the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before April 6, 2020. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Heather Hippsley,

Deputy General Counsel.

[FR Doc. 2020–02111 Filed 2–3–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Cervical Ripening in the Outpatient Setting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Cervical Ripening in the Outpatient Setting,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before 30 days after date of publication in the **Federal Register**.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Cervical Ripening in the Outpatient Setting. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Cervical Ripening in the Outpatient Setting,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/cervical-ripening/protocol.*

This is to notify the public that the EPC Program would find the following information on *Cervical Ripening in the Outpatient Setting* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on *ClinicalTrials.gov* along with the *ClinicalTrials.gov* trial number.
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ1: How do the effectiveness and harms of cervical ripening (CR) using prostaglandins compare in the outpatient *vs.* inpatient setting?

1a: How do effectiveness and harms vary by choice of prostaglandin?

1b: Do effectiveness and harms vary by important patient characteristics (such as gestational age, parity, uncomplicated pregnancy, prior cesarean delivery, etc.)?

KQ2: How do the effectiveness and harms of CR using mechanical methods (*e.g.,* balloon catheters) compare in the outpatient *vs.* inpatient setting?

2a: How do effectiveness and harms vary by choice of mechanical method in the inpatient versus the outpatient setting?

2b: Do effectiveness and harms vary by important patient characteristics (such as gestational age, parity, uncomplicated pregnancy, prior cesarean delivery, etc.)?

KQ3: How do the effectiveness and harms of CR in the *outpatient setting* vary by method of CR compared with each other?

3a: Do effectiveness and harms vary by important patient characteristics (such as gestational age, parity, uncomplicated pregnancy, prior cesarean delivery, etc.)?

KQ4: How do the effectiveness and harms of different methods and protocols for fetal surveillance compare with each other or with no monitoring in pregnant women undergoing CR with prostaglandins?

4a. Do effectiveness and harms vary by important patient characteristics (such as gestational age, parity, uncomplicated pregnancy, prior cesarean delivery, etc.)?

Contextual Question: What evidence informs preference for or tolerability of different methods of CR in the outpatient setting or outpatient compared to the inpatient setting?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

