Effective Health Care Program

Future Research Needs Paper
Number 22

Future Research Needs for Strategies To Reduce Cesarean Birth in Low-Risk Women

AHRQ
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Future Research Needs Paper

Number 22

Future Research Needs for Strategies To Reduce Cesarean Birth in Low-Risk Women

Identification of Future Research Needs From Comparative Effectiveness Review No. 80

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. 290-2007-10065-I

Prepared by:
Vanderbilt Evidence-based Practice Center
Nashville, TN

Investigators:
Rashonda M. Lewis, J.D., M.H.A.
J. Nikki McKoy, M.P.H.
Jeffrey C. Andrews, M.D.
Rebecca N. Jerome, M.L.I.S., M.P.H.
Frances E. Likis, Dr.P.H., N.P., C.N.M.
Tanya S. Surawicz, M.P.H.
Stephaine H. Walker, M.D., M.P.H.
Katherine E. Hartmann, M.D., Ph.D.

AHRQ Publication No. 12(13)-EHC131-EF
October 2012
Addendum added December 2012

Addendum to Future Research Needs for Strategies To Reduce Cesarean Birth in Low-Risk Women

This report was posted for public comment on the AHRQ Effective Health Care Web site from October 22, 2012, to November 19, 2012. A commenter noted that family medicine practitioners are important stakeholders to engage in research related to maternity care as they often provide care to pregnant women. The Comparative Effectiveness Review (CER) Key Informant group and Technical Expert Panel included two individuals representing family medicine. These representatives provided input and guidance as we developed the CER, including the CER section on future research needs, which served as the springboard for the Future Research Needs (FRN) prioritization project. Family medicine representatives also peer reviewed the full CER. In addition, the FRN stakeholder workgroup included a representative from family medicine. We did attempt, albeit unsuccessfully, to include additional family medicine representatives as part of the FRN stakeholder group. We agree that inclusion of family medicine practitioners as stakeholders is important; however, as this comment did not materially affect the content of the report, we did not make any changes.

A commenter also noted that further research in this area is not necessary; rather, the health care community should act on current knowledge about promoting vaginal births. We agree that the health care community should continue the use of evidence-based practices to reduce cesarean births. However, the CER identified a number of evidence gaps and methodologic challenges that can be and should be addressed by future studies. For the majority of strategies included in the CER, the evidence is insufficient, including many instances in which a single study is the only evidence supporting the approach. The top-tier research questions identified in the FRN report encompass strategies for which strength of evidence is insufficient to low due to few quality studies. Additional quality trials are needed to confirm the effectiveness of strategies and address methodologic limitations found in the current literature. As this comment did not materially affect the content of the report, we did not make any changes.

This report is based on research conducted by the Vanderbilt Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10065-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

The information in this report is intended to help health care researchers and funders of research make well-informed decisions in designing and funding research and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of scientific judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical research and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances.

None of the investigators have any affiliation or financial involvement that conflicts with the material presented in this report.

Suggested citation: Lewis RM, McKoy JN, Andrews JC, Jerome RN, Likis FE, Surawicz TS, Walker SH, Hartmann KE. Future Research Needs for Strategies To Reduce Cesarean Birth in Low-Risk Women. Future Research Needs Paper No. 22. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No.290-2007-10065-I.) AHRQ Publication No. 12(13)-EHC131-EF. Rockville, MD: Agency for Healthcare Research and Quality. October 2012. Addendum added December 2012. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

An important part of evidence reports is to not only synthesize the evidence, but also to identify the gaps in evidence that limited the ability to answer the systematic review questions. AHRQ supports EPCs to work with various stakeholders to identify and prioritize the future research that is needed by decisionmakers. This information is provided for researchers and funders of research in these Future Research Needs papers. These papers are made available for public comment and use and may be revised.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The evidence reports undergo public comment prior to their release as a final report.

We welcome comments on this Future Research Needs document. 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.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Stephanie Chang, M.D., M.P.H.
Director, EPC Program
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Shilpa H. Amin, M.D., M.BSc., FAAFP
Task Order Officer
Evidence-based Practice Center Program
Agency for Healthcare Research and Quality

Acknowledgments

We are indebted to the stakeholders who committed time, expertise, and thoughtful insight to this project. We appreciate the support of the AHRQ Task Officer, Shilpa Amin, M.D., M.BSc., FAAFP. Finally, we acknowledge the extraordinary contributions of our colleagues at the Vanderbilt Evidence-based Practice Center, authors of the 2012 Comparative Effectiveness Review, Strategies To Reduce Cesarean Birth in Low-Risk Women.

Future Research Needs for Strategies To Reduce Cesarean Birth in Low-Risk Women

Structured Abstract

Objectives. The objective of this Future Research Needs project is to identify top-priority research needs in the area of strategies to reduce cesarean birth in low-risk women. The research needs identified in this report include knowledge gaps related to the effectiveness of specific strategies for reducing use of cesarean birth compared with usual care, knowledge gaps about factors that drive patient and provider preferences and attitudes, and recommendations for methodologic improvements. This project builds on the evidence gaps and methodologic issues identified in the Comparative Effectiveness Review (CER) Strategies To Reduce Cesarean Birth in Low-Risk Women.

Data sources. In Phase 1, stakeholders participated in a teleconference and then a Web-based survey to build a comprehensive list of research questions and methodologic recommendations. In Phase 2, stakeholders participated in one conference call and completed three Web-based surveys to prioritize research questions and recommendations. We identified currently funded and recently completed research between February 2012 and June 2012. To identify currently funded or recently completed randomized controlled trials intended to reduce use of cesarean delivery, we conducted searches of U.S. government resources (i.e., ClinicalTrials.gov, NIH Reporter), international trial registries (e.g., Current Controlled Trials), and other potential funding sources such as relevant associations and organizations (e.g., American College of Nurse-Midwives, American Congress of Obstetricians and Gynecologists).

Results. Thirteen stakeholders representing the perspective of patient advocacy groups, academic researchers, obstetrician-gynecologists, nursing and nurse-midwifery professional organizations, payers, and national foundations and societies agreed to participate in one or more of the stages of ranking and prioritization. The group included five Key Informants/Technical Expert Panel members from the draft CER. In Phase 1, stakeholders generated a "snowballed" list of 47 research questions and 17 methodologic recommendations. In Phase 2, stakeholders worked from the snowballed list to prioritize research needs. In Phase 3, the Evidence-based Practice Center investigators developed recommendations for optimal study design.

Conclusions. Our multistep process for identifying, multiplying, and prioritizing research questions to advance research in the area of strategies to reduce cesarean birth in low-risk women resulted in an actionable list of research topics to fill specific knowledge gaps. The top-tier research questions reflect a focus on standardization strategies for induction and arrest of labor (three of the top five research questions), systems-level strategies (one of five), and novel staffing models (one of five). For strategies that standardize induction and definitions of arrest of labor, we recommend cluster randomized controlled trials with randomization of entire labor and delivery units. For trials of systems-level strategies and staffing models, we recommend multisite studies to improve power and generalizability. The top-tier methodologic improvements focused on improving the capture of short- and long-term birth outcomes.

Contents

Executive Summary ES-1
Background 1
2012 AHRQ Comparative Effectiveness Review 1
Key Questions Addressed by 2012 CER 2
Evidence Gaps Identified in Prior Work 4
Methods 7
Identification of Evidence Gaps 7
Criteria for Prioritization 8
Initial Voting 8
Initial Ranking 8
Final Ranking of Reduced List of Items 9
Engagement of Stakeholders, Researchers, and Funders 10
Research Question Development and Research Design Considerations 11
Results 12
Engagement of Stakeholders, Researchers, and Funders 12
Identification of Evidence Gaps 13
Prioritization 16
Research Needs 18
Identification of Current and Ongoing Studies 21
Discussion 22
Conclusion 24
References 25
Abbreviations 27

Tables

Table A. Evidence Gaps Identified in the Comparative Effectiveness Review ES-2
Table B. Methodologic Issues Identified in the Comparative Effectiveness Review ES-2
Table C. Top-Tier Research Questions From Final Prioritization ES-6
Table D. Top-Tier Methodologic Recommendations From Final Prioritization ES-6
Table 1. Evidence Gaps Identified in the Comparative Effectiveness Review 4
Table 2. Methodologic Issues Identified in the Comparative Effectiveness Review 5
Table 3. Snowballed List of Research Questions 14
Table 4. Snowballed List of Methodologic Recommendations 15
Table 5. Highest Priority Research Questions 18
Table 6. Highest Priority Methodologic Recommendations 21

Figures

Figure A. Analytic Framework for Strategies To Reduce Cesarean Birth in Low-Risk Women ES-3
Figure B. Stakeholder Participation at Each Phase of the Prioritization Process ES-5
Figure 1. Analytic Framework Illustrating Research Gaps 6
Figure 2. Identification of Evidence Gaps 8
Figure 3. Prioritization Process 9
Figure 4. Stakeholder Recruitment and Participation Results 12

Figure 5. Snowballing Results 13
Figure 6. Prioritization Results 17

Appendixes

Appendix A. Stakeholder Invitation Letter
Appendix B. Search Strategy for Ongoing Studies
Appendix C. List of Ongoing Studies
Appendix D. Prioritization Tools and Results

Executive Summary

Background

This investigation of future research needs builds on the Comparative Effectiveness Review (CER) Strategies To Reduce Cesarean Birth in Low-Risk Women, conducted by the Vanderbilt Evidence-based Practice Center (EPC). The rationale for the review is a concerning increase in cesarean use over the past decade. 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 more than 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]

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.[3,4] Nonetheless, relatively little focus has been placed on research specifically designed to assess strategies to reduce use of cesarean. The CER aimed to bring that literature to the forefront by systematically examining the outcomes of interventions intended to reduce use of cesarean among low-risk women.

The Comparative Effectiveness Review addressed 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?

After reviewing the evidence, the EPC investigators concluded that, while some strategies show promise, no particular strategy was uniformly successful in reducing cesareans. The strength of the evidence was low to insufficient for each of the strategies reviewed.

The CER noted topic-related evidence gaps in the literature and common methodologic issues. These gaps are summarized in Tables A and B, and categorized by the most relevant PICOTS (population, intervention, comparator, outcome, timing, and setting) elements. Two of the eight topic-related evidence gaps do not fit within the PICOTS framework and are described as "determinants." These gaps relate to macrolevel factors that influence patient, provider, and system preferences about cesarean and decisions to use cesarean. Similarly, two of the nine methodologic issues apply generally to studies and not to a specific PICOTS element. These issues are described as "cross-cutting."

Table A. Evidence gaps identified in the Comparative Effectiveness Review

Evidence Gap	Relevant PICOTS Elements
Gaps in knowledge about the determinants of cesarean use, including patient, sociocultural, and health care system characteristics	Determinants Timing Setting
Need for qualitative and quantitative research to help determine what factors are contributing to decisions to have elective cesarean	Determinants Timing Setting
Need for multisite research and research across the different racial/ethnic and socioeconomic groups representative of the U.S. population	Population Timing Setting
Need for randomized trials at the systems level to ascertain whether promising intervention components are indeed effective in promoting decreased use of cesarean	Intervention Timing Setting
Need for understanding of the mechanism by which interventions such as doula support exert an effect	Intervention Timing Setting
Gaps in understanding of the effects of staffing models and health care technologies on cesarean rates	Intervention Timing Setting
Need for understanding of the role of informed medical decisionmaking	Intervention Timing Setting
Need for understanding of the role of tort reform and subsequent litigation in cesarean trends	Intervention Timing Setting

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

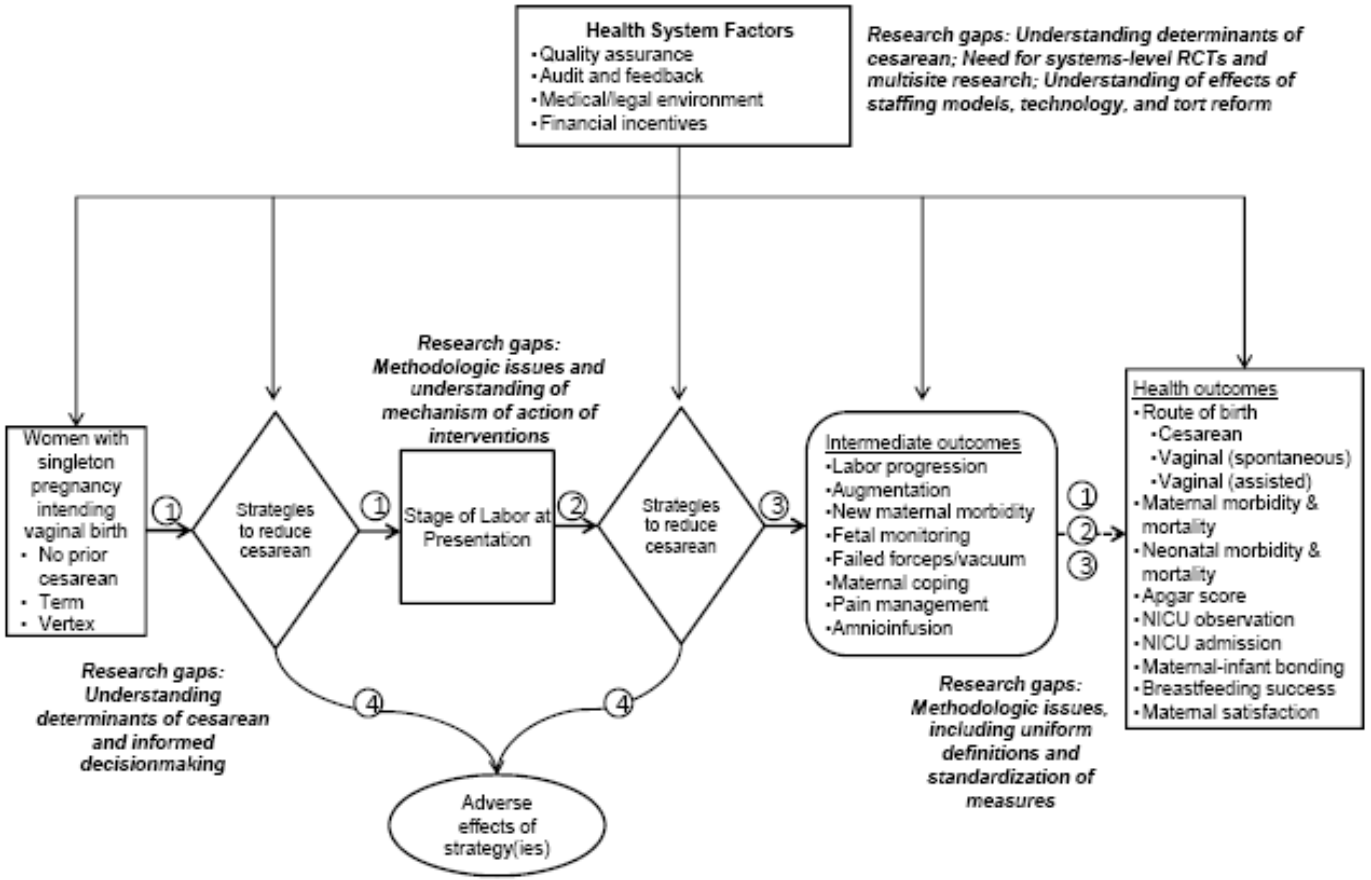
Table B. Methodologic issues identified in the Comparative Effectiveness Review

Methodologic Issue	Relevant PICOTS Element
Lack of appropriately powered randomized trials	Cross-cutting
Lack of power calculations based on plausible estimates	Cross-cutting
Need for validated consensus definitions of indications for cesarean	Intervention
Need for placebo, sham, or attention control comparison groups	Comparators
Need for replications and comparisons of promising interventions	Comparators
Need for tracking and reporting of total, primary, and repeat cesareans in studies not restricted to nulliparous women	Outcomes
Lack of secondary outcomes specified a priori	Outcomes
Need for expanded maternal and infant outcomes and measures of maternal coping, satisfaction, and perceived quality of the birth experience	Outcomes
Need for long-term followup of infants	Outcomes

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

Figure A presents the analytic framework for the CER, which has been modified here to illustrate research gaps identified in the report.

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



NICU = neonatal intensive care unit; RCT = randomized controlled trial
Note: Numbers in circles represent the position of Key Questions in the intervention process.

Methods

Our protocol for obtaining stakeholder input on research question prioritization was loosely based on the principles of the Delphi process, modified to maximize response and facilitate stakeholder discussions**.** The three phases of this project were (1) identification of evidence gaps, (2) stakeholder engagement and prioritization of future research needs, and (3) recommendations for optimal study design.

We invited 24 stakeholders with interests and expertise relevant to reducing use of cesarean. We aimed for balanced representation in the following areas: clinical practice, advocacy, research, and research funding. In phase 1, the EPC investigators developed a list of sample research questions and recommendations for methodologic improvements, based on gaps identified in the draft review of the CER and input from our EPC content experts. We invited the stakeholder panel to participate in a teleconference and then a Web-based survey to make the list broader and more comprehensive, and to suggest topics we may have omitted. We intentionally did not ask the stakeholders to rank questions or to suggest ways to reduce the number of items at this "snowballing" stage of the process, as we wanted to be as inclusive as possible to ensure that the review panel would have a complete and relatively unbiased list of research topics from which to begin the prioritization process.

In phase 2, stakeholders completed three rounds of a modified Delphi process to prioritize research needs. Stakeholders completed a multivoting survey in which they distributed 47 points among the research gaps and 17 points among the methodologic improvements. At the conclusion of this step, the items with the lowest one-third of responses were eliminated. During a teleconference, we asked stakeholders to examine the remaining questions for possible ways to reduce redundancies across questions and combine questions that could be answered in one study design. Next, stakeholders completed a ranking survey in which they ranked the remaining 26 research questions and 10 methodologic improvements from 1 to 26 (highest to lowest) and 1 to 10, respectively. The research questions and methodologic improvements that were ranked in the lowest one-third were eliminated. The last step of the modified Delphi process was the final ranking. Stakeholders ranked the remaining items across the seven domains from the Prioritization Criteria Method (PiCMe).[5] Responses to this final prioritization exercise were then used to create a ranked list of the topics. Items were ranked based on total points assigned to the following seven AHRQ criteria and placed in a top-, middle-, or low-tier category.

