: 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Postpartum Care for Women Up to One Year After Pregnancy

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 *Postpartum Care for Women Up to One Year After Pregnancy,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail 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.):

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5600 Fishers Lane

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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 *Postpartum Care for Women Up to One Year After Pregnancy*. AHRQ is conducting this technical brief pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

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 *Postpartum Care for Women Up to One Year After Pregnancy,* including those that describe adverse events. The entire research protocol is available online at:

https://effectivehealthcare.ahrq.gov/products/postpartum-care-one-year/protocol

This is to notify the public that the EPC Program would find the following information on *Postpartum Care for Women Up to One Year After Pregnancy* 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 e-mail 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)

KQ 1: What **healthcare delivery strategies** affect postpartum healthcare utilization and improve maternal outcomes within 1 year postpartum?

a. Do the **healthcare delivery strategies** affect postpartum healthcare utilization and improve maternal outcomes within 3 months postpartum? Does this relationship differ by timing of outcomes, specifically within 6 days postpartum, between 1 to 6 weeks postpartum, and between 6 weeks and 3 months postpartum?
b. Do the **healthcare delivery strategies** affect postpartum healthcare utilization and improve maternal outcomes between 3 months and 1 year postpartum?

KQ 2: Does **extension of health insurance coverage or improvements in access to healthcare** affect postpartum healthcare utilization and improve maternal outcomes within 1 year postpartum?

PICOTSD (Populations, Interventions, Comparators, Outcomes, Timing, Settings, and Design)

<u>Key Question 1 (Strategies for Healthcare Delivery)</u>

Populations

- Individuals (of any age) who are in the postpartum period (defined as within 1 year after giving birth).
  - For this review, "giving birth" is defined as a live birth, intrauterine fetal death (IUFD)/stillbirth, or induced abortion that occurred at 20 or more weeks of gestation (i.e., the duration of gestation that is commonly considered to denote the viability of the fetus).
- Eligible populations
  - Healthy individuals (general population)
  - Individuals at increased risk of postpartum complications due to pregnancy-related conditions (e.g., hypertensive disorders of pregnancy, gestational diabetes)
  - Individuals at increased risk of postpartum complications due to incident or newly diagnosed conditions postpartum (e.g., postpartum hypertension, postpartum depression, new-onset diabetes)

- *Exclude:*
    - *Individuals with specific health conditions not typically managed by providers of pregnancy and postpartum care, (e.g., multiple sclerosis, HIV, cancer, substance use disorders other than tobacco).*
    - *Individuals with diagnosed chronic conditions – pre-existing (non-gestational) diabetes, cardiac disease/risk factors (e.g., cardiomyopathy, pre-existing [non-gestational] hypertension), mood disorders (e.g., major depression, anxiety), stress urinary incontinence, and dyspareunia.*

Content of Interventions Provided (note that these are *not* the interventions being compared in the review)

Categories of interventions include components of the ACOG Postpartum Care Plan:[18]

- Counseling, support, and education regarding
    - Infant care and feeding
    - Reproductive life planning and contraception
    - Adverse pregnancy outcomes associated with cardiometabolic disease
    - Risks and behaviors associated with poor postpartum health
- Screening or prevention of:
    - Pregnancy complications
    - Common chronic health conditions (e.g., hypertension, diabetes)
    - Mental health conditions (e.g., depression, anxiety)
    - Common gynecologic problems (e.g., sexually transmitted infections, cervical cancer)
    - Common postpartum problems (e.g., stress urinary incontinence, dyspareunia)
- *Exclude:*
    - *Treatments for acute or emergency postpartum conditions (e.g., for mastitis, urinary tract infections, other infections)*
    - *Treatments or other interventions for conditions unrelated to pregnancy (e.g., HIV, schizophrenia)*

- *Treatments or other interventions for acute conditions during pregnancy or occurring around the time of giving birth (e.g., for postpartum hemorrhage, preeclampsia with severe features)*
- *Treatments or other interventions directed at the infant (e.g., well-child visits, otitis media, colic)*
- *Referral-only interventions (e.g., lactation consultants for specific lactation problems)*

Delivery Strategies

- **Where healthcare is delivered –** e.g., hospital, clinic, home visit, community health center, birth center, virtual care/telehealth, Women Infants and Children (WIC) program office/site
- **How healthcare is delivered –** e.g., dedicated postpartum care visit, as part of well-child visit, group visit
- **When healthcare is delivered** – e.g., timing before giving birth, after giving birth, or at postpartum visits
- **Who provides healthcare/support**
  - Predominantly health system-based care – e.g., OB/GYN, midwife, pediatrician, family physician, internist, physician assistant, nurse practitioner, nurse, lactation consultant (when integrated as part of the care), clinical psychologist or other mental health professional
  - Predominantly community-based care – e.g., doula support, community health worker, lay support, social worker/support, peer support, case manager
- **Healthcare coordination and management of care** – e.g., patient navigators, creation and implementation of post-birth care plans, strategies for continuity of care/care transitions, strategies to facilitate access to appointments/scheduling, postpartum specialty care clinics, multidisciplinary care models (e.g., maternal and child health centers, maternity care homes), evidence-based care protocols, incentives for care completion