PICOTS	Inclusion key question 1: Prostaglandin inpatient vs. outpatient	Inclusion key question 2: Mechanical method inpatient vs outpatient	Inclusion key question 3: Outpatient comparison of methods	Inclusion key question 4: Fetal surveillance	Exclusion
Population	• Pregnant women ≥37 weeks undergoing CR in the outpatient setting. • Important maternal subgroups: parity, maternal age, GBS status, diabetes (pregestational, gestational), hypertension (chronic, preeclampsia without severe features, gestational). • Important fetal subgroups: fetal growth restriction, gestational age (<39 weeks, 39 to 41 weeks, >41 weeks).	• Pregnant women ≥37 weeks undergoing CR in the outpatient setting. • Important maternal subgroups: parity, maternal age, GBS status, diabetes (pregestational, gestational), hypertension (chronic, preeclampsia without severe features, gestational). • Important fetal subgroups: fetal growth restriction, gestational age (<39 weeks, 39 to 41 weeks, >41 weeks).	• Pregnant women ≥37 weeks undergoing CR in the outpatient setting. • Important maternal subgroups: parity, maternal age, GBS status, diabetes (pregestational, gestational), hypertension (chronic, preeclampsia without severe features, gestational). • Important fetal subgroups: fetal growth restriction, gestational age (<39 weeks, 39 to 41 weeks, >41 weeks).	• Pregnant women ≥37 weeks undergoing CR with a prostaglandin. • Important maternal subgroups: parity, maternal age, GBS status, diabetes (pregestational, gestational), hypertension (chronic, preeclampsia without severe features, gestational). • Important fetal subgroups: fetal growth restriction, gestational age (<39 weeks, 39 to 41 weeks, >41 weeks).	Women with contraindications to CR in the outpatient setting: a multiple pregnancy, prior uterine rupture and breech presentation of the fetus.
Intervention	• Pharmacologic agents (prostaglandins) given in outpatient setting.	• Mechanical methods (balloon catheters, laminaria tents) used in outpatient setting.	Mechanical methods (balloon catheters, laminaria tents) or pharmacologic agents (prostaglandins).	• Any method of fetal surveillance.	• Catheters not available in the U.S. • Pharmacy-compounded prostaglandin products. • Other CR methods: Castor oil, nipple stimulation, membrane stripping, sexual intercourse, acupuncture/pressure, transcutaneous nerve stimulation, herbal compounds.
Comparator	• Mechanical (i.e., balloon catheters, luminaria tents) and/or pharmacologic (i.e., prostaglandins) methods in the inpatient setting.	• Mechanical (i.e., balloon catheters, luminaria tents) and/or pharmacologic (i.e., prostaglandins) methods in the inpatient setting.	• Any comparator including alternative mechanical device or protocol, alternative pharmacologic agent or dose, combination mechanical and pharmacologic, placebo, and other CR methods excluded as intervention (e.g., Castor oil, acupuncture).	• Another method of fetal surveillance. • Another protocol for fetal surveillance with the same method. • No monitoring.	• Catheters not available in the U.S. • Pharmacy-compounded prostaglandin products.
Outcomes Effectiveness (birth-related).	• Total time admission to vaginal delivery; total L&D length of stay [c]. • Cesarean delivery rate overall [c]. • Vaginal delivery within 24 hours. Failed induction rate, defined as: ○ CD in patient at <6cm dilation excluding fetal distress (labor dystocia, failure to progress, etc.). ○ CD in patient at <6 cm dilation for fetal distress. • Cervical assessment at time of admission (e.g., latent vs. active phase, Bishop score, cervical dilation). • Time from ROM to delivery	• Total time admission to vaginal delivery; total L&D length of stay [c]. • Cesarean delivery rate overall [c]. • Vaginal delivery within 24 hours. Failed induction rate, defined as: ○ CD in patient at <6cm dilation excluding fetal distress (labor dystocia, failure to progress, etc.). ○ CD in patient at <6 cm dilation for fetal distress. • Cervical assessment at time of admission (e.g., latent vs. active phase, Bishop score, cervical dilation). • Time from ROM to delivery	• Total time admission to vaginal delivery; total L&D length of stay [c]. • Cesarean delivery rate overall [c]. • Vaginal delivery within 24 hours. Failed induction rate, defined as: ○ CD in patient at <6cm dilation excluding fetal distress (labor dystocia, failure to progress, etc.). ○ CD in patient at <6 cm dilation for fetal distress. • Cervical assessment at time of admission (e.g., latent vs. active phase, Bishop score, cervical dilation). • Time from ROM to delivery • Breastfeeding [b]. • Maternal mood [b]. • Mother-baby attachment [b].	• Total time admission to vaginal delivery; total L&D length of stay [c]. • Cesarean delivery rate overall [c]. • Vaginal delivery within 24 hours. Failed induction rate, defined as: ○ CD in patient at <6cm dilation excluding fetal distress (labor dystocia, failure to progress, etc.). ○ CD in patient at <6 cm dilation for fetal distress. • Cervical assessment at time of admission (e.g., latent vs. active phase, Bishop score, cervical dilation). • Time from ROM to delivery.	Outcomes not listed in inclusion criteria.
Outcomes Fetal Harms	• Perinatal Mortality [c] • Hypoxic-ischemic [c] encephalopathy [c]. • Seizure [c] • Infection (confirmed sepsis or pneumonia) [c]. • Meconium aspiration syndrome [c]. • Birth trauma (e.g., bone fracture, neurologic injury, or retinal hemorrhage) [c]. • Intracranial or subgaleal hemorrhage [c]. • Need for respiratory support within 72 hours after birth. • Apgar score ≤3 at 5 minutes [a]. • Hypotension requiring vasopressor support. • Umbilical cord gas <pH 7.0 or 7.10.	• Perinatal Mortality [c] • Hypoxic-ischemic [c] encephalopathy [c]. • Seizure [c] • Infection (confirmed sepsis or pneumonia) [c]. • Meconium aspiration syndrome [c]. • Birth trauma (e.g., bone fracture, neurologic injury, or retinal hemorrhage) [c]. • Intracranial or subgaleal hemorrhage [c]. • Need for respiratory support within 72 hours after birth. • Apgar score ≤3 at 5 minutes [a]. • Hypotension requiring vasopressor support. • Umbilical cord gas <pH 7.0 or 7.10.	• Perinatal Mortality [c] • Hypoxic-ischemic [c] encephalopathy [c]. • Seizure [c] • Infection (confirmed sepsis or pneumonia) [c]. • Meconium aspiration syndrome [c]. • Birth trauma (e.g., bone fracture, neurologic injury, or retinal hemorrhage) [c]. • Intracranial or subgaleal hemorrhage [c]. • Need for respiratory support within 72 hours after birth. • Apgar score ≤3 at 5 minutes [a]. • Hypotension requiring vasopressor support. • Umbilical cord gas <pH 7.0 or 7.10.	• Perinatal Mortality [c] • Hypoxic-ischemic [c] encephalopathy [c]. • Seizure [c]. • Infection (confirmed sepsis or pneumonia) [c]. • Meconium aspiration syndrome [c]. • Birth trauma (e.g., bone fracture, neurologic injury, or retinal hemorrhage) [c]. • Intracranial or subgaleal hemorrhage [c]. • Need for respiratory support within 72 hours after birth. • Apgar score ≤3 at 5 minutes [a]. • Hypotension requiring vasopressor support. • Umbilical cord gas <pH 7.0 or 7.10.	Outcomes not listed in inclusion criteria.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