- Potential for significant health impact
- Potential to reduce variation in clinical practices
- Potential for significant economic impact
- Potential risk from inaction
- Potential to address inequities
- Potential to allow assessment of ethical, legal, and social issues pertaining to the condition
- Potential for new knowledge

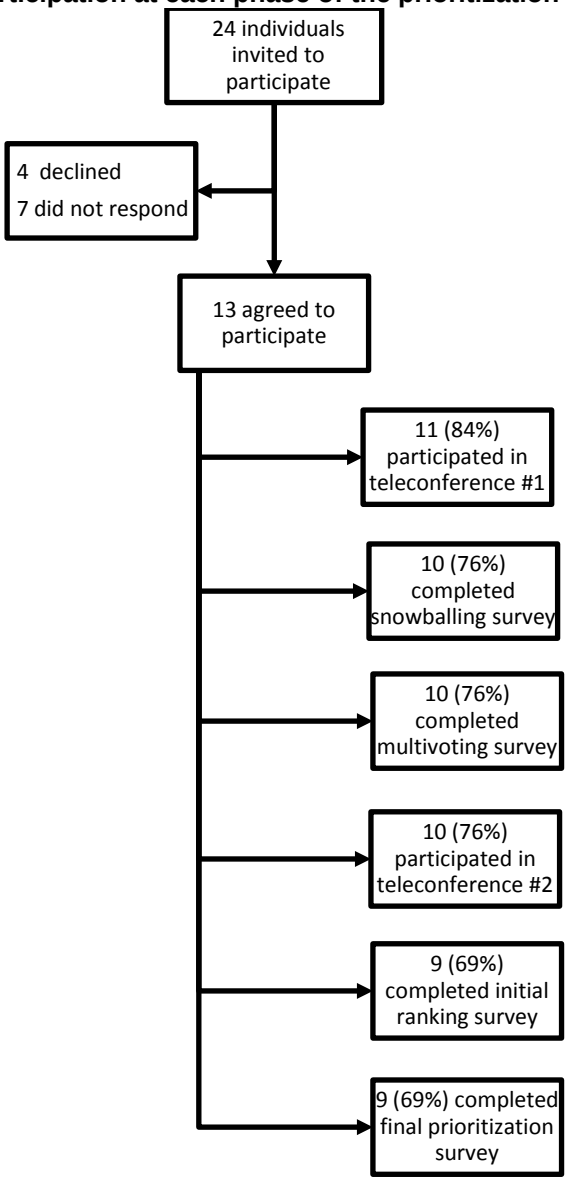
In phase 3, EPC investigators developed recommendations for optimal study designs for the remaining research questions.

Results

Of the 24 stakeholders invited, 13 agreed to participate. Members of the stakeholder group represented clinical practice, maternal health research, health policy, and patient advocacy. The

group included five Key Informants/Technical Expert Panel members from the CER. Stakeholder participation is summarized in Figure B.

Figure B. Stakeholder participation at each phase of the prioritization process



In phase 1, the EPC investigators developed a list of 12 sample research questions and 12 sample methodologic improvements based on evidence gaps identified in the draft review of the CER. This list served as the nidus for stakeholder snowballing. We invited the stakeholder panel to participate in a teleconference and then a Web-based survey to make the list broader and more comprehensive, and to suggest topics we may have omitted. During the snowballing process, stakeholders expanded the initial list to 47 research questions and 17 methodologic recommendations.

In phase 2, stakeholders completed three rounds of a modified Delphi process to identify and prioritize research needs. The final round of prioritization resulted in a list of 16 research questions and 7 recommendations for methodologic improvements ranked by total points

assigned to all 7 AHRQ criteria. Tables C and D present the top-tier future research questions and methodologic recommendations.

Table C. Top-tier research questions from final prioritization

Research Question
When strictly operationalized and compared in clinical trials, what components of systems interventions are effective in reducing cesarean use?
Can tighter standards for induction (indicated or elective) among primiparous patients reduce use of cesarean?
How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?
Would changing the timeframes for normal progress in latent and active labor reduce primary cesarean?
Do different staffing models, such as models that use hospitalists or midwives, reduce the number of cesarean births?

Table D. Top-tier methodologic recommendations from final prioritization

Methodologic Recommendation
Capture all categories of birth outcomes (primary and repeat cesarean, emergent cesarean, assisted vaginal, and spontaneous vaginal births) and related complications, and stratify outcomes by parity.
Develop registries that capture both short-term and long-term outcomes.

Discussion

This project resulted in a list of top-priority research needs that encompass a variety of topics, including standardization strategies for induction and arrest of labor, systems-level strategies, and novel staffing models. The top-tier methodologic recommendations highlight the importance of capturing both short- and long-term birth outcomes.

Inherent challenges face investigators and funding agencies that wish to better understand approaches to reduce use of cesarean among low-risk women. 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.[6] Much of this increase occurred in the past decade.[1] In the current cultural milieu, it cannot be taken for granted that all those who participate in decisions about births and in providing care for women during pregnancy and birth share an objective of reducing use of cesarean.

To obtain meaningful answers that are applicable to the care of women in the United States will require large-scale studies in this country. Several factors suggest that this research will need to be predominantly conducted as multisite randomized trials: (1) existing wide variability in use of cesarean means different settings will enter with a different baseline propensity to use cesarean; (2) baseline use patterns are only part of the culture of care at an institution and desire to change use of cesarean likely varies, so interventions need to be shown to be effective across settings; and (3) secular trends in cesarean use not related to the intervention being studied impair the ability of observational studies to definitively provide evidence for effectiveness. Some topics, such as investigation of comprehensive midwifery care to reduce cesarean use, will challenge the ability of the care system to identify sufficient numbers of providers across multiple sites who are able and willing to participate in such studies. Furthermore, as the methodologic recommendations of this report suggest, a substantial amount of consensus work needs to be done among researchers, professional organizations, and funders to ensure that the

metrics used in research produce data that can be synthesized across families of studies to reach sufficient strength of evidence to inform decisions about care around the Nation.

The priorities identified in this project suggest the importance of research at all points along the continuum represented by our analytic framework. Multiple points of influence need to be studied and the gaps are substantial. The efforts of the stakeholders and our team have identified a multidecade portfolio of questions that need answers.

The high-priority research needs identified in this project inform various points along our analytic framework and the research spectrum—from understanding determinants of cesarean to creating uniform standards and practices for induction and cesarean, exploratory studies, large trials in multiple settings for specific strategies, and creating uniform and expanded panels of outcomes to improve data collection efforts.

Conclusion

Our multistep process for identifying, multiplying, and prioritizing research questions to advance research in the area of strategies to reduce cesarean birth in low-risk women resulted in an actionable list of research topics to fill specific knowledge gaps. The highest priority research questions encompass many topics of interest, which reflect the large number of gaps in the literature. These topics include study of the influence of tighter standards and definitions for induction and cesarean use (elective and indicated); new measures for labor progress; and trials that test the effectiveness of systems-level strategies, midwifery care, payment reform, and novel staffing models for birth units. Randomized controlled trials, multisite studies that improve power and generalizability, and natural experiments were viewed as critical. The highest priority methodologic recommendations call for uniform use of consensus definitions and tracking of short- and long-term maternal and neonatal outcomes.

References

1. Menacker F, Hamilton BE. Recent trends in cesarean delivery in the United States. NCHS Data Brief. 2010 Mar;(35):1-8. PMID: 20334736.
2. Martin JA, Hamilton BE, Sutton PD, et al. Births: final data for 2007. Natl Vital Stat Rep. 2010 Aug 9;58(24):1-85. PMID: 21254725.
3. Bettes BA, Coleman VH, Zinberg S, et al. Cesarean delivery on maternal request: obstetrician-gynecologists' knowledge, perception, and practice patterns. Obstet Gynecol. 2007 Jan;109(1):57-66. PMID: 17197588.
4. Simpson KR, Thorman KE. Obstetric "conveniences": elective induction of labor, cesarean birth on demand, and other potentially unnecessary interventions. J Perinat Neonatal Nurs. 2005 Apr-Jun;19(2):134-44. PMID: 15923963.
5. Prioritization criteria methodology for future research needs proposals within the Effective Health Care Program. [Draft document.] Rockville, MD: Agency for Healthcare Research and Quality; 2012.
6. Zhang J, Troendle J, Reddy UM, et al. Contemporary cesarean delivery practice in the United States. Am J Obstet Gynecol. 2010 Oct;203(4):326 e1- e10. PMID: 20708166.

Background

2012 AHRQ Comparative Effectiveness Review

This investigation of future research needs for strategies to reduce cesarean birth builds on the work of the Vanderbilt University Evidence-based Practice Center (EPC). The Vanderbilt EPC conducted a comparative effectiveness review (CER) on Strategies To Reduce Cesarean Birth which is scheduled for release in June 2012. The rationale for the review cited specific trends in perinatal health with important public health implications.

Thirty-two percent of pregnancies in the United States conclude with a cesarean birth.[1] This record high rate reflects a relative increase of 53 percent in use of cesarean from 1991 to 2007.[1] The pattern of increasing use of cesarean has been concerning for decades, with the last decline of two to three percent occurring in the mid-1990s being fully reversed by 1999 and increasing more than 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."[7] 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 potential to complicate subsequent pregnancies.[8-9] Previously extraordinarily rare complications such as uterine rupture and abnormalities in placental attachment to the uterus, including placenta accreta and percreta, are becoming more common.[10-11] 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 a 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 created "code teams" that conduct practice drills to be prepared for the increasing number of these 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 nine percent to 37 percent for primary cesarean births.[12] 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 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.[13-16]

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.[17] 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 fetus with vertex presentation is 23.9 percent.[18-19] 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.[20-21]

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[22]
- Amplified perception of risk of medico-legal liability claims for less than perfect infant outcomes or for failing to intervene[23]
- Shifts in consumer attitude that include less fear of or regret about cesarean[24]
- Lower psychosocial or emotional value placed on the experience of vaginal birth[25]
- Concerns about pelvic floor damage and future continence[26-27]
- Maternal desire for greater control over the timing and circumstances of birth[3] such as maternal request for elective induction and cesarean[4]

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.[28-29]

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.[30-31] The state of general knowledge about evidence-based approaches to reduce cesarean overall is uncharted.

The comparative effectiveness review focused on strategies to reduce cesarean birth in low-risk women who have a singleton pregnancy, vertex presentation, term birth, and no previous cesarean births. The studies assessed strategies implemented specifically with the goal of reducing cesarean birth, including interventions used during prenatal care, during labor, and as part of health systems interventions. Comparators included usual care, placebo, and comparative strategies or combinations of strategies. Outcomes of interest included route of birth, maternal morbidity and mortality, and neonatal morbidity and mortality. Strategies crossed all health care settings, including home, hospital, provider offices, clinics, and community-based settings.

Key Questions Addressed by 2012 CER

The 2012 AHRQ comparative effectiveness review addressed 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?

Three Key Questions (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.

Key Question 4 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.

KQ1 and KQ2. After reviewing the evidence for KQs 1 and 2, the EPC team concluded that 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. Involvement of doulas for personalized support in labor was the only strategy to achieve evidence of benefit which was low due 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, labor support by nursing and midwifery students, modifications of pain management approaches, fetal pulse oximetry, and fetal assessment by ST analysis. 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. For each instance of inclusion in a successful pre-post intervention, there were instances of unsuccessful use of similar components.

Deficiencies in the strength of evidence most often related to:

- High proportion of strategies that were represented by only one study, often small, 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), or assisted vaginal births.
- Operational definitions of indications for cesarean are incompatible, or poorly described, across studies so that these outcomes cannot be aggregated with confidence across studies.

KQ3. 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 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. 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 and vomiting, and anesthesia-related side effects. Many of the studies included in the review, such as those related to psychosocial support, have no known adverse effects.

Evidence Gaps Identified in Prior Work

The recent comparative effectiveness review on strategies to reduce cesarean birth in low-risk women noted topic-related evidence gaps in the literature and common methodologic issues. These gaps are summarized in Table 1 and categorized by the most relevant PICOTS element(s). Two of the eight topic-related evidence gaps do not fit within the PICOTS framework and are described as "determinants." These gaps relate to macro-level factors that influence patient, provider, and system preferences about cesarean and decisions to use cesarean. Similarly, two of the nine methodologic issues (Table 2) apply generally to studies and not to a specific PICOTS element. These issues are described as "cross-cutting."

Table 1. Evidence gaps identified in the Comparative Effectiveness Review

Evidence Gap	Relevant PICOTS Element(s)
Gaps in knowledge about the determinants of cesarean use, including patient, sociocultural, and health care system characteristics	Determinants Timing Setting
Need for qualitative and quantitative research to help determine what factors are contributing to decisions to have elective cesarean	Determinants Timing Setting
Need for multisite research and research across the different racial/ethnic and socioeconomic groups representative of the U.S. population	Population Timing Setting
Need for randomized trials at the systems level to ascertain whether promising intervention components are indeed effective in promoting decreased use of cesarean	Intervention Timing Setting
Need for understanding of the mechanism by which interventions such as doula support exert an effect	Intervention Timing Setting
Gaps in understanding of the effects of staffing models and health care technologies on cesarean rates	Intervention Timing Setting
Need for understanding the role of informed medical decisionmaking	Intervention Timing Setting
Need for understanding the role of tort reform and subsequent litigation cesarean trends	Intervention Timing Setting

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

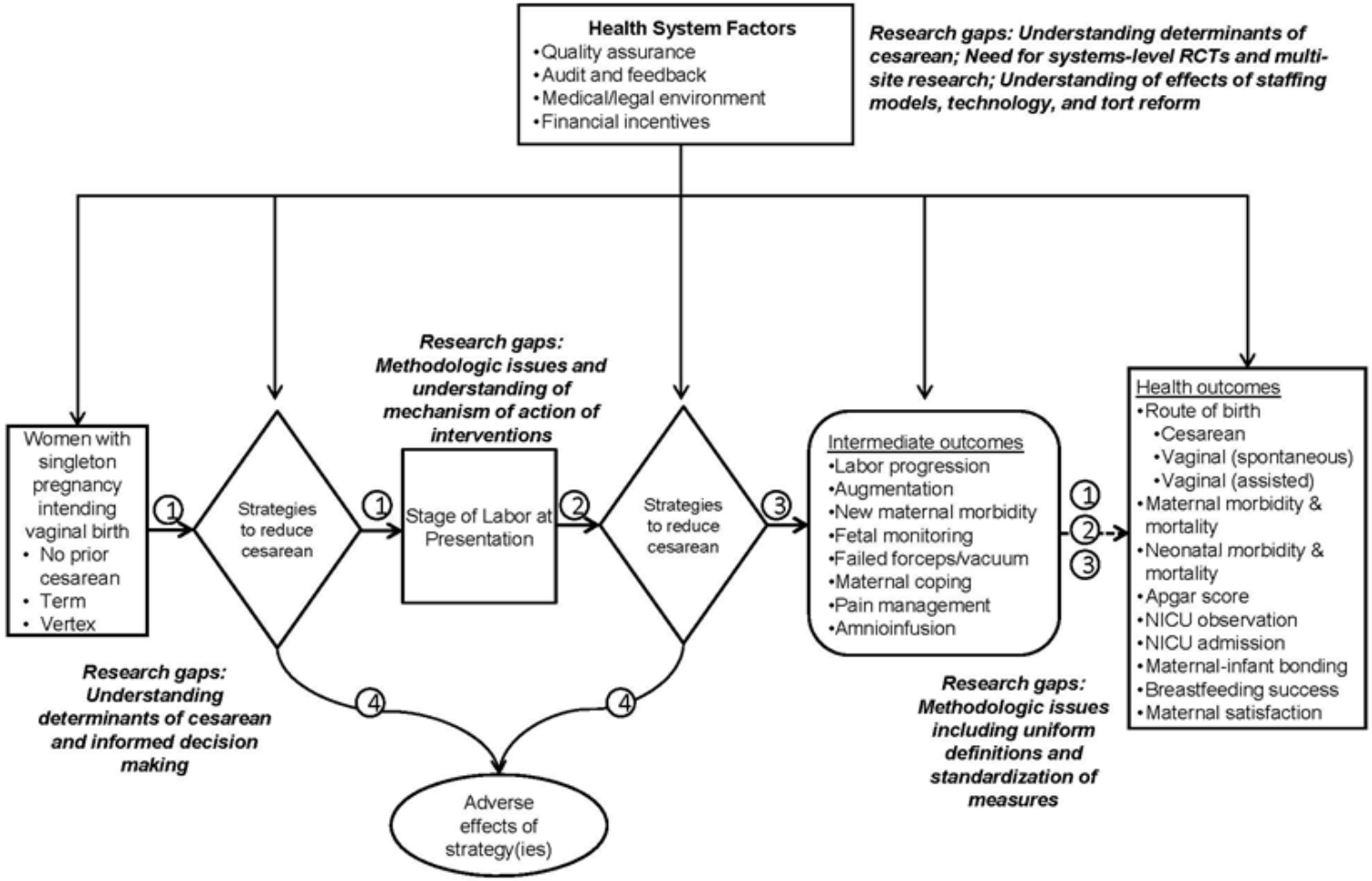
Table 2. Methodologic issues identified in the Comparative Effectiveness Review

Methodologic Issues	Relevant PICOTS Element
Lack of appropriately powered randomized trials	Cross-cutting
Lack of power calculations based on plausible estimates	Cross-cutting
Need for validated consensus definitions of indications for cesarean	Intervention
Need for placebo, sham, or attention control comparison groups	Comparators
Need for replications and comparisons of promising interventions	Comparators
Need for tracking and reporting of total, primary, and repeat cesareans in studies not restricted to nulliparous women	Outcomes
Lack of secondary outcomes specified a priori	Outcomes
Need for expanded maternal and infant outcomes and measures of maternal coping, satisfaction, and perceived quality of the birth experience	Outcomes
Need for long-term follow up of infants	Outcomes

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

The analytic framework for the 2012 CER has been modified here to illustrate research gaps identified in the report (Figure 1). 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. It shows how adverse events may occur at any point after the strategy has been implemented. The research gaps described in the framework align with one or more Key Questions. For example, the research gap "determinants of cesarean" appears early in the framework because it applies to all downstream Key Questions.

Figure 1. Analytic framework illustrating research gaps



NICU = Neonatal intensive care unit
Note: Numbers in circles indicate the position of Key Questions in intervention process.

Methods

Our protocol for obtaining stakeholder input on research question prioritization was loosely based on the principles of the Delphi process, modified to maximize response and facilitate stakeholder discussions. In short, we began by identifying a list of candidate research topics and initiating an iterative electronic process to refine and then rank the topic list. We also conducted two teleconferences that allowed personal interaction between the participants and discussion of the research priorities.

The protocol for this project was reviewed and approved by the Vanderbilt Institutional Review Board. Potential stakeholders were contacted by email, with a followup personal phone call as needed, to participate in the process.

The three phases of this project were (1) identification of evidence gaps, (2) stakeholder engagement and prioritization of future research needs, and (3) recommendations for optimal study design. This section summarizes these phases.