- **Information and communication technology** – e.g., bidirectional telemedicine, virtual televisits, phone visits, bidirectional texting, real-time chat-bots, smartphone or computer applications designed to enhance provision of postpartum healthcare
    - *Exclude: Social media or support groups (without provider involvement), web or device applications aimed at general health maintenance*
- **Interventions targeted at healthcare providers or systems** – e.g., interventions to improve guideline-adherent care, clinical decision support tools, interventions to help reduce healthcare inequities (e.g., promoting respectful care)
- *Exclude:*
    - *Referral-only interventions (e.g., lactation consultants for specific lactation problems)*
    - *Treatments for specific ailments or conditions (e.g., pelvic floor physical therapy, urinary incontinence treatment, contraception, pain treatment, cognitive behavioral therapy)*
    - *Insurance extension (which is covered in KQ 2)*

Comparator Delivery Strategies

- Standard delivery strategy
- Alternative delivery strategy

Outcomes (* and **bold** font denotes important outcomes that will be used when developing Strength of Evidence tables)

- Intermediate and healthcare utilization outcomes
    - **Attendance at postpartum visits***
    - **Unplanned care utilization (e.g., unplanned readmissions, emergency room visits)***
    - **Adherence to condition-specific screening/testing (e.g., blood pressure monitoring, glucose tolerance testing) or treatment***
    - **Transition to primary care provider for long-term care***
- Clinical outcomes (as appropriate, outcomes include incidence, prevalence/continuation, severity, and resolution)

- **Maternal mortality***
- **Symptoms or diagnosis of mental health conditions (e.g., anxiety, depression, substance use)***
- Patient-reported outcomes
  - **Quality of life (using validated measures)***
  - **Perceived stress***
  - Pain
  - Sleep quality
  - Fatigue
  - Sexual well-being and satisfaction
  - Awareness of risk factors for long-term ill health
- Physical health/medical outcomes
  - Postpartum onset of preeclampsia or hypertension
  - Infections (e.g., mastitis, wound infections)
  - Severe maternal morbidity
    - Cardiovascular disorders (e.g., cardiomyopathy)
    - Cerebrovascular disorders (e.g., stroke)
    - Bleeding
    - Venous thromboembolism
    - Other
- Interpregnancy interval
- Unintended pregnancies
- Contraceptive initiation and continuation
- Breastfeeding intention, initiation, duration, and exclusivity
- Reduction in health inequities (e.g., by race, ethnicity, geography, disability status)

- <u>Harms</u>
  - **Health inequities***
  - **Perceived discrimination***

- Over-utilization of healthcare
- Patient burden regarding postpartum care

Potential Effect Modifiers

- <u>Patient-level factors</u>
  - Age
  - Race/ethnicity
  - Gender identity
  - Sexual identity
  - Physical disability status
  - Socioeconomic status
  - Immigration status
  - Barriers to transportation to healthcare facility
  - Paid family leave policies (e.g., presence versus absence, different durations of leave)
  - Access to internet (for virtual care/telehealth questions)
  - Substance use/substance use disorder
  - Type of insurance coverage (insured versus uninsured, private versus public [e.g., Medicaid], insurance coverage of postpartum care, Medicaid insurance coverage extension or expansion)
  - Presence versus absence of disorders of pregnancy (e.g., hypertensive, cardiovascular, gestational diabetes mellitus) or peripartum complications that increase risk of postpartum complications
  - Preterm versus term delivery
  - Live birth versus stillbirth/spontaneous abortion/induced abortion
  - Number of infants (singleton versus twins/triplets, etc.)
  - Presence versus absence of a supportive partner
  - Infant health (e.g., neonatal intensive care unit [NICU] admission, congenital anomalies)

- Setting factors
    - Country (U.S. versus other high-income countries)
    - Geographic location (urban versus suburban versus rural)
    - Different levels of neighborhood vulnerability (e.g., social vulnerability index)
    - Volume of facility/hospital (high versus low)
    - Type of facility/hospital (private versus public)
    - Racial/ethnic concordance between provider and patient
    - Language concordance between provider and patient