PICOTS	Inclusion key question 1: Prostaglandin inpatient vs. outpatient	Inclusion key question 2: Mechanical method inpatient vs outpatient	Inclusion key question 3: Outpatient comparison of methods	Inclusion key question 4: Fetal surveillance	Exclusion
Outcomes Maternal Harms	• Hemorrhage requiring transfusion [c]. • Postpartum hemorrhage by mode (vaginal, cesarean) [c]. • Uterine infection (i.e., choriamnionitis, administration of antibiotics in labor other than GBS prophylaxis) [c]. • Placental abruption, Uterine rupture. • Umbilical cord prolapse • Duration of time between hospital admission to birth that is insufficient to enable complete GBS prophylaxis antibiotics administration per CDC guidelines.	• Hemorrhage requiring transfusion [c]. • Postpartum hemorrhage by mode (vaginal, cesarean) [c]. • Uterine infection (i.e., choriamnionitis, administration of antibiotics in labor other than GBS prophylaxis) [c]. • Placental abruption • Uterine rupture • Umbilical cord prolapse • Duration of time between hospital admission to birth that is insufficient to enable complete GBS prophylaxis antibiotics administration per CDC guidelines.	• Hemorrhage requiring transfusion [c]. • Postpartum hemorrhage by mode (vaginal, cesarean) [c]. • Uterine infection (i.e., choriamnionitis, administration of antibiotics in labor other than GBS prophylaxis) [c]. • Placental abruption, Uterine rupture. • Umbilical cord prolapse • Duration of time between hospital admission to birth that is insufficient to enable complete GBS prophylaxis antibiotics administration per CDC guidelines.	• Hemorrhage requiring transfusion [c]. • Postpartum hemorrhage by mode (vaginal, cesarean) [c]. • Uterine infection (i.e., choriamnionitis, administration of antibiotics in labor other than GBS prophylaxis) [c]. • Placental abruption • Uterine rupture • Umbilical cord prolapse • Duration of time between hospital admission to birth that is insufficient to enable complete GBS prophylaxis antibiotics administration per CDC guidelines.	Outcomes not listed in inclusion criteria.
Timing	Maternal outcomes • From CR initiation to within 1-week following delivery. Infant outcomes • Immediately following delivery.	Maternal outcomes • From CR initiation to within 1-week following delivery. Infant outcomes • Immediately following delivery.	Maternal and additional outcomes (i.e., breastfeeding, maternal mood, mother-baby attachment). • From CR initiation to 1-year postpartum. Infant outcomes • Immediately following delivery.	Maternal outcomes • From CR initiation to within 1-week following delivery. Infant outcomes • Immediately following delivery.	KQ 1,2,4: Outcomes occurring after 1-week post delivery. KQ3: Outcomes for breastfeeding, mother-infant attachment, and maternal mood occurring after 1 year post-delivery.
Setting	• Inpatient versus outpatient settings.	• Inpatient versus outpatient settings.	• Outpatient setting	• Inpatient and outpatient settings.	
Study design	• Randomized Controlled Trials; recent high quality Systematic Reviews; if RCT evidence for benefits is insufficient, include large, high quality cohort studies comparing inpatient and outpatient setting. • Include high quality cohort and case-control studies for harms.	• Randomized Controlled Trials; recent high quality Systematic Reviews; if RCT evidence for benefits is insufficient, include large, high quality cohort studies comparing inpatient and outpatient setting. • Include high quality cohort and case-control studies for harms.	• Randomized Controlled Trials; recent high quality Systematic Reviews; if RCT evidence for benefits is insufficient, include large, high quality cohort studies comparing inpatient and outpatient setting. • Include high quality cohort and case-control studies for harms.	• Randomized Controlled Trials; recent high quality Systematic Reviews; if RCT evidence for benefits is insufficient, include large, high quality cohort studies comparing inpatient and outpatient setting. • Include high quality cohort and case-control studies for harms.	Case series, pre-post studies, case reports.