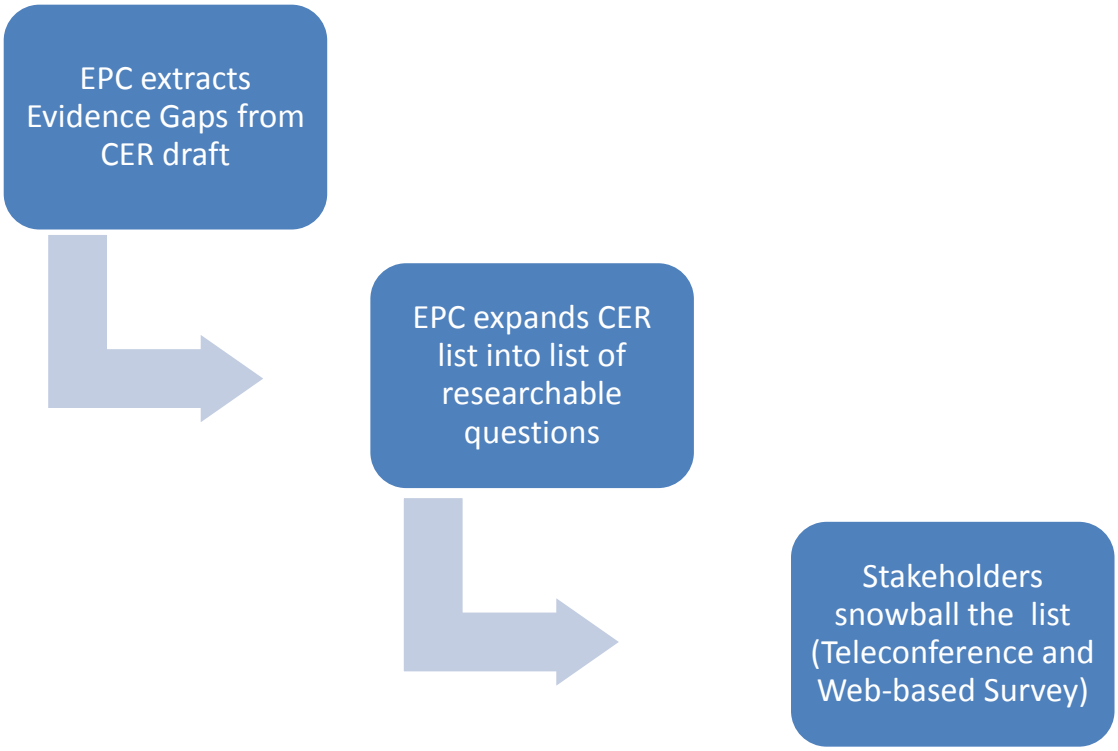
Identification of Evidence Gaps

In the draft CER, we identified research gaps for strategies to reduce cesarean birth for low-risk women. We then developed a list of sample research questions and methodologic recommendations, based on the draft review and input from our EPC content experts. We invited the stakeholder panel to participate in a teleconference and then a web-based survey to make the list broader and more comprehensive and to suggest topics we may have omitted. We intentionally did not ask the stakeholders to rank questions or to suggest ways to reduce the number of items at this snowballing point in the process, as we wanted to be as inclusive as possible, to ensure that the review panel would have a complete and relatively unbiased list of research topics from which to begin the prioritization process. Figure 2 illustrates the process.

We developed a list of ongoing research and funding opportunities to help determine if research needs were currently being addressed and the general direction of current research.

To identify currently funded or recently completed randomized trials intended to reduce use of cesarean birth (Appendix C), we conducted searches of U.S. government resources (i.e. ClinicalTrials.gov, NIH Reporter), international trial registries (e.g. Current Controlled Trials), and other potential funding sources such as relevant associations and organizations (e.g. American College of Nurse-Midwives, American Congress of Obstetricians and Gynecologists). Our searches were broad, employing the use of the keywords “cesarean” and “caesarean” with an accompanying scan of retrieved projects to identify those using a randomized trial design. We assessed the list against the CER inclusion criteria and shared the list with stakeholders at the beginning of the snowballing process.

Figure 2. Identification of evidence gaps



CER = Comparative Effectiveness Review; EPC = Evidence-based Practice Center

Criteria for Prioritization

Our protocol for prioritization included three iterative steps: initial voting, initial ranking, and final ranking of reduced list of items.

Initial Voting

We initiated prioritization with the snowballed list of items which included 47 research questions and 17 methodologic recommendations. Stakeholders were asked to respond to a web-based survey in which they distributed 47 points among the research gaps and 17 points among the methodologic issues. Items with the most points were considered the most popular. At the conclusion of this step the items with the lowest one-third of responses were eliminated. During a teleconference we asked stakeholders to examine the remaining questions for possible ways to reduce redundancies across questions and combine questions that could be answered in one study design

Initial Ranking

Stakeholders then ranked the remaining 26 research questions and 10 methodologic improvements from 1 to 26 and 1 to 10, respectively. The research questions and methodologic improvements that were ranked the lowest one-third were eliminated.

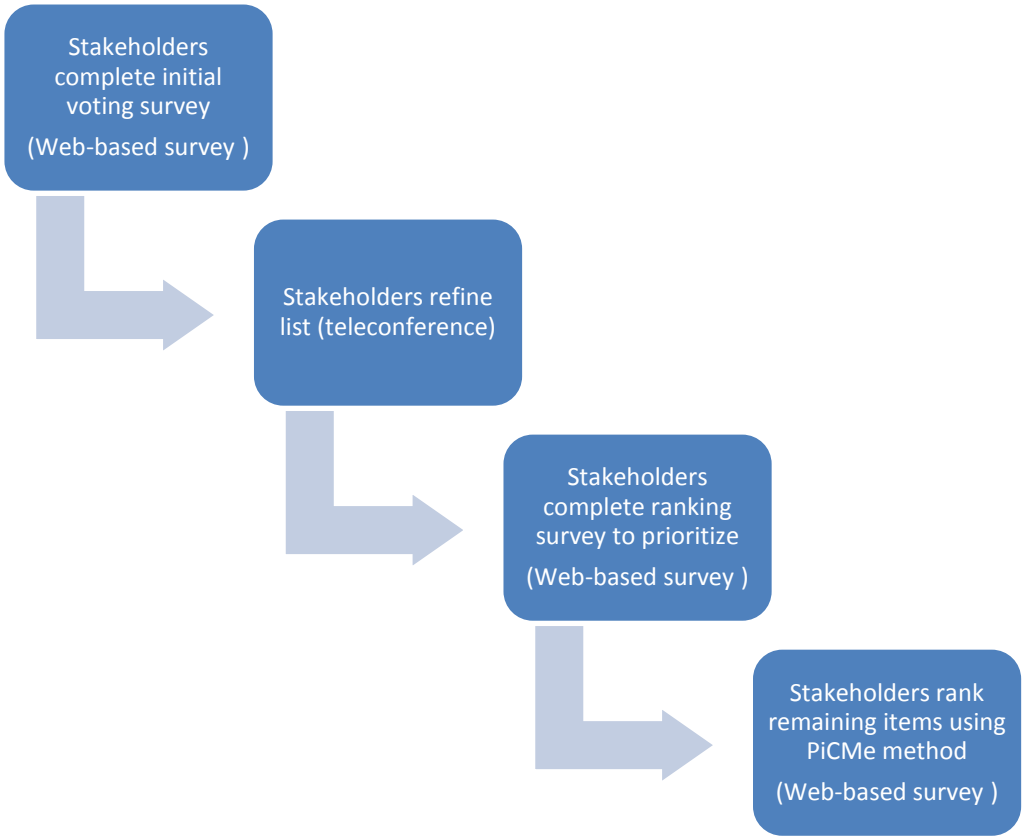
Final Ranking of Reduced List of Items

We then sent the reduced list of 16 future research questions and seven methodologic issues to the stakeholders and asked them to again rank items across the seven criteria from the AHRQ Prioritization Criteria Method (PiCMe). The seven criteria included:

- Potential for significant health impact
- Potential to reduce variation in clinical practices
- Potential for significant economic impact
- Potential risk from inaction
- Potential to address inequities
- Potential to allow assessment of ethical, legal, and social issues pertaining to the condition, and
- Potential for new knowledge

Responses to this final prioritization exercise were then used to create a ranked list of the topics. For this final prioritization step, we scored research questions and methodologic recommendations based on total points assigned to seven AHRQ criteria. We established tiers for top-, middle-, and lower-ranked items and created cut-off points where natural breaks in total points occurred. This tiered list represents our final list of research needs and recommendations. To provide more detail about top-tier items for each specific AHRQ criterion, we identified the top-five research questions and top-two methodologic recommendations for each criterion. Figure 3 describes the prioritization process.

Figure 3. Prioritization process



PiCMe = Prioritization Criteria Method

Engagement of Stakeholders, Researchers, and Funders

The Vanderbilt EPC investigators worked to develop a group of stakeholder individuals and organizations with expertise and vested interest in the topic. We aimed for balanced representation in the following areas: clinical practice, advocacy, research, and research funding

The EPC investigators developed an initial list of stakeholder individuals and organizations using (1) the CER Technical Expert Panel (TEP) list and (2) recommendations from the EPC, (3) authors in the related literature, and (4) advocates in the area of informed medical decision-making. The TEP list served as a logical starting place because TEP members are experts in the area of strategies to reduce cesarean birth, are knowledgeable about research and funding developments, and were familiar with the scope and findings from the CER. The EPC identified and invited candidate stakeholders based on likely availability, expertise, and ability to offer multiple perspectives (e.g. clinical and advocacy). EPC investigators recommended additional individuals and organizations not included in the original TEP list that represented stakeholder "types" identified in the project protocol (researchers, clinicians, and service providers; funding agency representatives; health care policymakers; representatives from professional societies/organizations; and patient advocacy groups).

Twenty-four invitations to participate were emailed to identified experts and/or stakeholder organizations (Appendix A). Reminder emails were sent as needed. The invitation included an overview of the project, what participation would entail, and contact information should they have any questions. The invitation informed stakeholders that participation was voluntary and described our efforts to maintain confidentiality and the risks and benefits of participation.

Many stakeholders represented multiple perspectives, e.g. clinician/researcher/advocate. We anticipated that no more than nine non-Federal stakeholders would participate in each step of research gap identification and prioritization. We obtained the standard AHRQ Conflict of Interest forms from all participants including our EPC faculty and staff. None of the identified stakeholders or EPC team members had a conflict judged to preclude participation in the process.

In order to increase stakeholder understanding of the purpose of the project, key steps, and how we would be soliciting their input over time, and to allow personal interaction among stakeholders, we conducted a teleconference. The teleconference also served as the starting point for stakeholder snowballing. Twelve out of 13 stakeholders participated in this teleconference. Prior to the call, we emailed each stakeholder the draft CER, slides describing the evidence gap identification and prioritization processes, a project timeline, and a list of sample research questions and methodologic recommendations. We spent a short amount of time—less than 15 minutes—with the project overview and reserved the majority of time for discussion of research needs.

With the permission of the stakeholders, we recorded and transcribed the teleconference. During the call, there was a fair amount of discussion about patient, physician, nurse, and hospital factors that influence cesarean use. As one stakeholder commented, "peripheral issues become important." There was some disagreement about whether there is sufficient evidence that specific factors (e.g. organizational culture, professional training, fear of pelvic floor disorders) influence patient and provider perceptions and decisions about cesarean birth. Other items that emerged during the snowballing process were tighter standards for induction and elective cesarean; uniform definitions for arrest of labor; the role of incentives (financial and nonfinancial); and effects of using updated labor curves, peer review systems, audit and feedback, public reporting, novel staffing and scheduling models, and systems-level strategies.

At the end of the teleconference, we summarized next steps, which included completing the snowballing process online, completing two prioritization surveys online, and participating in a second teleconference. After the call, we emailed a link for the snowballing survey and made it available for comment from March 21 to April 3, 2012. The survey asked stakeholders to add new questions and recommendations if they saw gaps in these lists and to provide feedback on the listed research questions and recommendations. Through the teleconference and online survey, the "snowballing process" yielded a total of 47 research questions and 17 recommendations.

During the prioritization process, stakeholders were able to provide input through three web-based surveys and a teleconference. The first survey (multivoting survey) asked stakeholders to distribute 47 points among the research gaps and 17 points among the methodologic recommendations. This survey was open from April 24 to May 8, 2012. When all surveys were returned, we totaled the number of points each item received, ranked items in order from most to least points, and eliminated the lowest one-third of the items. We conducted a teleconference to reduce redundancy in questions and build consensus on the current list of items. Stakeholders participated in two additional rounds of prioritization (See Criteria for Prioritization).

Responses to this final prioritization exercise were then used to create a ranked list of the topics. For this prioritization, research questions and methodologic recommendations were scored using both a combined score across each of the seven domains and by domain.

During the snowballing and ranking process the participant stakeholders had no information about the identities of the other participants. Until the conclusion of each step they did not have access to scores and then only to the aggregate. Beginning the process with recruitment of additional items was intended to allow the scope of topics for future research to expand and to ensure that a large number and range of potentially important topics were considered. Because the group did their work electronically, individual persuasiveness or dominance of the conversation by particular topics did not have potential to sway the group opinion or the overall process.

Research Question Development and Research Design Considerations

We did not have stakeholders rank study designs or provide input to proposed study designs, due to the length and complexity of this process as well as the wide range of stakeholder technical experience in this area. EPC investigators developed suggestions and considerations for optimal study designs.

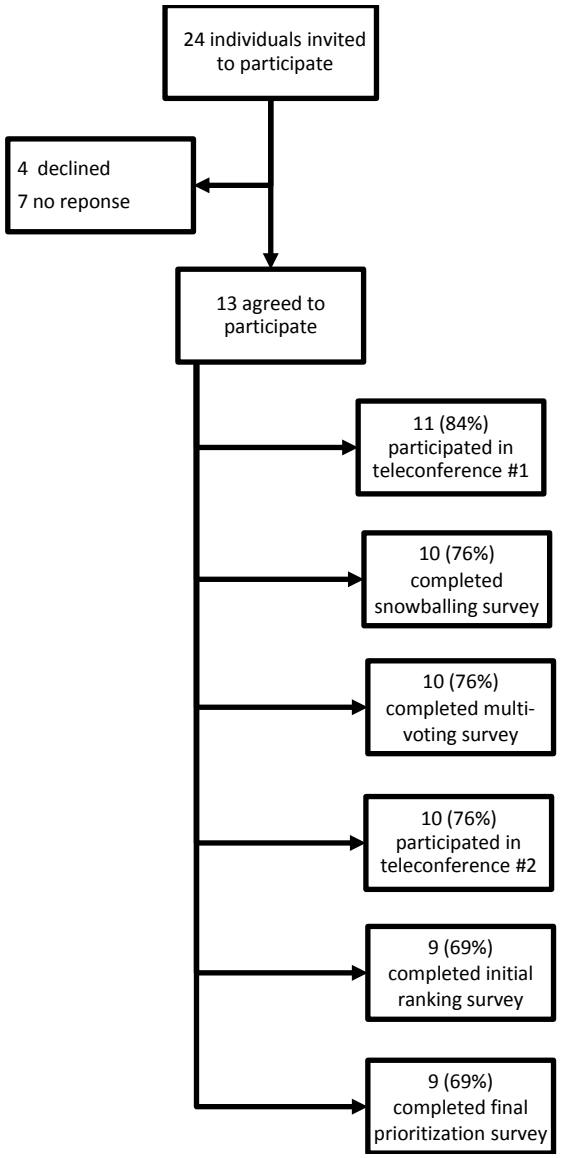
The final list of highest priority research needs and recommended study designs will be presented to the stakeholders when the draft report is posted for public comment.

Results

Engagement of Stakeholders, Researchers, and Funders

A total of 13 stakeholders (2 Federal, 11 non-Federal) representing the perspective of patient advocacy groups, academic researchers, obstetricians and gynecologists, nursing and nurse-midwifery professional organizations, the payor perspective, and national foundations and societies agreed to participate in one or more of the stages of ranking and prioritization. The group includes five Key Informants/Technical Expert Panel members from the draft CER. Throughout the teleconferences and surveys, stakeholder participation varied from 69 percent to 84 percent. Figure 4 presents stakeholder recruitment and participation results.

Figure 4. Stakeholder recruitment and participation results

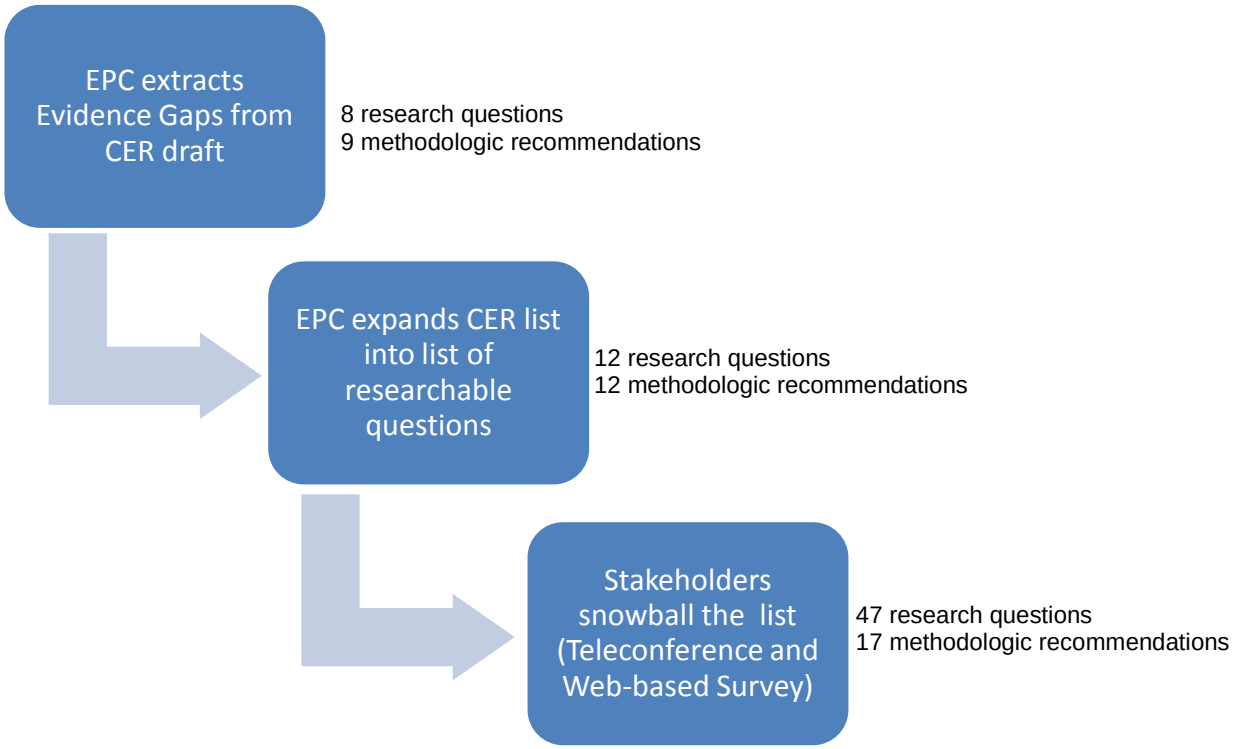


Identification of Evidence Gaps

In Phase 1, the EPC investigators started with the 17 evidence gaps identified in the draft review and translated these gaps into a list of 12 sample research questions and 12 sample methodologic recommendations that have potential utility for reducing cesarean birth. We invited the stakeholder panel to participate in a teleconference and then a web-based survey to make the list broader and more comprehensive and to suggest topics we may have omitted.

