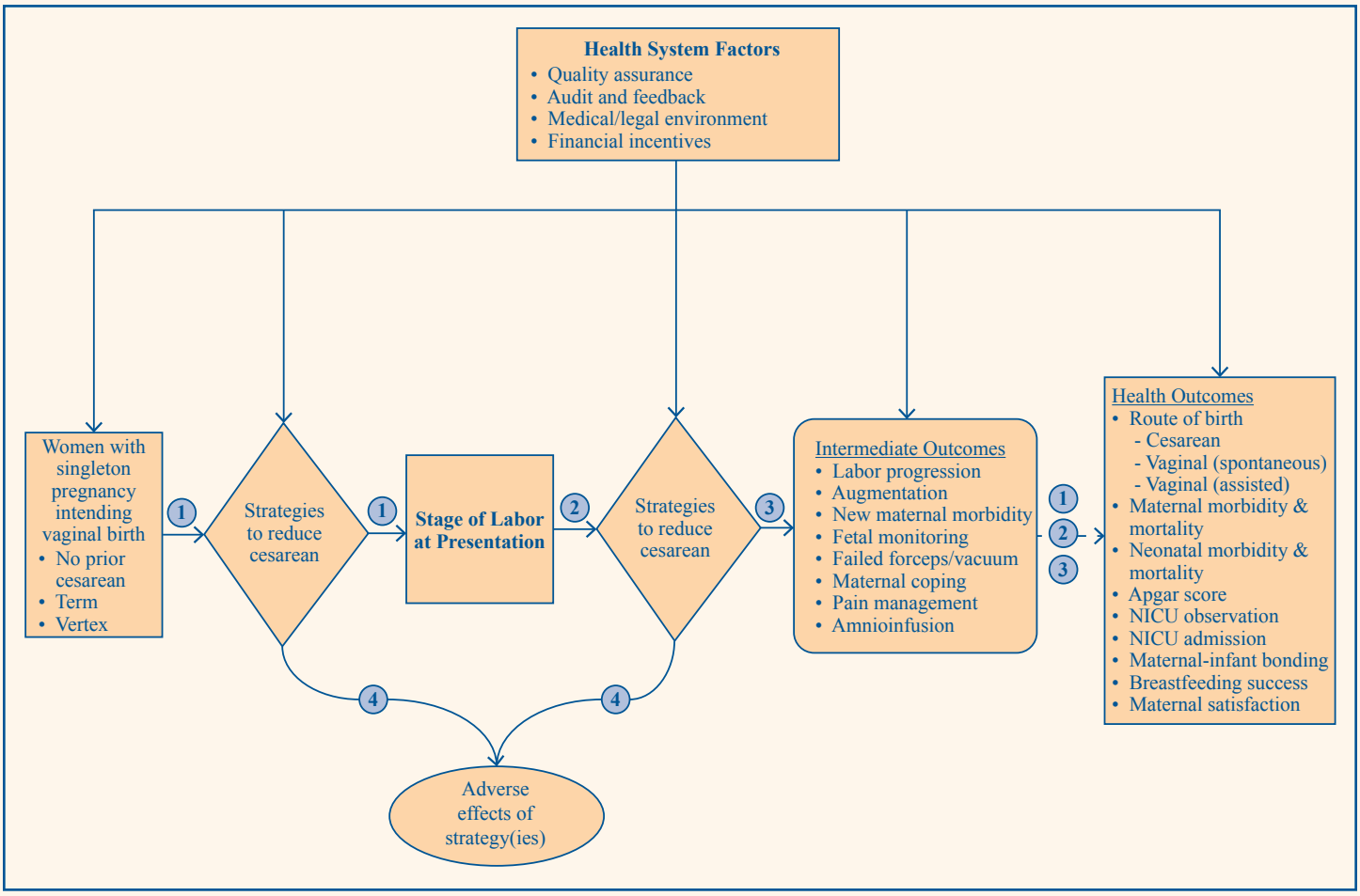
Input From Stakeholders

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

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.

