



Effective Health Care

Doula Support and Cesarean Section Rates

Results of Topic Selection Process & Next Steps

The nominator, International Childbirth Education Association, is interested in a new evidence review on the effectiveness of doula support in childbirth to advocate for the expansion of birth doula programs at hospitals.

We identified 2 reviews applicable to the scope of the nomination, and no new studies about the impact of doula employment and certification. Therefore, no further activity on this nomination will be undertaken by the Effective Health Care (EHC) Program.

Topic Brief

Topic Number and Name: #821, Doula support in lowering cesarean section rates

Nomination Date: 9/12/2018

Topic Brief Date: 10/18/2018

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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

Background

- There were 3,941,109 births in 2016, and¹ 31.9% were by cesarean delivery.²
- Doulas are nonmedical individuals who provide support to women during childbirth and the post-partum period.
- In a survey of childbearing women, 6% indicated that they had used doulas during their latest labor experience.³
- There are a number of organizations that provide training and certification of doulas, including the Childbirth and postpartum Professional Association, DONA International.
- In 2014 ACOG and SMGM released a consensus statement supporting the use of support personnel such as a doula to improve labor and delivery outcomes⁴
- Doula services are covered by Medicaid in Minnesota and Oregon⁵
- Proposed benefits include decreased cesarean section rates, higher breastfeeding rates, decreased postpartum depression, decreased use of pain medication during labor, and decreased likelihood of requiring oxytocin during labor.⁶

Nominator and Stakeholder Engagement

We clarified with the nominator the subgroups of interest, and she affirmed the scope of the nomination's key questions.

Key Questions and PICOs

The key questions for this nomination are:

1. Do doulas lower cesarean section rates?
 - a. Does this differ by employment?
 - b. Does this differ by certification?

To define the inclusion criteria for the key questions, we specify the population, interventions, comparators, and outcomes (PICO) of interest (Table 1).

Table 1. Key Questions and PICO

Key Questions	Effectiveness of antepartum doula
Population	Pregnant women in labor
Interventions	Doulas <ul style="list-style-type: none">• Employment by hospital or privately• Certification
Comparators	Usual care
Outcomes	<ul style="list-style-type: none">• Mode of delivery (vaginal delivery, cesarean section)• Patient labor experience• Adverse events

Methods

We assessed nomination for priority for a systematic review or other AHRQ EHC report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix A for detailed description of the criteria.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.

2. Establish the overall *importance* of a potential topic as representing a health or healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new systematic review or other AHRQ product would be duplicative.
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years on the key questions of the nomination. See Appendix B for sources searched.

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a literature search in PubMed from October 2013 to October 2018. See Appendix C for the PubMed search strategy and links to the ClinicalTrials.gov search.

We reviewed all identified titles and abstracts for inclusion and classified identified studies by key question and study design to assess the size and scope of a potential evidence review.

Results

See Appendix A for detailed assessments of all EPC selection criteria.

Appropriateness and Importance

This is an appropriate and important topic.

Desirability of New Review/Duplication

A new evidence review would be duplicative of an existing evidence review. We identified one completed systematic review and one in-process systematic review that covers the scope of the nomination. The Cochrane systematic review included subgroup analysis by employment; and the in-process AHRQ systematic review sought but did not find information in primary studies to perform subgroup analysis by certification. See Table 2, Duplication column; and Appendix A.

Impact of a New Evidence Review

A new systematic review may have limited impact. The use of doulas for decreasing cesarean section rates is supported by two major professional societies, the American College of Gynecology and Society for Fetal Maternal Medicine. The limited use of doulas may be related to a lack of awareness and cost. There is a diversity of certification programs available. The

contribution of these factors to effectiveness is unknown and could theoretically be impactful. See Appendix A.

Feasibility of a New Evidence Review

A new evidence review is not feasible. For completeness a feasibility search was undertaken to identify studies that might address the subquestions of interest to the nominator.

We found five studies comparing outcomes for women with doula support to those without doula support. We identified no studies that assessed the impact of certification or type of employment on outcomes. See Table 2, Feasibility column.

Table 2. Key Questions and Results for Duplication and Feasibility

Key Question	Duplication (10/2015-10/2018)	Feasibility (10/2013-10/2018)
KQ 1: Effectiveness of doula support <ul style="list-style-type: none"> Differential effect by employer Differential effect by certification 	Total number of identified systematic reviews-2 <ul style="list-style-type: none"> AHRQ EPC: 1⁷ Cochrane: 1⁸ Employer of doula support-1 <ul style="list-style-type: none"> Cochrane: 1⁸ Certification-0	<u>Size/scope of review</u> Relevant Studies Identified: 5 <ul style="list-style-type: none"> Case control⁹ Cohort¹⁰⁻¹² RCT¹³ Employer of doula support-0 Certification-0 <u>Clinicaltrials.gov</u> <ul style="list-style-type: none"> Not yet recruiting NCT03461640 Complete: NCT02550730 NCT00664118

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; CS=cesarean section; EPC=Evidence-based Practice Center; KQ=Key Question

Summary of Findings

- Appropriateness and importance: The topic is both appropriate and important.
- Duplication: A new review would be duplicative of an existing product. We identified one completed and one in-process systematic review that covers the scope of the nomination.
- Impact: A new systematic review may have limited impact potential. Two major professional societies support the use of doulas to prevent cesarean sections. Underuse of this service may be related to lack of awareness and cost.
- Feasibility: A new systematic review is not feasible due to the lack of studies focused on the subgroups of interest (employer of doula support and certification).