During the teleconference and snowballing survey, stakeholders expanded the initial list to 47 research questions and 17 methodologic recommendations. These items encompassed a wide range of topics and are presented in Tables 3–4. Figure 5 shows the snowballing process and results for Phase 1.

Figure 5. Snowballing results



CER = Comparative Effectiveness Review; EPC = Evidence-based Practice Center

Table 3. Snowballed list of research questions

Research Questions
1. Why do some patients prefer to undergo elective cesarean?
2. 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?
3. What patient preferences influence decisions to convert to primary cesarean during labor, e.g. pain management, progress of labor, fears about fetal well-being?
4. What physician factors contribute to 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?
5. What physician factors contribute to use of cesarean during labor, e.g. residency training, attitude toward elective cesarean, practice size, practice setting, shift/time of day, use of hospitalists, personal birth experience?
6. To what extent do nonfinancial incentives such as time savings, control, and perceived improvement in patient relations affect physician decisions to use cesarean?
7. What nurse or midwife factors contribute to the use of cesarean during labor?
8. What nurse or midwife factors contribute to the use of elective cesarean?
9. 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 patterns, provider attitudes toward cesarean use?
10. 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 patterns, provider attitudes toward cesarean use?
11. Do audit and feedback interventions influence physician use of cesarean?
12. Do interventions aimed at disrupting staffing and scheduling phenomena—such as the increase in cesarean near change of shifts and differential rates through the week—have promise?
13. Does cesarean use correlate with specific days of the week or time of day?
14. Do different staffing models such as use of hospitalists and integration of midwives reduce the number of cesarean births?
15. Do provider peer-review models change provider patterns of cesarean use?
16. Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?
17. Do natural experiments in payment reform support assertions that certain incentive structures contribute to the use of cesarean?
18. To what degree is use of cesarean driven by uniform compensation for vaginal and cesarean birth as tested by an RCT?
19. Does public reporting of hospital primary and total cesarean rates affect hospital cesarean rates over time?
20. Does public reporting of hospital primary and total cesarean rates affect hospital induction rates over time?
21. Does public reporting of physician primary and total cesarean rates affect physician use of cesarean over time?
22. Does public reporting of physician primary and total cesarean rates affect physician use of induction over time?
23. Does use of informed medical decisionmaking models change patient decisions about desire for cesarean or for procedures such as induction that may increase risk of cesarean?
24. Is the Bishop's score routinely used by providers as a decisionmaking tool? If not, why not?
25. To what extent do patient educational and support tools affect patient decisions to undergo elective cesarean?
26. To what extent do educational tools that manage patient expectations and describe the risks of cesarean influence use of cesarean during labor?
27. 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?
28. When strictly operationalized and compared in clinical trials what components of systems intervention are effective in reducing cesarean use?
29. Can technologies to enhance fetal surveillance [specify most promising - are there any technology studies worth doing?] improve infant outcomes while reducing cesarean?
30. Does a protocol for use of scalp pH sampling reduce use of cesarean?

Table 3. Snowballed list of research questions (continued)

Research Questions
31. Does outpatient hyaluronidase injection into the cervix for cervical ripening at term reduce risk of cesarean (replication of single promising trial)?
32. Does active management of labor, using updated U.S. labor curves, reduce use of cesarean in U.S. community care settings?
33. Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?
34. Does elective induction at 39 weeks vs. expectant management at 39 weeks influence use of cesarean?
35. 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?
36. What is the mechanism by which doula support exerts an effect?
37. Does midwifery care throughout pregnancy in a hospital setting reduce use of cesarean among low-risk women when compared in a randomized clinical trial to obstetric care?
38. 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?
39. Can tighter standards for elective induction among primiparous patients reduce use of cesarean?
40. Can tighter standards for indicated induction among primiparous patients reduce use of cesarean?
41. How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?
42. How does implementing a standard indication list affect physicians' use of cesarean?
43. Would changing the definition of when active labor starts reduce use of cesarean?
44. Would changing the timeframes for normal progress in latent and active labor reduce primary cesareans?
45. Would a tighter definition of elective cesarean affect physicians' use of cesarean?
46. What scales/indices best capture factors that mothers and partners value about their birth?
47. 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?
48. What factors have resulted in the change in patterns of the diagnosis of dystocia over the decades?

Table 4. Snowballed list of methodologic recommendations

Methodologic Recommendations
1. Develop data-driven estimates of plausible decreases in cesarean for use in power calculations.
2. Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.
3. Include placebo, sham, or attention control comparison groups, and innovative means of masking patients and providers in studies of interventions.
4. Conduct studies directly comparing and combining candidate strategies to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.
5. Design studies with pre-specified secondary outcomes and adequate power for these outcomes.
6. Conduct studies that allow stratification on patient characteristics such as nulliparity and multiparity and have adequate power to detect differences across strata.
7. Track and report total, primary, and repeat cesareans in studies not restricted to nulliparous women.
8. Capture all categories of birth outcomes (cesarean, emergent cesarean, assisted vaginal, and spontaneous vaginal 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.
9. Include robust measures of maternal coping, satisfaction, and perceived quality of the birth experience.
10. Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.
11. Include maternal length of stay and incidence of specific complications such as chorioamnionitis, endometritis, and wound healing complications, as outcomes in studies.
12. Conduct multisite studies to improve applicability and ensure power and precision.
13. Conduct larger trials of health system interventions.
14. Develop registries that capture both long-term and short-term outcomes
15. Determine the best measures of patient and provider route of birth preferences.
16. Consider the relationship between refined definitions of indications for cesarean and existing population based measures (e.g. hospital discharge data) to better identify algorithms that can be used to document indications in both clinical and nonclinical databases.
17. Future studies should include a full range of practice settings including community hospitals, birth centers, and health systems.

Prioritization

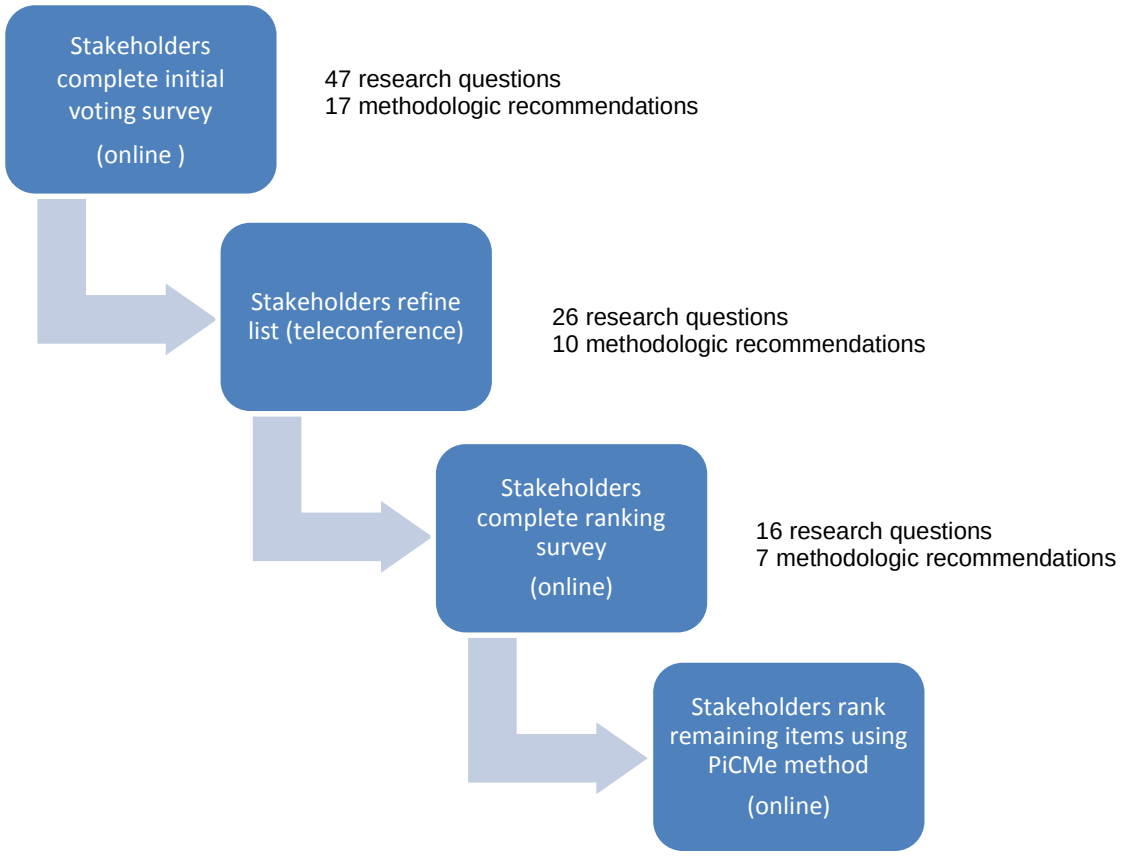
During initial voting, stakeholders were asked to respond to a Web-based survey in which they distributed 47 points among the research gaps and 17 points among the methodologic issues (Figure 6). Once the surveys were completed, we totaled points for each item, ranked items based on number of points assigned, and eliminated the lowest one-third responses. (Appendix D). The top five research questions were the following:

1. 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?
2. Why do some patients prefer to undergo elective cesarean?
3. Do different staffing models such as use of hospitalists and integration of midwives reduce the number of cesarean births?
4. 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?
5. Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?

The top two methodologic recommendations were:

1. Capture all categories of birth outcomes (cesarean, emergent cesarean, assisted vaginal, and spontaneous vaginal 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.
2. Future studies should include a full range of practice settings including community hospitals, birth centers, and health systems.

Figure 6. Prioritization results



PiCMe = Prioritization Criteria Method

After the initial voting, we held a second teleconference to discuss results. During the call, stakeholders agreed to eliminate the lowest one-third of items, and combined similar questions to reduce redundancies. This process resulted in a list of 26 research questions and 10 methodologic recommendations.

Next, stakeholders completed an electronic survey and ranked the remaining 26 research questions and ten methodologic improvements from 1 (highest priority) to 26 (lowest priority) and from 1 to 10, respectively. We totaled points for these items, ranked them from fewest points (highest priority) to most points and eliminated the bottom one-third items, leaving 16 research questions and seven methodologic recommendations.

After the initial ranking, the top five research questions were:

1. Can tighter standards for induction (indicated or elective) among primiparous patients reduce use of cesarean?
2. Do different staffing models, e.g. models that use hospitalists or midwives, reduce the number of cesarean births?
3. How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?
4. Would changing the timeframes for normal progress in latent and active labor reduce primary cesareans?
5. 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?

The top two methodologic recommendations were:

1. Capture all categories of birth outcomes (cesarean, emergent cesarean, assisted vaginal, and spontaneous vaginal 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.
2. Conduct studies that allow stratification on patient characteristics such as nulliparity and multiparity and have adequate power to detect differences across strata.

Research Needs

For the final prioritization step, we scored research questions and methodologic recommendations based on total points assigned to seven AHRQ potential value criteria. We established tiers for top-, middle-, and lower-ranked items and created cutoff points where natural breaks in total points assigned occurred. In Tables 5–6, we present research questions and methodologic recommendations by tier. We present the top five research questions and top two methodologic recommendations for each AHRQ criterion in Appendix D, Tables D7–D8.

The top-tier research questions reflect a focus on standardization strategies for induction and arrest of labor (three of five), systems-strategies (one of five) and staffing models (one of five). For strategies that standardize induction and arrest of labor, we recommend cluster randomized controlled trials with randomization of entire labor and delivery units. For trials of systems-level strategies and staffing models, we recommend studies multisite studies to improve power and generalizability.

Table 5. Highest priority research questions

Research Question	Tier	Relevant PICOTS Area(s)	Study Design Comments/Suggestions
When strictly operationalized and compared in clinical trials, what components of systems interventions are effective in reducing cesarean use?	Top	**Intervention:** promising components of interventions from observational studies **Comparator:** alternated combinations of components **Setting:** any U.S. hospital	Multisite efforts likely required for power and to enhance generalizability.
Can tighter standards for induction (indicated or elective) among primiparous patients reduce use of cesarean?	Top	**Population:** primiparous women **Intervention:** standards developed by consensus from EBM guidance/reviews **Comparator:** prior standards	Cluster RCT with randomization at level of whole labor and delivery unit.
How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?	Top	**Intervention:** standards developed by consensus from EBM guidance/reviews **Comparator:** usual care	Cluster RCT with randomization at level of whole labor and delivery unit.
Would changing the timeframes for normal progress in latent and active labor reduce primary cesarean?	Top	**Intervention:** strict implementation of action lines **Comparator:** usual care **Outcome:** primary cesarean	Cluster RCT with randomization at level of whole labor and delivery unit.

Table 5. Highest priority research questions (continued)

Research Question	Tier	Relevant PICOTS Area(s)	Study Design Comments/Suggestions
Do different staffing models, such as models that use hospitalists or midwives, reduce the number of cesarean births?	Top	**Intervention:** novel staffing model **Comparator:** conventional staffing model **Setting:** any U.S. hospitals	Multisite efforts likely required for power and to enhance generalizability.
Does midwifery care throughout pregnancy in a hospital setting reduce use of cesarean among low-risk women when compared in a randomized clinical trial to obstetric care?	Middle	**Intervention:** continuity of prenatal care and birth with midwives **Comparator:** continuity of prenatal care and birth with physicians **Setting:** any U.S. prenatal care/birth setting	Challenges presented by the availability of midwives; however, important to be conducted in the United States and not to infer outcomes from other health systems.
Do natural experiments in payment reform support assertions that certain incentive structures contribute to the use of cesarean?	Middle	**Intervention:** new models of flat payment for birth regardless of route **Comparator:** prior payment schedules	Capture existing natural experiments happening around the country by state and by payors' policy changes.
To what extend do educational and decision support tools that describe the risk of cesarean influence use of induction, elective cesarean and cesareans during labor?	Middle	**Intervention:** distinctive educational and decision support tools for patients **Comparator:** no use of educational and decision support tools **Outcomes:** induction, elective and indicated cesarean	Randomized controlled trials and observational studies (especially qualitative) would be appropriate.
What physician factors contribute to the use of cesarean during labor, such as residency training, attitude toward cesarean, practice setting, practice size, shift/time of day, use of hospitalists, personal birth experience?	Middle	Determinants	Qualitative, semi-quantitative, and observational research efforts potentially including use of methods such as focus groups, individual interviews, surveys, predictive models and sociologic analyses.
Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?	Middle	**Intervention:** determining progress of labor with contemporary U.S. labor curves to define arrest of labor and response **Comparator:** no formalized use of tracking labor or prior versions of labor curve **Setting:** any U.S. hospital	These updated labor curves reflect changing U.S. demographics (age, body mass index, parity) and should be compared along with an action plan compared to no formal use of labor curves/usual care. To compare to prior versions will require larger trials.
What factors drive a patient's decision to undergo a primary cesarean during labor, such as prior cesarean, fears, satisfaction with progress of labor, satisfaction with pain management, etc?	Middle	Determinants	Qualitative, semi-quantitative, and observational research efforts potentially including use of methods such as focus groups, individual interviews, surveys, predictive models and sociologic analyses.

Table 5. Highest priority research questions (continued)

Research Question	Tier	Relevant PICOTS Area(s)	Study Design Comments/Suggestions
Does public reporting affect induction and cesarean rates over time, such as public reporting of total and primary cesarean rates for individual physicians, public reporting of primary and total cesarean rates for hospitals?	Middle	**Intervention:** distinctive versions of public reporting **Outcomes:** primary and total cesarean rates **Comparator:** no public reporting	Could potentially operationalize at county or state level as block randomized trials.
Do audit and feedback interventions influence physician use of cesarean?	Middle	**Intervention:** audit and feedback with institutional/department awareness of individual data **Comparator:** usual	Could be paired in 2x2 trials designs with public reporting intervention as above.
To what extent do nonfinancial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?	Middle	Determinants	Qualitative, semi-quantitative, and observational research efforts potentially including use of methods such as focus groups, individual interviews, surveys, predictive models and sociologic analyses.
What hospital factors contribute to the use of cesarean during labor, such as teaching status, geographical region, urban location, socioeconomic status of patients, staffing and scheduling patterns, provider attitudes toward cesarean use?	Lower	Determinants	National database efforts that expand on prior risk adjustment models and seek additional explanatory variables would have value for understanding contemporary drivers of cesarean use.

Table 6. Highest priority methodologic recommendations

Methodologic Recommendation	Tier	Relevant PICOTS Area(s)	Study Design Comments/Suggestions
Capture all categories of birth outcomes (primary and repeat cesarean, emergent cesarean, assisted vaginal, and spontaneous vaginal births) and related complications and stratify outcomes by parity.	Top	**Outcomes** (operationalize outcome definitions for each category of birth, maternal and neonatal outcomes for consistency across literature)	Unified definitions with validation studies to determine if operational definitions are uniformly applied are crucial to being able to compare findings in this literature and to aggregate results for efforts such as meta-analysis.
Develop registries that capture both short-term and long-term outcomes.	Top	**Outcomes** (uniform birth, maternal, and infant outcomes needed as above)	Incorporating uniform operational definitions within a registry would allow for the first time ability to refine knowledge about determinants of cesarean from a national sample of varied settings and populations.
Future studies should include a full range of practice settings including community hospitals and birth centers.	Middle	**Setting:** all birth settings in the United States	Research needs to be extended past academic/tertiary care sites in order to reflect the settings in which women receive birth care.
Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.	Middle	**Outcomes** (these are needed to understand potential adverse consequences for infants)	Diverse settings and uniform definitions would be required. Should become part of registry efforts.
Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.	Middle	**Intervention** (operationalize definitions of indications to make them discrete, nonoverlapping categories)	Unified definitions with validation studies to determine if operational definitions are uniformly applied are crucial to being able to compare findings in this literature and to aggregate results for efforts such as meta-analysis.
Include maternal length of stay and incidence of specific complications such as chorioamnionitis, endometritis, and wound healing complications, as outcomes in studies.	Lower	**Outcomes** (these are needed to understand potential adverse consequences for mothers)	Diverse settings and uniform definitions would be required. Should become part of registry efforts.
Determine the best measures of patient and provider route of birth preferences.	Lower	**Outcomes** (development of measurement tools is necessary)	We need greater understanding from diverse populations of women and providers about how they interpret the relative value of outcomes and gauge satisfaction with the birth experience.

Identification of Current and Ongoing Studies

Few studies explicitly set out to reduce cesarean births. We identified six ongoing randomized controlled trials using the search criteria from the original review. The RCTs addressed pregnancy/fetal monitoring (1), prolonged pregnancy (1), maternal obesity/weight gain (3), and labor dystocia (1). The RCTs that address fetal monitoring and labor dystocia may address the research needs we identified in this project.