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

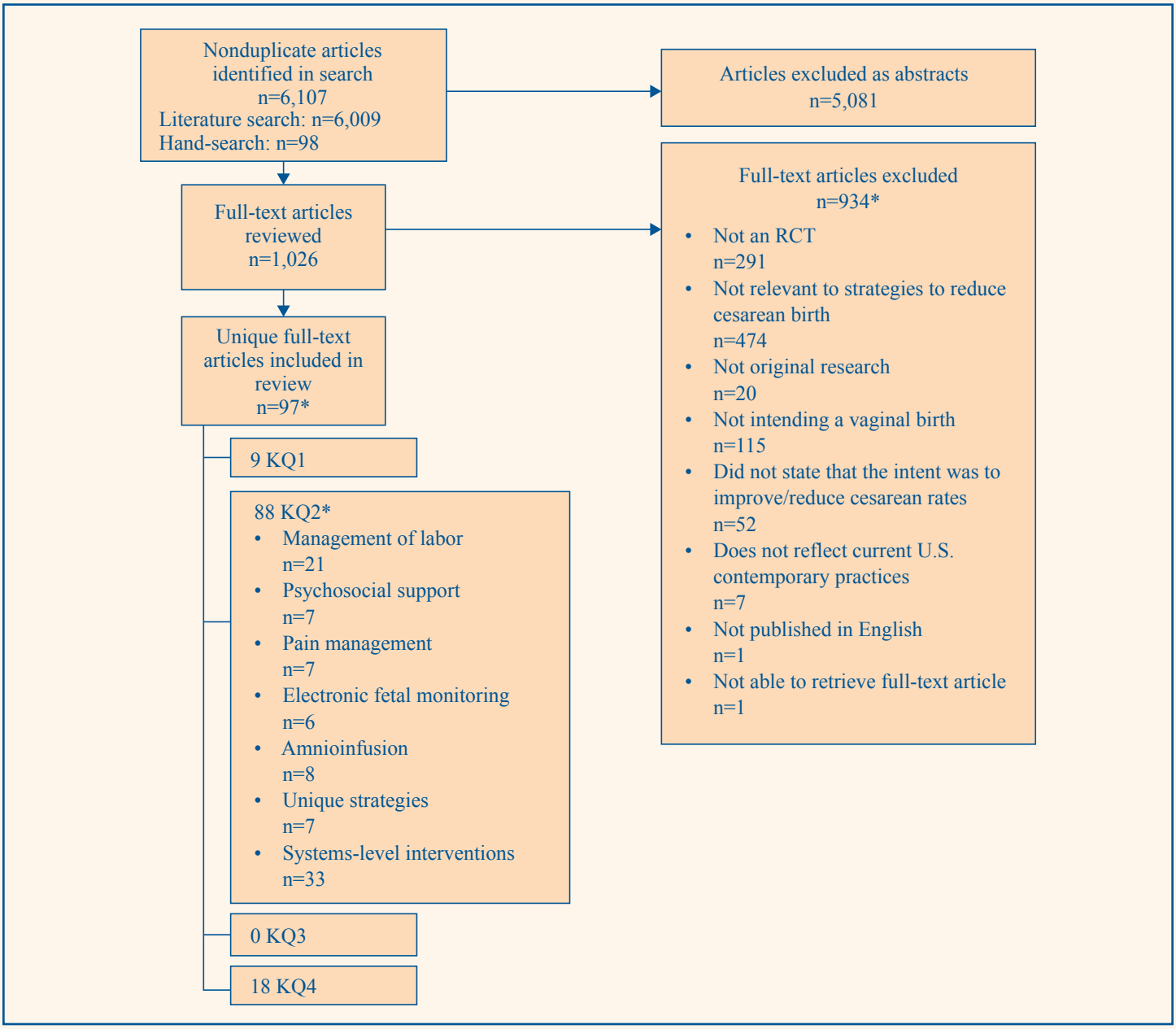
Literature Search Yield

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.

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

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.

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 ropivicaine 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**
KQ1. Strategies During Pregnancy (n=9)					
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
KQ2. Strategies During Labor					
Management of Labor (n=21)					
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**
KQ2. Strategies During Labor (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 studies and 1 fair-quality study
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, 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	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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Full Report

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