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Appendix A. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes
1b. Is the nomination a request for a systematic review?	Yes
1c. Is the focus on effectiveness or comparative effectiveness?	Yes
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	The US fertility rate was 60.3 births per 1000 women 15-44 years old in 2017. In 2016 31.9% of births were by cesarean section.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes. Patients, physicians and healthcare organizations are concerned about the rates of cesarean section.
2c. Represents important uncertainty for decision makers	Unclear.
2d. Incorporates issues around both clinical benefits and potential clinical harms	Yes
2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	This can be costly for women if doula services are not a covered benefit. Cesarean sections are more expensive to the healthcare system than spontaneous vaginal births.
3. Desirability of a New Evidence Review/Duplication	

Selection Criteria	Assessment
<p>3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)</p>	<p>We found 2 reviews that covered KQ 1. The Cochrane systematic review and draft AHRQ systematic review both assessed the impact of doulas on cesarean section. The Cochrane review addressed the subquestion on doula employment (specifically those employed privately); and the AHRQ review sought but did not find information about doula employment and certification, though this was not explicitly stated in the draft report.</p> <ul style="list-style-type: none"> • Bohren et al (Cochrane, 2017)⁸ found that women who received continuous labor support may be more likely to give birth spontaneously. In addition, continuous support was most effective at reducing cesarean birth when they were present in a doula role. <ul style="list-style-type: none"> • The review did not included subgroup analysis by certification. • The review included subgroup analysis by characteristic of the continuous support (employed by the hospital, a member of the women’s social network, or neither (such as a doula employed by the women)). The largest effect on spontaneous vaginal delivery was seen in the group of women supported by people not employed by the hospital or chosen by the women, for example, doulas. A smaller effect size was seen with support given by hospital staff. • For cesarean section outcome: in nine trials, the support was provided by a woman who was not a member of the hospital staff and not part of the woman’s social network (such as a doula employed by the women) (average RR 0.61, 95% CI 0.45 to 0.83). • AHRQ in-process systematic review on labor dystocia⁷. KQ 3 focused on supportive care measures during spontaneous labor including emotional support by doulas on outcomes, including cesarean section deliveries. <ul style="list-style-type: none"> ○ We confirmed with the staff that they sought information about subgroups related to doulas reported in studies, and this would have included certification, training, and employment. ○ Outcomes included CS rate, birth experience and adverse events. ○ The final report, with an updated search and conclusions, is expected to be completed in December 2018.
<p>4. Impact of a New Evidence Review</p>	

Selection Criteria	Assessment
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	<p>In 2016 ACOG reaffirmed its 2014 joint consensus statement with the Society for Maternal-Fetal Medicine on Safe Prevention of the Primary Cesarean Delivery⁴. In it they support continuous support personnel, such as a doula, based on evidence from a 2013 Cochrane systematic review. They also note that this intervention is likely underused.</p> <p>There is a diversity of certification programs available. The contribution of this factor to effectiveness is unknown and could theoretically be impactful.</p>
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Likely there is practice variation; only 6% of women use a doula during labor. This may be due to a lack of information and limited insurance coverage for this support. ¹⁴
5. Primary Research	
<p>5. Effectively utilizes existing research and knowledge by considering:</p> <ul style="list-style-type: none"> - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies) 	<p>For completeness a feasibility search was undertaken to identify studies that might address the subquestions of interest to the nominator.</p> <p>A new systematic review is not feasible. We identified five studies on the effectiveness of doula support during labor. One was an RCT¹³, three were cohort studies¹⁰⁻¹², and one was a case-control study⁹. No studies that addressed the subquestions of interest to the nominator.</p> <p>We identified three studies through Clinicaltrials.gov. Two have been completed with no results available; and the third has not begun recruitment. None address the subquestions of interest to the nominator. All compare a doula or support person to usual care.</p>

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; KQ=Key Question

Appendix B. Search for Evidence Reviews (Duplication)

Listed below are the sources searched, hierarchically

Primary Search
AHRQ: Evidence reports and technology assessments https://effectivehealthcare.ahrq.gov/ ; https://www.ahrq.gov/research/findings/ta/index.html ; https://www.ahrq.gov/research/findings/evidence-based-reports/search.html
Cochrane Systematic Reviews http://www.cochranelibrary.com/
AHRQ Products in development https://effectivehealthcare.ahrq.gov/
Cochrane Protocols http://www.cochranelibrary.com/

Appendix C. Search Strategy & Results (Feasibility)

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to October 04, 2018

Date Searched: October 5, 2018

Searched by: Robin Paynter, MLIS

#	Searches	Results
1	cesarean section/ or cesarean section, repeat/ or vaginal birth after cesarean/ or "trial of labor"/ or delivery, obstetric/ or labor, obstetric/ or obstetric labor complications/ or parturition/	103706
2	(cesarean* or c-section* or birth* or childbirth* or deliver* or intrapartum* or labor* or labour* or parturition*).ti,kf.	357704
3	or/1-2	402194
4	Doulas/	110
5	(doula* or monitrice*).tw,kf. or ((continuous* or companion* or emotion* or physic* or psycholog* or social*) adj5 support*).ti.	10045
6	or/4-5	10072
7	and/3,6	399
8	limit 7 to (adaptive clinical trial or clinical study or clinical trial, all or clinical trial or controlled clinical trial or pragmatic clinical trial or randomized controlled trial)	38
9	limit 7 to (meta analysis or systematic reviews)	28

ClinicalTrials.gov

Date Searched: October 5, 2018

OTHER TERMS: doula OR monitrice = 16 results

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