Discussion

The purpose of this project was to generate a list of high-priority future research needs for strategies to reduce cesarean birth by soliciting stakeholder input through a multistep consensus building process. In the first phase of this process, stakeholders used a two-step snowballing process to expand an initial list of research questions and methodologic recommendations. In the second phase, we engaged stakeholders in a series of prioritization steps that resulted in a gradual reduction of listed items. In the final round of prioritization, stakeholders ranked the remaining 16 research questions and 10 methodologic recommendations across 7 AHRQ potential value criteria. These ranked items were assigned to top-, middle- and lower-priority tiers.

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. The CER concluded that while some strategies show promise, no particular strategy was uniformly successful in reducing cesareans. The strength of the evidence was low to insufficient for each of the strategies reviewed. While certain components of systems-level strategies were common among successful strategies, none were supported by a randomized trial.

Two changes are recommended for future stakeholder engagement processes. First, allow ample time—at least a month—for recruitment of desired stakeholder "types." To achieve diversity and balance in the stakeholder group, we recruited predetermined types so that the perspective of clinicians, payors, policy, research, and advocacy were represented. Half of the stakeholders we initially invited declined to participate, which meant added time for additional rounds of invitations to achieve a workgroup of 12 members.

Second, allow opportunities for personal interaction among stakeholders. There was a high level of participation during our two teleconferences. To mitigate scheduling conflicts, we included a link for an online availability survey in the invitations. This allowed stakeholders who agreed to participate in the project to indicate their availability for two future teleconferences. The result was a majority of stakeholders joining the teleconferences and high levels of exchange among stakeholders during the two calls**.**

Throughout the teleconferences and Web-based surveys, stakeholders provided valuable input on research questions and methods and raised important issues for consideration. During the first teleconference, stakeholders were asked to add new items or revise existing items on the list of 12 sample research questions and 12 sample methodologic recommendations. During the discussion, stakeholders raised questions about the importance of "peripheral issues," such as organizational culture, patient and provider attitudes and preferences, and whether there is sufficient evidence that certain patient, provider and hospital factors influence cesarean use. There was a heavy focus on the need for uniformity of definitions, standards and tracked outcomes related to induction and cesarean. Other items that emerged during the snowballing process (teleconference and web-based survey) were tighter standards for induction and elective cesarean; uniform definitions for arrest of labor; the role of incentives (financial and nonfinancial); and effects of using updated labor curves, peer review systems, audit and feedback, public reporting, novel staffing and scheduling models, and systems-level strategies. Overall, the snowballing process added 35 research questions and 14 recommendations.

During the prioritization phase, stakeholders raised a number of issues. Following the initial voting survey, we held a second teleconference to facilitate discussion of survey results, including the proposed cutpoint of the lowest one-third of items, and reduce any redundancies on the list. During this call, stakeholders raised five issues about the process and survey items:

- Concerns about the initial voting process, specifically the ability of a single stakeholder to influence rankings by concentrating all points on a single item or a few items. This happened with items from the initial voting survey that ranked first and second. The item "What factors drive a patient's decision to undergo a primary cesarean during labor, such as prior cesarean, general fears, fear of future pelvic floor disorders" received all 22 out of 25 points from one voter and ranked first. Similarly, the item "Why do some patients prefer to undergo elective cesarean" received all 23 points from one voter and ranked second.
- Concerns that some items on the list are too similar to be ranked separately.
- Concerns about whether research questions about factors that influence cesarean use are hypothesis driven, that is, are these researchable questions.
- Observations that some of the methodologic improvements listed on the survey are basic clinical trial standards that should be acknowledged and followed by researchers. These items included the following:
    - Develop data-driven estimates of plausible decreases in cesarean for use in power calculations.
    - Design studies with prespecified secondary outcomes and adequate power for these outcomes.
    - Include placebo, sham, or attention control comparison groups, and innovative means of masking patients and providers in studies in interventions.
    - Conduct multisite studies to improve applicability and ensure power and precisions. Stakeholders discussed the absence of these basic criteria from the literature, but agreed to remove these items from the list. In the report, the authors would emphasize the importance of these basic consort criteria.

We addressed these issues by explaining that:

1. The initial voting process is a widely used nominal group process and meant to identify priority topics. The process is designed to mimic an in-person group discussion, where participants can promote one topic or many topics. This process is typically followed up with a ranking process that is more consensus driven. We explained that we would followup the initial voting survey with a ranking survey that was designed to give each voter response equal weight.
2. Stakeholders would be able to combine similar items into one survey question during the teleconference.
3. Stakeholders would be able to address this issue in the next two prioritization steps. During the initial ranking, they would be asked to rank research questions in importance from 1 (most important) to 26 (least important). Stakeholders who felt these questions were not hypothesis driven questions could presumably rank them lower than other items. Similarly, stakeholders would be able to address the value of these determinants questions in the final round of prioritization, where they would be asked to rank each item across the seven potential value criteria.

This final prioritization steps resulted in a list of top priority research needs that encompass a variety of topics including (1) tighter standards and definitions for induction and cesarean use (elective and indicated); (2) new measures for labor progress; and (3) trials for systems level strategies to reduce cesarean use and novel staffing models. The top methodologic recommendations focused on improved capture of birth outcomes. Based on the distribution of

points across the seven AHRQ criteria, stakeholders gave the most attention to the "potential for significant health impact" and "potential to reduce variation in clinical practices" criteria.

Inherent challenges face investigators and funding agencies who wish to better understand approaches to reduce use of cesarean among low-risk women. 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.[6] Much of this increase occurred in the past decade.[1] In the current cultural milieu it cannot be taken for granted that all those who participate in decisions about births and in providing care for women during pregnancy and birth share an objective of reducing use of cesarean.

To obtain meaningful answers that are applicable to the care of women in the United States will require large-scale studies in this country. Several factors suggest this research will need to be predominantly conducted as multisite randomized trials: (1) existing wide variability in use of cesarean means different settings will enter with a different baseline propensity to use cesarean; (2) baseline use patterns are only part of the culture of care at an institution and desire to change use of cesarean likely varies so that interventions need to be shown to be effective across settings; and (3) secular trends in cesarean use, not related to the intervention being studied, impair the ability of observational studies to definitively provide evidence for effectiveness. Some topics, such as investigation of comprehensive midwifery care to reduce cesarean use, will challenge the ability of the care system to identify sufficient numbers of providers across multiple sites who are able and willing to participate in such studies. Furthermore, as the methodologic recommendations of this report suggest, a substantial amount of consensus work needs to be done among researchers, professional organizations, and funders to ensure that the metrics used in research produce data that can be synthesized across families of studies to reach sufficient strength of evidence to inform decisions about care around the nation.

The high priority research needs identified in this project suggest the importance of research at all points along the continuum represented by our analytic framework. Multiple points of influence need to be studied, and the gaps are substantial. The efforts of the stakeholders and our team have identified a multidecade portfolio of questions that need answers.

The high priority research needs identified in this project offer guidance at various points along our analytic framework and the research spectrum—from understanding determinants of cesarean to creating uniform standards and practices for induction and cesarean, exploratory studies, large trials in multiple settings for specific strategies, and creating uniform and expanded panels of outcomes to improve data collection efforts.

Conclusion

Our multistep process for identifying, multiplying, and prioritizing research questions to advance research in the area of strategies to reduce cesarean birth in low-risk women resulted in an actionable list of research topics to fill specific knowledge gaps. The highest priority research questions encompass many topics of interest, which reflects the large number of gaps in the literature. These topics include: tighter standards and definitions for induction and cesarean use (elective and indicated), new measures for labor progress, and trials that test effectiveness of systems level strategies and novel staffing models. Randomized controlled trials and multisite studies that improve power and generalizability and natural experiments were viewed as critical. The highest priority methodologic recommendations call for improved definitions and tracking of short- and long-term birth outcomes.

References

1. Menacker F, Hamilton BE. Recent trends in cesarean delivery in the United States. NCHS Data Brief 2010 Mar(35):1-8. PMID: 20334736.
2. Martin JA, Hamilton BE, Sutton PD, et al. Births: final data for 2007. Natl Vital Stat Rep. 2010 Aug 9;58(24):1-85. PMID: 21254725.
3. Bettes BA, Coleman VH, Zinberg S, et al. Cesarean delivery on maternal request: obstetrician-gynecologists' knowledge, perception, and practice patterns. Obstet Gynecol. 2007 Jan;109(1):57-66. PMID: 17197588.
4. Simpson KR, Thorman KE. Obstetric "conveniences": elective induction of labor, cesarean birth on demand, and other potentially unnecessary interventions. J Perinat Neonatal Nurs. 2005 Apr-Jun;19(2):134-44. PMID: 15923963.
5. Prioritization criteria methodology for future research needs proposals within the Effective Health Care Program. Rockville, MD: Agency for Healthcare Research and Quality; 2012.
6. Zhang J, Troendle J, Reddy UM, et al. Contemporary cesarean delivery practice in the United States. Am J Obstet Gynecol. 2010 Oct;203(4):326 e1- e10. PMID: 20708166.
7. The Joint Commission. Specifications manual for Joint Commission national quality core measures. 2010. http://manual.jointcommission.org/releases/TJC2010B/MIF01067.html. Accessed on February 4 2011.
8. . National Institutes of Health Consensus Development conference statement: vaginal birth after cesarean: new insights March 8-10, 2010. Obstet Gynecol. 2010 Jun;115(6):1279-95. PMID: 20502301.
9. NIH consensus development statement on cesarean childbirth. The Cesarean Birth Task Force. Obstet Gynecol. 1981 Apr;57(4):537-45. PMID: 7243111.
10. Getahun D, Oyelese Y, Salihu HM, et al. Previous cesarean delivery and risks of placenta previa and placental abruption. Obstet Gynecol. 2006 Apr;107(4):771-8. PMID: 16582111.
11. Blanchette H. The rising cesarean delivery rate in America: what are the consequences? Obstet Gynecol. 2011 Sep;118(3):687-90. PMID: 21860302.
12. Clark SL, Belfort MA, Hankins GD, et al. Variation in the rates of operative delivery in the United States. Am J Obstet Gynecol. 2007 Jun;196(6):526 e1-5. PMID: 17547880.
13. Wennberg J. Which rate is right? N Engl J Med. 1986 Jan 30;314(5):310-1. PMID: 3941721.
14. Wennberg JE. Tracking Medicine: A Researcher's Quest to Understand Health Care. Oxford, England: Oxford University Press; 2010.
15. Baicker K, Buckles KS, Chandra A. Geographic variation in the appropriate use of cesarean delivery. Health Aff (Millwood). 2006 Sep-Oct;25(5):w355-67. PMID: 16895942.
16. Luthy DA, Malmgren JA, Zingheim RW, et al. Physician contribution to a cesarean delivery risk model. Am J Obstet Gynecol. 2003 Jun;188(6):1579-85; discussion 85-7. PMID: 12824996.
17. National Center for Health Statistics. Healthy People 2000 Final Review. Hyattsville, MD: Public Health Service; 2001.
18. U.S. Department of Health and Human Services. Healthy People 2010: Understanding and Improving Health. Washington, DC: U.S. Government Printing Office; 2000. http://www.healthypeople.gov/2010. Accessed on May 5 2011.
19. U.S. Department of Health and Human Services. Healthy People 2020. Washington, DC; 2011. http://www.healthypeople.gov/2020/default.aspx. Accessed on May 5 2011.

20. Cyr RM. Myth of the ideal cesarean section rate: commentary and historic perspective. Am J Obstet Gynecol. 2006 Apr;194(4):932-6. PMID: 16580278.

21. Resnik R. Can a 29% cesarean delivery rate possibly be justified? Obstet Gynecol. 2006 Apr;107(4):752-4. PMID: 16582108.

22. Gruber J, Kim J, Mayzlin D. Physician fees and procedure intensity: the case of cesarean delivery. J Health Econ. 1999 Aug;18(4):473-90. PMID: 10539618.

23. Zwecker P, Azoulay L, Abenhaim HA. Effect of fear of litigation on obstetric care: a nationwide analysis on obstetric practice. Am J Perinatol. 2011 Apr;28(4):277-84. PMID: 21249618.

24. Dursun P, Yanik FB, Zeyneloglu HB, et al. Why women request cesarean section without medical indication? J Matern Fetal Neonatal Med. 2011 Sep;24(9):1133-7. PMID: 21668323.

25. Quiroz LH, Blomquist JL, Macmillan D, et al. Maternal goals for childbirth associated with planned vaginal and planned cesarean birth. Am J Perinatol. 2011 Oct;28(9):695-702. PMID: 21660899.

26. O'Boyle AL, Davis GD, Calhoun BC. Informed consent and birth: protecting the pelvic floor and ourselves. Am J Obstet Gynecol. 2002 Oct;187(4):981-3. PMID: 12388991.

27. Handa VL, Blomquist JL, Knoepp LR, et al. Pelvic floor disorders 5-10 years after vaginal or cesarean childbirth. Obstet Gynecol. 2011 Oct;118(4):777-84. PMID: 21897313.

28. Bayrampour H, Heaman M. Advanced maternal age and the risk of cesarean birth: a systematic review. Birth. 2010 Sep;37(3):219-26. PMID: 20887538.

29. Kulie T, Slattengren A, Redmer J, et al. Obesity and women's health: an evidence-based review. J Am Board Fam Med. 2011 Jan-Feb;24(1):75-85. PMID: 21209347.

30. Khunpradit S, Tavender E, Lumbiganon P, et al. Non-clinical interventions for reducing unnecessary caesarean section. Cochrane Database Syst Rev. 2011(6):CD005528. PMID: 21678348.

31. Catling-Paull C, Johnston R, Ryan C, et al. Non-clinical interventions that increase the uptake and success of vaginal birth after caesarean section: a systematic review. J Adv Nurs. 2011 Aug;67(8):1662-76. PMID: 21535091.

Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CER	Comparative Effectiveness Review
EHC	Effective Health Care
EBM	Evidence-based medicine
EPC	Evidence-based Practice Center
KQ	Key Question
NICU	Neonatal intensive care unit
PiCMe	Prioritization Criteria Method
PSCOS	Population, Strategy, Comparator, Outcome, Setting
RCT	Randomized clinical trial
VBAC	Vaginal birth after cesarean

Appendix A. Stakeholder Invitation Letter

My name is Dr. Katherine Hartmann. As Director of the Vanderbilt Evidence-based Practice Center I am writing to invite you to participate in a research study. The Agency for Healthcare Research and Quality (AHRQ) is undertaking a concerted effort to further develop the Future Research sections of its systematic reviews. To that end the Vanderbilt Evidence-based Practice Center (EPC) is conducting a project to expand and prioritize the knowledge gaps and research needs identified in the Future Research section of the Comparative Evidence Review of Strategies to Reduce Cesarean Birth.

You have been identified as a stakeholder with interests and experience relevant to reducing use of cesarean in one or more of the following areas:
1. Advocacy
2. Clinical practice
3. Research
4. Research funding priorities

Your involvement could include participation in one or more of the following activities (you are not required to participate in all components of the research to participate in the project):

1. Participating in a one-hour conference call to expand a list of research needs related to reducing use of cesarean.
2. Prioritizing of these research needs via a web-based ranking system (two week access to online site).
3. Participating in a second group conference call (one hour) to refine the list of prioritized research needs.
4. Prioritizing the refined list of needs via web-based ranking system (two week access to online site).
5. Reviewing the Strategies to Reduce Cesarean Births Future Research Needs report (participants will have four weeks to review and comment on the report available on a public web site).

Please let us know via email by February 15, 2012 if you are willing to participate by contacting Rashonda Lewis at rashonda.m.lewis@vanderbilt.edu or 615-936-2653. If you are able to participate we request that you complete the attached Doodle to indicate your availability for our first meeting.

Doodle link: http://www.doodle.com/7sribep32kdxdaay

Participation is voluntary:
Participation in this project is completely voluntary, and you may discontinue your participation at any time. Approximately 12 stakeholders will be asked to participate in one or more of the activities listed above.

Confidentiality:
All the information we receive from you, including your name and any other identifying information (if applicable), will be strictly confidential and will be on password protected server maintained by computer services at Vanderbilt University. We will not use any information that would make it possible for anyone to identify the opinions you contributed in any presentation or written report about this project. Conference calls will be recorded so that a comprehensive transcript can be produced. Digital files of the recordings will be destroyed upon completion of the transcript approximately 7-10 days after the call, and names and other identifying information will be deleted from all electronic and paper copies of transcripts. Written consent will be required before you can participate in any project activities. Since names are not required as part of the study data, no identifying information, such as the participants' names will be part of study data. If this information is recorded on phone conversations or documents we receive from you it will be kept only to determine that we have received all responses and will be destroyed or deleted within 7 days of the submission of the final report on or about August 15, 2012.

Risks and Benefits of Participating:
There is a slight risk your organization's name could be disclosed, but all efforts are made to reduce this possibility. The benefit of participating in this project is the knowledge that you are assisting AHRQ and the Vanderbilt Evidence-based Practice Center in moving forward research related to strategies to reducing use of cesareans. Lists and rankings of research needs from each participant will be combined and a summary of this information will be generated by analysts at the Vanderbilt EPC. No individual names will be mentioned in the summary.

If you have questions about this project:
If you have questions about this project, you may "reply" to this email and we will respond to your questions as soon as possible. You may also call us at 615-936-2653.
If you have questions about the rights of participants in a research project, you may contact the Vanderbilt Institutional Review Board directly at 1-866-224-8273 or www.mc.vanderbilt.edu/irb.

Thank you for considering participating in this project.