[c] (Bolded) items indicate Primary Outcomes.
CR = cervical ripening; CD = cesarean delivery; KQ = Key Question; ROM = rupture of membrane; CDC = Centers for Disease Control and Prevention; L&D = labor and delivery; RCTs = randomized controlled trials.

Dated: January 29, 2020.

Virginia L. Mackay-Smith,

Associate Director, Office of the Director, AHRQ.

[FR Doc. 2020–02058 Filed 2–3–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*Evaluating the Dissemination and Implementation of PCOR to Increase Referral, Enrollment, and Retention through Automatic Referral to Cardiac Rehabilitation (CR) with Care Coordination.*'' In accordance with the Paperwork Reduction Act, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by 60 days after date of publication.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Evaluating the Dissemination and Implementation of PCOR to Increase Referral, Enrollment, and Retention through Automatic Referral to Cardiac Rehabilitation (CR) With Care Coordination

The aim of AHRQ's TAKEheart project is to (a) raise awareness about the benefits of cardiac rehabilitation (CR) after myocardial infarction or coronary revascularization, then to (b) disseminate knowledge about the best practices to increase referrals to CR, and, finally, (c) to increase CR uptake.

Currently over two-thirds of eligible cardiac patients are not referred to CR despite extensive evidence of its effectiveness in preventing subsequent morbidity; national estimates of referral range from 10–34%. To help improve CR rates, the Million Hearts® Cardiac Rehabilitation Collaborative—an initiative co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS)—developed a Cardiac Rehabilitation Change Package (CRCP) and established a national goal of 70% participation in CR by 2022 for eligible patients. Recognizing that widespread adoption of the CRCP could help hospitals enhance CR rates, the CDC turned to AHRQ with a request that AHRQ consider disseminating and implementing evidence for CR and practices that promote CR. The CRCP is designed to facilitate this dissemination and implementation process.

AHRQ reviewed this request in the context of its Patient Centered