Regards—
Rashonda M. Lewis, JD, MHA
Investigator, Vanderbilt Evidence-based Practice Center
Healthcare Liaison, Davidson County, TN National Children's Study Center
Institute for Medicine and Public Health
2525 West End Ave, Suite 600, Sixth Floor
Nashville, TN 37203-1738
Phone: (615) 936-2653
Fax: (615) 936-8291
rashonda.m.lewis@vanderbilt.edu

For
Katherine E. Hartmann, MD, PhD
Lucius M. Burch Professor of Obstetrics and Gynecology
Associate Dean for Clinical and Translational Scientist Development
Director, Vanderbllt AHRQ Evidence-based Practice Center
Deputy Director, Institute for Medicine and Public Health

Appendix B. Search Strategy for Ongoing Studies

Table B1. PubMed search strategies (last updated February 6, 2012)

Search terms		Search results
#1	(cesarean section[mh:noexp] OR cesarean[tiab] OR caesarean[tiab] OR c-section[tiab]) AND pregnancy[mh]	39219
#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]	3193379
#3	#1 AND #2 AND eng[la] AND humans[mh]	7208
#4	#3 AND newspaper article[pt]	7
#5	#3 AND letter[pt]	105
#6	#3 AND comment[pt]	94
#7	#3 AND case reports[pt]	348
#8	#3 AND review[pt]	583
#9	#3 AND practice guideline[pt]	11
#10	#3 AND clinical conference[pt]	4
#11	#3 AND editorial[pt]	36
#12	#3 AND historical article[pt]	11
#13	#3 AND meta-analysis[pt]	167
#14	#3 AND congresses[pt]	5
#15	#3 AND in vitro[pt]	51
#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)	6017*

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 B2. CINAHL search results (last updated February 6, 2012)

Search terms		Search results
#1	"cesarean" OR (MH "Cesarean Section") OR “caesarean” OR “c-section”	8228
#2	(MH "Pregnancy") OR "pregnancy"	83572
#3	#1 AND #2	6740
#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")	520573
#5	#3 AND #4 AND English Language	1779
#6	#5 AND Publication Type: Letter	77
#7	#5 AND Publication Type: Commentary	146
#8	#5 AND Publication Type: Case study	71
#9	#5 AND Publication Type: Review	85
#10	#5 AND Publication Type: Practice Guidelines	12
#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	347
#17	#5 NOT #16	1432
#18	#17 Exclude MEDLINE records	254

Key: MH major heading

Appendix C. List of Ongoing Studies

Current RCTs (in progress/not yet published): reduction of cesarean
Last updated June 13, 2012

ClinicalTrials.gov: Current or pending RCTs
Study Title: Reduction of Cesareans by Nitric Oxide (NO) Donors in Post Term Pregnancies
Conditions: Prolonged Pregnancy; "Nulliparity"
Interventions: Drug: IMN; Drug: Placebo
Sponsor: Assistance Publique - Hôpitaux de Paris
Study Design: Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
NCT Number: NCT00930618
Completion Date: June 2012
Last Updated Date: April 7, 2011
Outcome Measures: Number of cesarean sections; Number of labor inductions; Number of spontaneous labors; Cesarean for failed labor induction; Cesarean for FHR abnormalities; Cesarean for arrested labor; Bishop score at 41+2, 41+4, and labor induction; Isosorbide mononitrate adverse effects; Maternal satisfaction; Neonatal morbidity

Study Title: Fetal ST Segment and T Wave Analysis in Labor
Conditions: Pregnancy; Obstetric Labor; Parturition
Intervention: Device: fetal STAN monitor
Sponsors: Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); Neoventa Medical
Study Design: Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Prevention
NCT Number: NCT01131260
Completion Date: June 2012
Last Updated Date: April 20, 2011
Outcome Measures: Intrapartum fetal death; Neonatal Death; Apgar score <= 3 at 5 minutes; Neonatal seizure; Cord artery pH <= 7.05 and base deficit >= 12 mmol/L; Intubation for ventilation at delivery; Presence of neonatal encephalopathy; Cesarean delivery; Indication for cesarean delivery; Forceps or vacuum delivery; Chorioamnionitis; Postpartum hemorrhage; Postpartum endometritis; Duration of labor post-randomization; Length of hospital stay; Maternal heart rate; Maternal blood pressure; Maternal oxygen saturation; Neonatal death; Apgar score at 5 minutes; Umbilical arterial blood gases; Need for chest compression or intubation for ventilation in the delivery room; Special care nursery admission (anything more than well-baby nursery); Seizure; ST events; Shoulder dystocia

Study Title: Fit For Delivery: A Study of the Effect of Exercise Sessions and Nutritional Counselling on Pregnancy Outcome

Conditions: Pregnancy; Obesity; Diabetes
Intervention: Behavioral: Nutritional counseling and twice weekly exercise groups
Sponsor: Sorlandet Hospital HF
Study Design: Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Investigator); Primary Purpose: Prevention
NCT Number: NCT01001689
Completion Date: November 2013
Last Updated Date: December 20, 2011
Outcome Measures: Maternal weight gain in pregnancy; Weight of the newborn; Maternal serum glucose level, measured fasting and after a 2 hour glucose challenge test; Maternal weight retention; Measurement of serum levels of hormones which regulate serum glucose levels, in both the pregnant woman and her newborn baby.; Incidence of operative vaginal delivery and Cesarean section

Study Title: Metformin in Obese Non-diabetic Pregnant Women
Conditions: Pregnancy Complications; Obesity
Interventions: Drug: Metformin; Drug: Placebo
Sponsors: Epsom and St Helier University Hospitals NHS Trust; Fetal Medicine Foundation; King's College Hospital NHS Trust
Study Design: Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Prevention
NCT Number: NCT01273584
Completion Date: September 2014
Last Updated Date: January 31, 2012
Outcome Measures: Birth Weight centile (z-score); Maternal Weight gain; Development of Gestational Diabetes; Development of hypertension/Preeclampsia; Caesarian Section; Postpartum haemorrhage; Neonatal Hypoglycemia; Prematurity; Hyperbilirubinemia; Polycythaemia; Respiratory Distress; Macrosomia/Large for Gestational Age; Birth Trauma; Apgar score <6; Admission to level 2 or greater neonatal unit; Stillbirth/Intrauterine deaths; 2nd trimester miscarriages

Study Title: Accelerated Titration of Oxytocin for Nulliparous Patients With Labour Dystocia: ACTION Pilot Study
Condition: Labour Dystocia
Intervention: Drug: Oxytocin
Sponsors: Ottawa Hospital Research Institute; The Physicians' Services Incorporated Foundation; The Ottawa Hospital; Canadian Institutes of Health Research (CIHR); Sainte Justine Hospital Research Institute
Study Design: Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
NCT Number: NCT01397630

Completion Date: September 2013
Last Updated Date: July 18, 2011
Outcome Measures: Consent Rate; Protocol Violation Rate; Maternal satisfaction; Caesarean section rate; Rate of Maternal and Fetal/Neonatal Adverse Events

Study Title: High Dose Versus Low Dose Oxytocin for Augmentation of Delayed Labour
Condition: Birth; Delayed
Intervention: Drug: Syntocinon
Sponsor/Collaborators: Göteborg University; Sahlgrenska University Hospital, Sweden; NU Hospital Group
Study Design: Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor);
NCT Number: NCT01587625
Completion Date: December 2015
Last Updated Date: April 27, 2012

Study Title: Patient Satisfaction of Cervical Ripening in an Outpatient Setting
Condition: Pregnancy
Interventions: Other: Patient discharged home after foley bulb placement.; Other: Inpatient
Sponsor: Cedars-Sinai Medical Center
Study Design: Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
NCT Number: NCT01605474
Completion Date: NR
Last Updated Date: May 23, 2012

NIH Reporter: RCTs

Project Number: 5R01HD058061-03 Contact PI / Project Leader: STEVENS, VICTOR J

Title: WEIGHT MANAGEMENT FOR IMPROVED PREGNANCY OUTCOMES

Awardee Organization: KAISER FOUNDATION RESEARCH INSTITUTE

Abstract Text: DESCRIPTION (provided by applicant): Historically, under nutrition has been a major health concern. Recently however, over nutrition has also become a serious public health problem in the United States and other industrialized countries. With the new obesity epidemic we see increasing morbidity, mortality, and public health burden, particularly among reproductive-aged women. Whereas morbid obesity was once rare among pregnant women, a rapidly increasing proportion of obstetrics patients now have levels of obesity which dramatically increase their risk of serious pregnancy complications. These complications include increased risk of miscarriage, stillbirth, having a fetus that is too large leading to cesarean section or birth injuries for mom and baby from vaginal delivery, and death of the infant in the newborn period. More than 1/3 of women in the U.S. are now starting their pregnancies with a body mass index or 30 or greater, a condition that was unusual to rare 50 years ago. Given the serious consequences of added weight gain during pregnancy for obese women, such as gestational diabetes, pre-eclampsia, or cesarean delivery, the best strategy during their pregnancy may be to maintain a steady weight rather than gaining 15 pounds or more. Unfortunately, there is little research on the efficacy and feasibility of minimizing weight gain during pregnancy. This study is designed to address that problem. Two hundred women with BMIs of 30 or greater at the start of their pregnancy will be recruited for this feasibility test. All participants will be members of a nonprofit managed care organization that provides high-quality obstetrics care. Patients who volunteer to participate will be randomly assigned to either a weight maintenance intervention or to usual care. Participants assigned to the intervention will participate in a weight maintenance program designed to help them eat a nutritionally balanced diet and to also control energy intake to minimize weight gain during their pregnancy. Participants (and their babies) in both groups will participate in follow- up assessments at 2 weeks postpartum, 6 months postpartum and one year postpartum. The primary outcome measures will be mothers' weight gain during pregnancy, the amount of weight retained after delivery, and the proportion of large for gestational age infants. Secondary outcomes will include multiple safety measures of the mothers and their babies. In addition to measures of safety, our secondary analyses will address the feasibility and acceptability of a weight management intervention among obese pregnant women. PUBLIC HEALTH RELEVANCE: Obesity and excessive weight gain during pregnancy lead to increased risks of high blood pressure, gestational diabetes, large infants, and cesarean section. This study will test an intensive, weight management program for obese pregnant women to prevent too much weight gain and reduce risk of pregnancy complications. Given that pregnancy is one of the primary reasons women seek medical care, interventions that prevent excessive weight gain during pregnancy could have significant public health impact by preventing worsening obesity and its long-term effects on mothers and their babies.

Public Health Relevance Statement:

PROJECT NARRATIVE: Obesity and excessive weight gain during pregnancy lead to increased risks of high blood pressure, gestational diabetes, large infants, and cesarean section. This study will test an intensive, weight management program for obese pregnant women to prevent too much weight gain and reduce risk of pregnancy complications. Given that pregnancy is one of the primary reasons women seek medical care, interventions that prevent excessive weight gain

during pregnancy could have significant public health impact by preventing worsening obesity and its long-term effects on mothers and their babies.
Project Start Date: 12-MAY-2009
Project End Date: 30-APR-2013
Administering Institutes or Centers: EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

NIH Reporter: other studies of potential interest

Project Number: 1G13LM010878-01 Contact PI / Project Leader: WOLF, JACQUELINE HELENE
Title: A SOCIAL HISTORY OF CESAREAN SECTION IN THE UNITED STATES
Awardee Organization: OHIO UNIVERSITY ATHENS
Abstract Text: DESCRIPTION (provided by applicant): Between 1965 and 1987 the cesarean section rate in the U.S. rose 455 percent, from 4.5 percent to 25 percent of births. While cesarean section was an appropriate and necessary procedure in a significant number of these births, the World Health Organization (WHO) has long estimated that the optimal cesarean section rate is between 5 and 10 percent of births and that a rate above 15 percent is apt to do more harm than good. Recent studies seem to corroborate WHO's assertion that the effects of a high cesarean section rate on a largely low-risk population are costly in both monetary and health terms. The proposed book will be the first in-depth social history of cesarean section in the 19th- and 20th-century U.S. and the first to examine the historical, cultural, and social issues, in addition to the medical factors, that have contributed to today's cesarean section rate of 32 percent. The book has four objectives: (1) To examine how the definition of "normal" labor and birth changed over the course of the nineteenth and twentieth centuries and to study the effect of that changing definition on lay and medical views of medical intervention during birth, particularly the performance of cesarean section. (2) To explore how standard obstetric treatment changed over this same period, particularly when medical personnel encountered a birth they deemed problematic. (3) To examine how the meaning of risk in relation to birth changed over time and to study how this change shaped medical and lay attitudes toward vaginal versus cesarean birth. (4) To study how historical, social, and cultural forces seemingly unrelated to health and medicine shape medical decisions and standard medical practices particularly in an arena such as birth, an event that represents so many societal hopes and concerns. In essence, this social history will examine the historical, social, cultural, and medical factors that shape standard obstetric practices, using cesarean section as a case study. As a historian of medicine, the P.I. will trace the social and cultural context of cesarean section over a roughly 200-year period from a time when the operation was among the most fatal of surgical procedures to the present day when the medical and lay communities view cesarean section as comparable and, at times, preferable to vaginal birth. Data for this book will be culled from oral history interviews with mothers and physicians and myriad archival and published sources including women's letters and diaries; physicians' personal papers; obstetric textbooks; articles in medical journals, newspapers, and magazines; doctors' casebooks; lying-in hospital casebooks; the papers of medical charities, home birthing services, lying-in hospitals, birth reform organizations, and medical and health insurance organizations; pregnancy and childbirth advice manuals; and physicians' and women's biographies and autobiographies.
Public Health Relevance Statement:
Project Narrative This social history of cesarean section in the United States over the last 200 years will examine the historical, cultural, social, and medical factors that have contributed to the current cesarean section rate of 32 percent. The World Health Organization (WHO) has long estimated that the optimal cesarean section rate is between 5 and 10 percent of births and that a rate above 15 percent is apt to do more harm than good and recent studies seem to corroborate WHO's assertion that the effects of a high cesarean section rate on a largely low-risk population are costly in both monetary and health terms. A thorough exploration of the historical emergence

of cesarean section as a routine surgical intervention can help clarify the reasons for the lack of an evidence-based foundation for its frequency and, in doing so, aid in mitigating the current cesarean section rate and its negative effects on women's and children's health.
Project Start Date: 15-SEP-2011
Project End Date: 14-SEP-2014

Project Number: 1ZIAHD008794-05
NIDB Annual Report
Contact PI / Project Leader: SCHISTERMAN, ENRIQUE
Title: CONSORTIUM ON SAFE LABOR Awardee Organization: EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
Abstract Text: A consortium of 12 clincial institutions (19 hospitals) located in all nine districts of the American College of Obstetricians and Gynecologists in the U.S. provided electronic obstetric, labor and newborn data to create a perinatal database with more than 200,000 deliveries. Selected information were downloaded from the hospital databases and transferred in a de-identified format to the Data Coordinating Center for data auditing, cleaning, recoding and compilation. The de-identified database will be used for secondary data analyses to answer the following questions: What is the currect cesarean delivery practice in the U.S.? How can we reduce the cesarean delivery rate? What is the labor pattern in contemporary population? How to define normal and abnormal labor? When is the best time to perform a cesarean delivery in protracted labor? Answers to these questions may have important clinical implications.

CenterWatch: no relevant studies identified

Roche trials database: no relevant studies identified

Current Controlled Trials (international register): 2 relevant studies, both already published and indexed in PubMed (2005)

Foundation for the Advancement of Midwifery: no relevant studies identified

International Cesarean Awareness Network: no studies identified

American Association of Birth Centers: no studies identified

Hudson Valley Birth Network: no studies identified

Lamaze International: no studies identified

North American Registry of Midwives: no studies identified

American College of Nurse-Midwives: no studies identified

Appendix D. Prioritization Tools and Results

1. Snowballing Survey
2. Initial Voting Survey
3. Initial Ranking Survey
4. Final Ranking Survey
5. Initial and Final Ranking Results

Snowballing Survey

Strategies to Reduce Cesarean Birth Among Low Risk Women--Snowballing Survey

Resize font: A | A

Returning?

Thank you for your participation in the Future Research Needs project for Strategies to Reduce Cesarean Birth Among Low Risk Women.

Our project team has compiled an initial list of research questions and recommendations for methodologic improvements. The purpose of this part of our work is to generate an exhaustive list of important research questions and research recommendations. We would like your input in the form of adding new questions and recommendations if you see gaps in these lists.

Please also provide any additional general feedback on the listed research questions and recommendations.

We ask that you provide your additional research questions and recommendations by Tuesday, April 3, 2012.

If you have any questions or concerns regarding the survey or overall project, please contact Rashonda Lewis at rashonda.m.lewis@vanderbilt.edu.

Your answers to the following questions will remain confidential. We are collecting this information in order to describe survey respondents. No information will be used at an individual level or aggregated in a way to allow for respondent identification.

1) **Please enter your name:**

2) **What professional organizations relevant to pregnancy care do you belong to?**

Expand

3) **Have you/your partner had a personal birth experience?** ○ Yes ○ No reset

4) **Have you/your partner had vaginal birth(s)?** ○ Yes ○ No reset

5) **Have you/your partner had obstetrical care providers?** ○ Yes ○ No reset

6) **Have you/your partner had midwifery care providers?** ○ Yes ○ No reset

7) **Have you/your partner had family medicine care providers?** ○ Yes ○ No reset

8) **Have you/your partner had home birth(s)?** ○ Yes ○ No reset

SNOWBALLING RESEARCH QUESTIONS AND METHODOLOGIC IMPROVEMENTS

Examples of Research Questions of Potential Utility in Reducing Use of Cesarean

(To later be ranked by clinical importance, feasibility, contribution to knowledge gaps, and overall importance.)

1. What is the mechanism by which doula support exerts an effect?

2. 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?

3. Do different staffing models like use of hospitalists and integration of midwives reduce the number of cesarean births?

4. Can technologies to enhance fetal surveillance [specify most promising - are there any technology studies worth doing?] improve infant outcomes while reducing cesarean?

5. What patient factors contribute to use of elective cesarean?

6. What patient factors contribute to the use of cesarean during labor?

7. What physician factors contribute to the use of elective cesarean?

8. What physician factors contribute to the use of cesarean during labor?

9. What nurse or midwife factors contribute to the use of cesarean during labor?

10. What nurse or midwife factors contribute to the use of elective cesarean?

11. What hospital factors contribute to the use of cesarean during labor?

12. What hospital factors contribute to the use of elective cesarean?

13. 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?

14. 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?

15. As assessed by sociologic models, are current cesarean rates perceived as concerning or not among members of the public, women of childbearing age, obstetrical care providers, payors, and policy makers?

16. Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?

17. Does outpatient hyaluronidase injection into the cervix for cervical ripening at term reduce risk of cesarean (replication of single promising trial)?

18. When strictly operationalized and compared in clinical trials what components of systems intervention are effective?

19. Does active management of labor, using updated US labor curves, reduce use of cesarean in US community care settings?

20. Do provider peer-review models change provider patterns of cesarean use?

21. Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?

22. Does public reporting of hospital and physician outcomes (induction rates and cesarean rates) reduce use of cesarean?

23. Does midwifery care through-out pregnancy, and in labor in a hospital setting, reduce use of cesarean among low-risk women when compared in a randomized clinical trial to obstetric care?

24. 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?

25. Does a protocol for use of scalp pH sampling reduce use of cesarean?

26. Can tighter standards for induction among primiparous patients reduce use of cesarean?

27. What factors have resulted in the change in patterns of the diagnosis of dystocia over the decades?

28. How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?

29. To what degree is use of cesarean driven by compensation? (address in RCT of altered payment incentives)?

Attachment: Examples of Research Questions of Potential Utility in Reducing Use of Cesarean.docx (0.01 MB)

9) **ADDITIONAL COMMENTS ON RESEARCH QUESTIONS**

In the space below, please comment on any of the research questions above.

Expand

10) **In the space below, please add any additional research questions you find to be imperative when addressing knowledge gaps and research needs in the context of reducing the use of cesarean.**

Expand

Examples of Recommendations for Methodologic Improvements to Research on Reducing Cesarean

(To later be ranked for importance to reducing bias, promoting research quality, and enhancing applicability of findings)

1. Develop data-driven estimates of plausible decreases in cesarean for use in power calculations.

2. Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.

3. Include placebo, sham, or attention control comparison groups, and innovative means of masking patients and providers in studies of interventions.

4. Conduct studies directly comparing and combining candidate strategies to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.

5. Design studies with pre-specified secondary outcomes and adequate power for these outcomes.

6. Conduct studies that allow stratification on patient characteristics such as nulliparity and multiparity and have adequate power to detect differences across strata.

7. Track and report total, primary, and repeat cesareans in studies not restricted to nulliparous women.

8. 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.

9. Include robust measures of maternal coping, satisfaction, and perceived quality of the birth experience. [Or could be a research question: what scales/indices best capture factors that mothers and partners value about their birth?]

10. Expand infant outcomes to include a uniform panel of measures that capture infant status better than Apgar scores and NICU admission.

11. Include maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications, as outcomes.

12. Conduct multisite studies to improve applicability and assure power and precision.

13. Conduct larger trials of health system interventions.

Attachment: Examples of Recommendations for Methodologic Improvements to Research on Reducing Cesarean.docx (0.01 MB)

11) **ADDITIONAL COMMENTS ON METHODOLOGIC IMPROVEMENTS**

In the space below, please comment on any of the methodologic improvements above.

Expand

12) **In the space below, please add any additional recommendations about methodologic improvements you find to be imperative when addressing knowledge gaps and research needs in the context of reducing the use of cesarean.**

Expand

Submit

Save & Return Later

Initial Voting Survey

Confidential

Prioritization Survey #1 Future Research Needs--Strategies to Reduce Cesarean Birth

Below are the lists of research questions and methodologic improvements resulting from the teleconference and snowballing survey.

For this survey we are using a process called "multi-voting". It allows each individual to distribute a predetermined number of points across items. When all surveys are returned we will total the number of points each research question and methodologic improvement item received and rank them in order from most to least points. This will allow us to trim those ranked near the bottom.

You have 47 points to to distribute among the research questions and 17 points to distribute among the methodologic improvements.

You may use any strategy you wish. For instance, it would be allowable to give one point to each of the 47 items or to give all 47 points to a single item.

Strategically, individuals will often give a larger number of points, for instance 5 or 10, to a specific topic or set of topics that they find very compelling with the goal of trying to assure it stays on the list. Summed over a group of people, this process is helpful for ranking of priorities.

Thank you!

Research Questions of Potential Utility in Reducing Use of Cesarean

You have 47 total points. Distribute your 47 points among the research questions you feel are most important.

1. Why do some patients prefer to undergo elective cesarean?	_____ (Each item can receive 0-47 points.)
2. 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?	_____ (Each item can receive 0-47 points.)
3. 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?	_____ (Each item can receive 0-47 points.)
4. 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?	_____ (Each item can receive 0-47 points.)

5. 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?

_____ (Each item can receive 0-47 points.)

6. To what extent do non-financial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?

_____ (Each item can receive 0-47 points.)

7. What nurse or midwife factors contribute to the use of cesarean during labor?

_____ (Each item can receive 0-47 points.)

8. What nurse or midwife factors contribute to the use of elective cesarean?

_____ (Each item can receive 0-47 points.)

9. 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?

_____ (Each item can receive 0-47 points.)

10. 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?

_____ (Each item can receive 0-47 points.)

11. Do audit and feedback interventions influence physician use of cesarean?

_____ (Each item can receive 0-47 points.)

12. 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?

_____ (Each item can receive 0-47 points.)

13. Does use of cesareans correlate with specific days of the week or time of day?

_____ (Each item can receive 0-47 points.)

14. Do different staffing models like use of hospitalists and integration of midwives reduce the number of cesarean births?

_____ (Each item can receive 0-47 points.)

15. Do provider peer-review models change provider patterns of cesarean use?

_____ (Each item can receive 0-47 points.)

16. Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?

_____ (Each item can receive 0-47 points.)

17. Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?

_____ (Each item can receive 0-47 points.)

18. To what degree is use of cesarean driven by uniform compensation for vaginal and cesarean birth as tested by an RCT?

_____ (Each item can receive 0-47 points.)

19. Does public reporting of hospital primary and total cesarean rates affect hospital cesarean rates over time?

_____ (Each item can receive 0-47 points.)

20. Does public reporting of hospital primary and total cesarean rates affect hospital induction rates over time?

_____ (Each item can receive 0-47 points.)

21. Does public reporting of individual physician primary and total cesarean rates affect physician use of cesarean over time? _____ (Each item can receive 0-47 points.)

22. Does public reporting of individual physician primary and total cesarean rates affect physician use of induction over time? _____ (Each item can receive 0-47 points.)

23. 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? _____ (Each item can receive 0-47 points.)

24. Is the Bishop's score routinely used by providers as a decision making tool? If not, why not? _____ (Each item can receive 0-47 points.)

25. To what extent do patient educational and decision support tools affect patient decisions to undergo elective cesarean? _____ (Each item can receive 0-47 points.)

26. To what extent do educational tools that manage patient expectations and describe the risks of cesarean influence use of cesareans during labor? _____ (Each item can receive 0-47 points.)

27. 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? _____ (Each item can receive 0-47 points.)

28. When strictly operationalized and compared in clinical trials what components of systems intervention are effective in reducing cesarean use? _____ (Each item can receive 0-47 points.)

29. Can technologies to enhance fetal surveillance [specify most promising - are there any technology studies worth doing?] improve infant outcomes while reducing cesarean? _____ (Each item can receive 0-47 points.)

29a. Please note any technologies worth studying. _____

30. Does a protocol for use of scalp pH sampling reduce use of cesarean? _____ (Each item can receive 0-47 points.)

31. Does outpatient hyaluronidase injection into the cervix for cervical ripening at term reduce risk of cesarean (replication of single promising trial)? _____ (Each item can receive 0-47 points.)

32. Does active management of labor, using updated US labor curves, reduce use of cesarean in US community care settings? _____ (Each item can receive 0-47 points.)

33. Does use of the Consortium for Safe Labor labor curves reduce use of cesarean? _____ (Each item can receive 0-47 points.)

34. Does elective induction at 39 week vs. expectant management at 39 weeks influence use of cesarean? _____ (Each item can receive 0-47 points.)

35. 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? _____ (Each item can receive 0-47 points.)

36. What is the mechanism by which doula support exerts an effect? _____ (Each item can receive 0-47 points.)

37. 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?
_____ (Each item can receive 0-47 points.)

38. 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?
_____ (Each item can receive 0-47 points.)

39. Can tighter standards for elective induction among primiparous patients reduce use of cesarean?
_____ (Each item can receive 0-47 points.)

40. Can tighter standards for indicated induction among primiparous patients reduce use of cesarean?
_____ (Each item can receive 0-47 points.)

41. How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?
_____ (Each item can receive 0-47 points.)

42. How does implementing a standard indication list affect physician's use of cesarean?
_____ (Each item can receive 0-47 points.)

43. Would changing the definition of when active labor starts reduce use of cesarean?
_____ (Each item can receive 0-47 points.)

44. Would changing the timeframes for normal progress in latent and active labor reduce primary cesareans?
_____ (Each item can receive 0-47 points.)

45. Would a tighter definition of elective cesarean affect physician's use of cesarean?
_____ (Each item can receive 0-47 points.)

46. 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?
_____ (Each item can receive 0-47 points.)

47. What factors have resulted in the change in patterns of the diagnosis of dystocia over the decades?
_____ (Each item can receive 0-47 points.)

TOTAL POINTS GIVEN
_____ (The total should be less than or equal to 47.)

Recommendations for Methodologic Improvements

You have 17 total points. Distribute your 17 points among the methodologic improvements you feel are most important.

1. Develop data-driven estimates of plausible decreases in cesarean for use in power calculations.	_____ (Each item can receive 0-17 points.)
2. Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.	_____ (Each item can receive 0-17 points.)
3. Include placebo, sham, or attention control comparison groups, and innovative means of masking patients and providers in studies of interventions.	_____ (Each item can receive 0-17 points.)
4. Conduct studies directly comparing and combining candidate strategies to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.	_____ (Each item can receive 0-17 points.)
5. Design studies with pre-specified secondary outcomes and adequate power for these outcomes.	_____ (Each item can receive 0-17 points.)
6. Conduct studies that allow stratification on patient characteristics such as nulliparity and multiparity and have adequate power to detect differences across strata.	_____ (Each item can receive 0-17 points.)
7. Track and report total, primary, and repeat cesareans in studies not restricted to nulliparous women.	_____ (Each item can receive 0-17 points.)
8. 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.	_____ (Each item can receive 0-17 points.)
9. Include robust measures of maternal coping, satisfaction, and perceived quality of the birth experience.	_____ (Each item can receive 0-17 points.)
10. Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.	_____ (Each item can receive 0-17 points.)
11. Include maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications, as outcomes in studies.	_____ (Each item can receive 0-17 points.)
12. Conduct multisite studies to improve applicability and assure power and precision.	_____ (Each item can receive 0-17 points.)
13. Conduct larger trials of health system interventions.	_____ (Each item can receive 0-17 points.)
14. Develop registries that capture both short term and long term outcomes.	_____ (Each item can receive 0-17 points.)
15. Determine the best measures of patient and provider route of birth preferences.	_____ (Each item can receive 0-17 points.)

16. Consider the relationship between refined definitions of indications for cesarean and existing population based measures (e.g. hospital discharge data) to better identify algorithms that can be used to document indications in both clinical and non-clinical databases.

_____
(Each item can receive 0-17 points.)

17. Future studies should include a full range of practice settings including community hospitals and birth centers.

_____
(Each item can receive 0-17 points.)

TOTAL POINTS GIVEN

_____
(The total should be less than or equal to 17.)

Initial Ranking Survey

Confidential

Prioritization Survey #2 Future Research Needs--Strategies to Reduce Cesarean Birth

Below are the lists of research questions and methodologic improvements resulting from the May 14th teleconference and first prioritization survey.

Please rank all items from 1st (most important) to 26th (least important) for research questions and from 1st (most important) to 10th (least important) for methodologic improvements .

Thank you!

Research Questions of Potential Utility in Reducing Use of Cesarean Please rank all items from 1st (most important) to 26th (least important).

1) What factors drive a patient's decision to undergo a primary cesarean during labor, e.g. prior cesarean, fears, satisfaction with progress of labor, satisfaction with pain management, etc.?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

2) Do different staffing models, e.g. models that use hospitalists or midwives, reduce the number of cesarean births?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

3) 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?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

4) Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

5) Does elective induction at 39 weeks vs. expectant management at 39 weeks influence use of cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

6) Can tighter standards for induction (indicated or elective) among primiparous patients reduce use of cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

7) To what extent do non-financial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

8) Do audit and feedback interventions influence physician use of cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

9) To what extent do educational and decision support tools that manage patient expectations and describe the risks of cesarean influence use of induction, elective cesarean and cesareans during labor?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

10) What nurse or midwife factors contribute to the use of cesarean during labor?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

11) Would changing the timeframes for normal progress in latent and active labor reduce primary cesareans?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

12) What hospital factors contribute to the use of cesarean, e.g. teaching status, geographical region, urban location, socioeconomic status of patients, staffing and scheduling pattern, provider attitudes toward cesarean use?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

13) How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

14) Do provider peer-review models change provider patterns of cesarean use?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

15) Does public reporting affect induction and cesarean rates over time, e.g. public reporting of total and primary cesarean rates for individual physicians, public reporting of primary and total cesarean rates for hospitals?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

16) Does a protocol for use of scalp pH sampling reduce use of cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

17) Does midwifery care throughout pregnancy in a hospital setting reduce use of cesarean among low-risk women when compared in a randomized clinical trial to obstetric care?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

18) Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

19) What factors have resulted in the change in patterns of the diagnosis of dystocia over the decades?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

20) Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

21) When strictly operationalized and compared in clinical trials, what components of systems interventions are effective in reducing cesarean use?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

22) 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?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

23) 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?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

24) 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?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

25) 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?

☐ 1st ☐ 2nd ☐ 3rd
☐ 4th ☐ 5th ☐ 6th
☐ 7th ☐ 8th ☐ 9th
☐ 10th ☐ 11th ☐ 12th
☐ 13th ☐ 14th ☐ 15th
☐ 16th ☐ 17th ☐ 18th
☐ 19th ☐ 20th ☐ 21st
☐ 22nd ☐ 23rd ☐ 24th
☐ 25th

Recommendations for Methodologic Improvements	**Please rank all items from 1st (most important) to 10th (least important).**
26) Capture all categories of birth outcomes (primary and repeat cesarean, emergent cesarean, assisted vaginal and spontaneous births) and related complications and stratify outcomes by parity.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
27) Future studies should include a full range of practice settings including community hospitals, birth centers and health systems.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
28) Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
29) Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
30) Develop registries that capture both short term and long term outcomes.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
31) Include robust measures of maternal coping, satisfaction, and perceived quality of the birth experience.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
32) Determine the best measures of patient and provider route of birth preferences.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
33) Consider the relationship between refined definitions of indications for cesarean and existing population based measures (e.g. hospital discharge data) to better identify algorithms that can be used to document indications in both clinical and non-clinical databases.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
34) Conduct studies directly comparing and combining candidate strategies to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th
35) Include in studies maternal health outcomes, including maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications.	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th

Final Ranking Survey

Confidential

Prioritization Survey #3 Future Research Needs--Strategies to Reduce Cesarean Birth

Thank you for participating in the Future Research Needs Project for Strategies to Reduce Cesarean Birth.

Below are the lists of highest ranking research questions and methodologic improvements resulting from the previous ranking survey and our last call.

In this final survey, we ask that you rank each question or improvement in methods from 1 (lowest) to 5 (highest) across seven AHRQ prioritization criteria:

-Potential for significant health impact on the current and future health status of people with respect to burden of the disease and health outcomes: mortality, morbidity, and quality of life.

-Potential to reduce important inappropriate (or unexplained) variation in clinical practices known to relate to quality of care, including potential to resolve controversy or dilemmas in what constitutes appropriate health care, and potential to improve decision-making for patient or provider, by decreasing uncertainty.

-Potential for significant (nontrivial) economic impact related to the costs of health service: to reduce unnecessary or excessive costs; to reduce high costs due to high volume use; to reduce high costs due to high unit cost or aggregate cost. Costs may impact consumers, patients, health care systems, or payers.

-Potential risk from inaction: Unintended harms from lack of prioritization of proposed research; opportunity cost of inaction.

-Potential to address inequities, vulnerable, diverse populations (including issues for patient subgroups); potential to reduce health inequities.

-Potential to allow assessment of ethical, legal, social issues pertaining to the condition.

-Potential for new knowledge (Research would not be redundant; Question not sufficiently researched, including completed and in-process research; Utility of available evidence limited by changes in practice, e.g., disease detection or evolution in technology).

When all surveys are returned we will total the number of points each research question and methodologic improvement item received and rank them in order from most to least points by each of the seven prioritization criterion.

The survey will close on May 31, 2012. If you have questions, please contact Rashonda Lewis by phone at (615) 936-2653 or by email at rashonda.m.lewis@vanderbilt.edu.

Thank you!

Research Questions of Potential Utility in Reducing Use of Cesarean
Please rank each item, from 1 (low) to 5 (high), for each of the following criterion:

-Potential for significant health impact.
-Potential to reduce variation in clinical practices.
-Potential for significant economic impact.
-Potential risk from inaction.
-Potential to address inequities.
-Potential to allow assessment of ethical, legal, social issues pertaining to the condition.
-Potential for new knowledge.

1. Can tighter standards for induction (indicated or elective) among primiparous patients reduce use of cesarean?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

2. How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

3. Would changing the timeframes for normal progress in latent and active labor reduce primary cesarean?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

4. 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?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

5. Do different staffing models, e.g. models that use hospitalists or midwives, reduce the number of cesarean births?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

6. Does elective induction at 39 weeks vs. expectant management at 39 weeks influence use of cesarean?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

7. Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

8. To what extent do non-financial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

9. Does public reporting affect induction and cesarean rates over time, e.g. public reporting of total and primary cesarean rates for individual physicians, public reporting of primary and total cesarean rates for hospitals?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

10. Do audit and feedback interventions influence physician use of cesarean?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

11. To what extent do educational and decision support tools that manage patient expectations and describe the risks of cesarean influence use of induction, elective cesarean and cesareans during labor?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

12. When strictly operationalized and compared in clinical trials, what components of systems interventions are effective in reducing cesarean use?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

13. Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

14. 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?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

15. What factors drive a patient's decision to undergo a primary cesarean during labor, e.g. prior cesarean, fears, satisfaction with progress of labor, satisfaction with pain management, etc?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

16. 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?

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Recommendations for Methodologic Improvements

Please rank each item, from 1 (low) to 5 (high), for each of the following criterion:

-Potential for significant health impact.

-Potential to reduce variation in clinical practices.

-Potential for significant economic impact.

-Potential risk from inaction.

-Potential to address inequities.

-Potential to allow assessment of ethical, legal, social issues pertaining to the condition.

-Potential for new knowledge.

1. Capture all categories of birth outcomes (primary and repeat cesarean, emergent cesarean, assisted vaginal and spontaneous births) and related complications and stratify outcomes by parity.

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

2. Future studies should include a full range of practice settings including community hospitals and birth centers.

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

3. Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

4. Develop registries that capture both short term and long term outcomes.

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

5. Include maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications, as outcomes in studies.

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

6. Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

7. Determine the best measures of patient and provider route of birth preferences.

Potential for significant health impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to reduce variation in clinical practices.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for significant economic impact related to the costs of health service.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to address inequities.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential to allow assessment of ethical, legal, and social issue pertaining to the condition.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential for new knowledge.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Initial and Final Ranking Results

Table D1. Initial list from Comparative Effectiveness Review

Examples of Research Questions of Potential Utility in Reducing Use of Cesarean
What is the mechanism by which doula support exerts an effect?
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?
Do different staffing models like use of hospitalists and integration of midwives reduce the number of cesarean births?
Can technologies to enhance fetal surveillance [specify most promising – are there any technology studies worth doing?] improve infant outcomes while reducing cesarean?
What patient and physician factors contribute to use of elective cesarean?
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?
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?
As assessed by sociologic models, are current cesarean rates perceived as concerning or not among members of the public, women of childbearing age, obstetrical care providers, payors, and policy makers.
Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?
Does outpatient hyaluronidase injection into the cervix for cervical ripening a term reduce risk of cesarean (replication of single promising trial)?
When strictly operationalized and compared in clinical trials what components of systems intervention are effective?
Does active management of labor, using updated US labor curves, reduce use of cesarean in US community care settings?
Examples of Recommendations for Methodologic Improvements to Research on Reducing Cesarean
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 pre-specified 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. [Or could be a research question: what scales/indices best capture factors that mothers and partners value about their birth?]
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.

Table D2. Snowballing Survey results

Research Questions
1. Why do some patients prefer to undergo elective cesarean?
2. What factor's drive a patient's decision to undergo a primary cesarean during labor, e.g. prior cesarean, general fears, fear of future pelvic floor disorders?
3. 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?
4. What physician factors contribute to 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?
5. What physician factors contribute to use of cesarean during labor, e.g. residency training, attitude toward elective cesarean, practice size, practice setting, shift/time of day, use of hospitalists, personal birth experience?
6. To what extent do nonfinancial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?
7. What nurse or midwife factors contribute to the use of cesarean during labor?
8. What nurse or midwife factors contribute to the use of elective cesarean?
9. 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 patters, provider attitudes toward cesarean use?
10. 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 patters, provider attitudes toward cesarean use??
11. Do audit and feedback interventions influence physician use of cesarean?
12. 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?
13. Does cesarean use correlate with specific days of the week or time of day?
14. Do different staffing models like use of hospitalists and integration of midwives reduce the number of cesarean births?
15. Do provider peer-review models change provider patterns of cesarean use?
16. Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?
17. Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?
18. To what degree is use of cesarean driven by uniform compensation for vaginal and cesarean birth as tested by an RCT?
19. Does public reporting of hospital primary and total cesarean rates affect hospital cesarean rates over time?
20. Does public reporting of physician primary and total cesarean rates affect physician use of cesarean over time?
21. Does public reporting of physician primary and total cesarean rates affect physician use of induction over time?
22. 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?
23. Is the Bishop's score routinely used by providers as a decision making tool? If not, why not?
24. To what extent to patient educational and support tools affect patient decisions to undergo elective cesarean?
25. To what extent do educational tools that manage patient expectations and describe the risks of cesarean influence use of cesareans during labor?
26. 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?
27. When strictly operationalized and compared in clinical trials what components of systems intervention are effective in reducing cesarean use?
28. Can technologies to enhance fetal surveillance [specify most promising - are there any technology studies worth doing?] improve infant outcomes while reducing cesarean?
29. Does a protocol for use of scalp pH sampling reduce use of cesarean?

Table D2. Snowballing Survey results (continued)

Research Questions
30. Does outpatient hyaluronidase injection into the cervix for cervical ripening at term reduce risk of cesarean (replication of single promising trial)?
31. Does active management of labor, using updated US labor curves, reduce use of cesarean in US community care settings?
32. Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?
33. Does elective induction at 39 weeks vs. expectant management at 39 weeks influence use of cesarean?
34. 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?
35. What is the mechanism by which doula support exerts an effect?
36. 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?
37. 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?
38. Can tighter standards for elective induction among primiparous patients reduce use of cesarean?
39. Can tighter standards for indicated induction among primiparous patients reduce use of cesarean?
40. How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?
41. How does implementing a standard indication list affect physicians' use of cesarean?
42. Would changing the definition of when active labor starts reduce use of cesarean?
43. Would changing the timeframes for normal progress in latent and active labor reduce primary cesareans?
44. Would a tighter definition of elective cesarean affect physicians' use of cesarean?
45. What scales/indices best capture factors that mothers and partners value about their birth?
46. 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?
47. What factors have resulted in the change in patterns of the diagnosis of dystocia over the decades?

Table D2. Snowballing Survey results (continued)

Methodologic Recommendations
1. Develop data-driven estimates of plausible decreases in cesarean for use in power calculations.
2. Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.
3. Include placebo, sham, or attention control comparison groups, and innovative means of masking patients and providers in studies of interventions.
4. Conduct studies directly comparing and combining candidate strategies to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.
5. Design studies with pre-specified secondary outcomes and adequate power for these outcomes.
6. Conduct studies that allow stratification on patient characteristics such as nulliparity and multiparity and have adequate power to detect differences across strata.
7. Track and report total, primary, and repeat cesareans in studies not restricted to nulliparous women.
8. 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.
9. Include robust measures of maternal coping, satisfaction, and perceived quality of the birth experience.
10. Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.
11. Include maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications, as outcomes in studies.
12. Conduct multisite studies to improve applicability and assure power and precision.
13. Conduct larger trials of health system interventions.
14. Develop registries that capture both long term and short term outcomes.
15. Determine the best measures of patient and provider route of birth preferences.
16. Consider the relationship between refined definitions of indications for cesarean and existing population based measures (e.g. hospital discharge data) to better identify algorithms that can be used to document indications in both clinical and nonclinical databases.
17. Future studies should include a full range of practice settings including community hospitals and birth centers.

Table D3. Initial voting results: Research questions

Research Questions	Total Points
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?	25 (22 from 1 vote)
Why do some patients prefer to undergo elective cesarean?	23 (23 from 1 vote)
Do different staffing models like use of hospitalists and integration of midwives reduce the number of cesarean births?	21
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?	20
Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?	18
Does elective induction at 39 week vs. expectant management at 39 weeks influence use of cesarean?	18
Can tighter standards for elective induction among primiparous patients reduce use of cesarean?	18
To what extent do nonfinancial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?	17
Do audit and feedback interventions influence physician use of cesarean?	17
To what extent do educational tools that manage patient expectations and describe the risks of cesarean influence use of cesareans during labor?	17
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?	17
Can tighter standards for indicated induction among primiparous patients reduce use of cesarean?	17
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?	16
Would changing the definition of when active labor starts reduce use of cesarean?	16
Would changing the timeframes for normal progress in latent and active labor reduce primary cesareans?	16
Does public reporting of individual physician primary and total cesarean rates affect physician use of cesarean over time?	14
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?	13
To what degree is use of cesarean driven by uniform compensation for vaginal and cesarean birth as tested by an RCT?	13
How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?	13
Do provider peer-review models change provider patterns of cesarean use?	12
Does public reporting of hospital primary and total cesarean rates affect hospital cesarean rates over time?	12
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?	11
Does a protocol for use of scalp pH sampling reduce use of cesarean?	11
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?	11
What nurse or midwife factors contribute to the use of cesarean during labor?	10
Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?	10
What factors have resulted in the change in patterns of the diagnosis of dystocia over the decades?	10
Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?	9
To what extent do patient educational and decision support tools affect patient decisions to undergo elective cesarean?	9
When strictly operationalized and compared in clinical trials what components of systems intervention are effective in reducing cesarean use?	9

Table D3. Initial voting results: Research questions (continued)

Research Questions	Total Points
Does public reporting of hospital primary and total cesarean rates affect hospital induction rates over time?	8
Does public reporting of individual physician primary and total cesarean rates affect physician use of induction over time?	8
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?	7
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?	7
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?	6
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?	6
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?	6
Does use of cesareans correlate with specific days of the week or time of day?	4
Is the Bishop's score routinely used by providers as a decision making tool? If not, why not?	4
Can technologies to enhance fetal surveillance [specify most promising - are there any technology studies worth doing?] improve infant outcomes while reducing cesarean?	4
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?	3
Does outpatient hyaluronidase injection into the cervix for cervical ripening at term reduce risk of cesarean (replication of single promising trial)?	2
Does active management of labor, using updated US labor curves, reduce use of cesarean in US community care settings?	2
How does implementing a standard indication list affect physician's use of cesarean?	2
What nurse or midwife factors contribute to the use of elective cesarean?	1
What is the mechanism by which doula support exerts an effect?	1
Would a tighter definition of elective cesarean affect physician's use of cesarean?	0

Items highlighted in pink represent the lower-third responses that were eliminated from the priority list.

Table D4. Initial voting results: Methodologic recommendations

Methodologic Recommendations	Total Points
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.	21
Conduct studies that allow stratification on patient characteristics such as nulliparity and multiparity and have adequate power to detect differences across strata.	13
Conduct larger trials of health system interventions.	13
Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.	12
Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.	11
Develop registries that capture both short term and long term outcomes.	11
Future studies should include a full range of practice settings including community hospitals and birth centers.	11
Include robust measures of maternal coping, satisfaction, and perceived quality of the birth experience.	8
Develop data-driven estimates of plausible decreases in cesarean for use in power calculations.	7
Design studies with pre-specified secondary outcomes and adequate power for these outcomes.	7
Track and report total, primary, and repeat cesareans in studies not restricted to nulliparous women.	7
Determine the best measures of patient and provider route of birth preferences.	7
Consider the relationship between refined definitions of indications for cesarean and existing population based measures (e.g. hospital discharge data) to better identify algorithms that can be used to document indications in both clinical and nonclinical databases.	7
Conduct studies directly comparing and combining candidate strategies to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.	5
Include maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications, as outcomes in studies.	5
Include placebo, sham, or attention control comparison groups, and innovative means of masking patients and providers in studies of interventions.	2
Conduct multisite studies to improve applicability and assure power and precision.	2

Items highlighted in pink represent the lower-third responses that were eliminated from the priority list.

Table D5. Initial ranking results: Research questions

Research Questions	Total Points
Can tighter standards for induction (indicated or elective) among primiparous patients reduce use of cesarean?	76
Do different staffing models, e.g. models that use hospitalists or midwives, reduce the number of cesarean births?	85
How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?	86
Would changing the timeframes for normal progress in latent and active labor reduce primary cesareans?	86
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?	95
Does elective induction at 39 weeks vs. expectant management at 39 weeks influence use of cesarean?	95
Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?	106
To what extent do educational and decision support tools that manage patient expectations and describe the risks of cesarean influence use of induction, elective cesarean and cesareans during labor?	114
To what extent do nonfinancial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?	115
When strictly operationalized and compared in clinical trials, what components of systems interventions are effective in reducing cesarean use?	116
Does public reporting affect induction and cesarean rates over time, e.g. public reporting of total and primary cesarean rates for individual physicians, public reporting of primary and total cesarean rates for hospitals?	119
Do audit and feedback interventions influence physician use of cesarean?	121
Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?	136
What hospital factors contribute to the use of cesarean, e.g. teaching status, geographical region, urban location, socioeconomic status of patients, staffing and scheduling pattern, provider attitudes toward cesarean use?	137
What factors drive a patient's decision to undergo a primary cesarean during labor, e.g. prior cesarean, fears, satisfaction with progress of labor, satisfaction with pain management, etc.?	142
Does midwifery care throughout pregnancy in a hospital setting reduce use of cesarean among low-risk women when compared in a randomized clinical trial to obstetric care?	151
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?	152
What nurse or midwife factors contribute to the use of cesarean during labor?	170
What factors have resulted in the change in patterns of the diagnosis of dystocia over the decades?	171
Can protocols supporting trial of induction of labor make it realistic for physicians to send a patient home if indication of labor does not progress in a timely fashion?	171
Does a protocol for use of scalp pH sampling reduce use of cesarean?	177
Do provider peer-review models change provider patterns of cesarean use?	179
Do natural experiments in tort reform support assertions that liability concerns contribute to use of cesarean?	185
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?	187
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?	214

Items highlighted in pink represent the lower-third responses that were eliminated from the priority list.

Table D6. Initial ranking results: Methodologic recommendations

Methodologic Recommendations	Total Points
Capture all categories of birth outcomes (primary and repeat cesarean, emergent cesarean, assisted vaginal and spontaneous births) and related complications and stratify outcomes by parity.	21
Future studies should include a full range of practice settings including community hospitals, birth centers and health systems.	40
Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.	44
Develop registries that capture both short term and long term outcomes.	45
Include in studies maternal health outcomes, including maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications.	45
Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.	49
Determine the best measures of patient and provider route of birth preferences.	61
Include robust measures of maternal coping, satisfaction, and perceived quality of the birth experience.	64
Conduct studies directly comparing and combining candidate strategies to detect additive and multiplicative effects of combining two effective interventions over each effective intervention alone.	66
Consider the relationship between refined definitions of indications for cesarean and existing population based measures (e.g. hospital discharge data) to better identify algorithms that can be used to document indications in both clinical and nonclinical databases.	70

Items highlighted in pink represent the lower-third responses that were eliminated from the priority list.

Table D7. Final prioritization results: Research questions

Research Questions	AHRQ Potential Value Criteria: Health impact	Reduce variation	Economic impact	Risk from inaction	Address inequities	Ethical, legal, social	New knowledge	Total Points	Tier
When strictly operationalized and compared in clinical trials, what components of systems interventions are effective in reducing cesarean use?	45	43	40	32	28	25	40	253	Top
Can tighter standards for induction (indicated or elective) among pimiparous patients reduce use of cesarean?	43	44	33	38	34	28	32	252	Top
How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?	41	47	35	34	31	25	35	248	Top
Would changing the timeframes for normal progress in latent and active labor reduce primary cesarean?	41	46	34	29	30	26	35	241	Top
Do different staffing models, e.g. models that use hospitalists or midwives, reduce the number of cesarean births?	42	39	39	30	29	26	34	239	Top
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?	40	34	35	29	31	25	33	227	Middle
Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?	37	34	36	29	28	32	29	225	Middle
To what extent do educational and decision support tools that manage patient expectations and describe the risks of cesarean influence use of induction, elective cesarean and cesareans during labor?	36	34	30	28	32	31	31	222	Middle
Does elective induction at 39 weeks vs. expectant management at 39 weeks influence use of cesarean?	36	38	35	27	29	26	26	217	Middle
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?	36	34	31	26	28	28	33	216	Middle
Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?	36	38	29	26	27	23	33	212	Middle
What factors drive a patient's decision to undergo a primary cesarean during labor, e.g. prior cesarean, fears, satisfaction with progress of labor, satisfaction with pain management, etc?	35	30	30	23	29	35	29	211	Middle
Does public reporting affect induction and cesarean rates over time, e.g. public reporting of total and primary cesarean rates for individual physicians, public reporting of primary and total cesarean rates for hospitals?	35	31	33	28	29	25	30	211	Middle
Do audit and feedback interventions influence physician use of cesarean?	36	36	31	28	27	26	24	208	Middle
To what extent do nonfinancial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?	33	31	32	26	28	29	27	206	Middle
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?	32	29	27	26	26	25	24	189	Lower

Table D8. Final prioritization results: Methodologic recommendations

Methodologic Recommendations	AHRQ Potential Value Criteria								
	Health impact	Reduce variation	Economic impact	Risk from inaction	Address inequities	Ethical, legal, social	New knowledge	Total Points	Tier
Capture all categories of birth outcomes (primary and repeat cesarean, emergent cesarean, assisted vaginal and spontaneous births) and related complications and stratify outcomes by parity.	49	43	38	40	36	36	39	281	Top
Develop registries that capture both short term and long term outcomes.	48	43	38	33	33	34	40	269	Top
Future studies should include a full range of practice settings including community hospitals, birth centers and health systems.	45	41	35	33	37	31	36	258	Middle
Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.	45	42	37	33	32	29	38	256	Middle
Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.	45	41	33	31	29	27	32	238	Middle
Include in studies maternal health outcomes, including maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications.	39	33	36	29	28	25	35	225	Lower
Determine the best measures of patient and provider route of birth preferences.	34	29	31	28	30	33	31	216	Lower

Table D9. Top-five items for each AHRQ criterion*

	AHRQ Criteria							
Research Question	Health impact	Reduce variation	Economic impact	Risk from inaction	Address inequities	Ethical, legal, social	New knowledge	Tier
When strictly operationalized and compared in clinical trials, what components of systems interventions are effective in reducing cesarean use?	✓	✓	✓	✓			✓	Top
Can tighter standards for induction (indicated or elective) among pimiparous patients reduce use of cesarean?	✓	✓		✓	✓	✓	✓	Top
How does implementing uniform definitions for arrest of labor and its management influence use of cesarean?	✓	✓	✓	✓	✓		✓	Top
Would changing the timeframes for normal progress in latent and active labor reduce primary cesarean?	✓	✓		✓	✓		✓	Top
Do different staffing models, e.g. models that use hospitalists or midwives, reduce the number of cesarean births?	✓	✓	✓	✓	✓		✓	Top
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?	✓		✓	✓	✓		✓	Middle
Do natural experiments in payment reform support the assertions that certain incentive structures contribute to the use of cesarean?			✓	✓		✓		Middle
To what extent do educational and decision support tools that manage patient expectations and describe the risks of cesarean influence use of induction, elective cesarean and cesareans during labor?					✓	✓		Middle
Does elective induction at 39 weeks vs. expectant management at 39 weeks influence use of cesarean?					✓			Middle
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?						✓	✓	Middle
Does use of the Consortium for Safe Labor labor curves reduce use of cesarean?							✓	Middle
What factors drive a patient's decision to undergo a primary cesarean during labor, e.g. prior cesarean, fears, satisfaction with progress of labor, satisfaction with pain management, etc?					✓	✓		Middle
Does public reporting affect induction and cesarean rates over time, e.g. public reporting of total and primary cesarean rates for individual physicians, public reporting of primary and total cesarean rates for hospitals?					✓			Middle

*This table presents research questions with checkmarks to indicate those items that appear in the top-five for **each specific AHRQ criterion**. An AHRQ criterion with more than five checked items reflects tied rankings for two or more of the items. The tier assigned (last column) to each research question is based on total points assigned for **all seven AHRQ criteria**.

Table D9. Top-five items for each AHRQ criterion* (continued)

	AHRQ Criteria							
Research Question	Health impact	Reduce variation	Economic impact	Risk from inaction	Address inequities	Ethical, legal, social	New knowledge	Tier
Do audit and feedback interventions influence physician use of cesarean?								Middle
To what extent do nonfinancial incentives such as time savings, control and perceived improvement in patient relations affect physician decisions to use cesarean?						✓		Middle
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?								Lower

*This table presents research questions with checkmarks to indicate those items that appear in the top-five for **each specific AHRQ criterion**. An AHRQ criterion with more than five checked items reflects tied rankings for two or more of the items. The tier assigned (last column) to each research question is based on total points assigned for **all seven AHRQ criteria**.

Table D10. Top-tier methodologic recommendations

	AHRQ Criteria							
Methodologic Recommendations	Health impact	Reduce variation	Economic impact	Risk from inaction	Address inequities	Ethical, legal, social	New knowledge	Tier
Capture all categories of birth outcomes (primary and repeat cesarean, emergent cesarean, assisted vaginal and spontaneous births) and related complications and stratify outcomes by parity.	✓	✓	✓	✓	✓	✓	✓	Top
Develop registries that capture both short term and long term outcomes.	✓	✓	✓	✓		✓	✓	Top
Future studies should include a full range of practice settings including community hospitals, birth centers and health systems.				✓	✓			Middle
Expand infant outcomes to include a uniform panel of measures that capture infant status and development better than Apgar scores and NICU admission, including post-discharge measures.			✓	✓				Middle
Develop definitions of indications for cesarean that can be validated from medical records and case-report forms.								Middle
Include in studies maternal health outcomes, including maternal length of stay and incidence of specific complications like chorioamnionitis, endometritis, and wound healing complications.								Lower
Determine the best measures of patient and provider route of birth preferences.								Lower

*This table presents research questions with checkmarks to indicate those items that appear in the top-two for **each specific AHRQ criterion**. An AHRQ criterion with more than two checked items reflects tied rankings for two or more of the items. The tier assigned (last column) to each research question is based on total points assigned for **all seven AHRQ criteria**.