Timing

- *Delivery strategy and comparator delivery strategy*: antenatal or postpartum (or both)
    - If the service is delivered antenatally, the strategy must be aimed at postpartum health (not just that the outcome was measured during the postpartum period).
- *Outcome measurement*: For KQ 1a: within 3 months after giving birth. For KQ 1b: 3 months to 1 year after giving birth (except interpregnancy interval, unintended pregnancies, and chronic diseases [e.g., diabetes, hypertension], which can be later)

Settings

- High-income countries (as classified by the World Bank – see https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups)
- Outpatient care
- *Exclude: Institutionalized settings (e.g., prisons)*

Design

- Randomized controlled trials (N ≥10 participants per group)
- Nonrandomized comparative studies, longitudinal (prospective or retrospective) (N ≥30 participants per group)
- Case-control studies (N ≥30 participants per group)

- *<u>Exclude</u>: Single-group (noncomparative) studies, comparative cross-sectional studies (without a discernable time-period between implementation of strategy for intervention and measurement of outcomes), qualitative studies*

<u>Key Question 2 (Extension of Healthcare or Insurance Coverage)</u>

Populations

- Individuals (of any age) who are in the postpartum period (defined as within 1 year after giving birth).
  - For this review, "giving birth" is defined as a live birth, intrauterine fetal death (IUFD)/stillbirth, or induced abortion that occurred at 20 or more weeks of gestation (i.e., the duration of gestation that is commonly considered to denote the viability of the fetus).
- Eligible populations
  - Healthy individuals (general population)
  - Individuals at increased risk of postpartum complications due to pregnancy-related conditions (e.g., hypertensive disorders of pregnancy, gestational diabetes)
  - Individuals at increased risk of postpartum complications due to incident or newly diagnosed conditions postpartum (e.g., postpartum hypertension, postpartum depression, new-onset diabetes)
- *<u>Exclude</u>:*
  - *Individuals with specific health conditions not typically managed by providers of pregnancy and postpartum care, (e.g., multiple sclerosis, HIV, cancer, substance use disorders other than tobacco).*
  - *Individuals with diagnosed chronic conditions – pre-existing (non-gestational) diabetes, cardiac disease/risk factors (e.g., cardiomyopathy, pre-existing [non-gestational] hypertension), mood disorders (e.g., major depression, anxiety), stress urinary incontinence, and dyspareunia.*

Interventions

- More comprehensive insurance coverage
- Extended duration of insurance coverage
- More continuous insurance coverage
- Better/more continuous access to care as the result of a targeted program at the state, system, or provider level (e.g., Medicaid expansion)

Comparators

- Less comprehensive level of or no insurance coverage
- Less continuous insurance coverage
- Worse, less continuous, or no access to healthcare

Outcomes (* and **bold** font denotes important outcomes that will be used when developing Strength of Evidence tables)

- <u>Intermediate and healthcare utilization outcomes</u>
  - **Attendance at postpartum visits***
  - **Unplanned care utilization (e.g., readmissions, emergency room visits)***
  - **Adherence to condition-specific screening/testing (e.g., blood pressure monitoring, glucose tolerance testing) or treatment***
  - **Transition to primary care provider for long-term care***
- <u>Clinical outcomes</u> (as appropriate, outcomes include incidence, prevalence/continuation, severity, and resolution)
  - **Maternal mortality***
  - **Symptoms or diagnosis of mental health conditions (e.g., anxiety, depression, substance use)***
  - Patient-reported outcomes
    - **Quality of life (using validated measures)***
    - **Perceived stress***

        - Pain
        - Sleep quality
        - Fatigue
        - Sexual well-being and satisfaction
        - Awareness of risk factors for long-term ill health
    - Physical health/medical outcomes
        - Postpartum onset of preeclampsia or hypertension
        - Infections (e.g., mastitis, wound infections)
        - Severe maternal morbidity
            - Cardiovascular disorders (e.g., cardiomyopathy)
            - Cerebrovascular disorders (e.g., stroke)
            - Bleeding
            - Venous thromboembolism
            - Other
    - Interpregnancy interval
    - Unintended pregnancies
    - Contraceptive initiation and continuation
    - Breastfeeding intention, initiation, duration, and exclusivity
    - Reduction in health inequities (e.g., by race, ethnicity, geography, disability status)
- <u>Harms</u>
    - **Health inequities***
    - **Perceived discrimination***
    - Over-utilization of healthcare
    - Patient burden regarding postpartum care

Potential Effect Modifiers

- <u>Patient-level factors</u>
    - Age

- Race/ethnicity
- Gender identity
- Sexual identity
- Physical disability status
- Socioeconomic status
- Immigration status
- Barriers to transportation to healthcare facility
- Paid family leave policies (e.g., presence versus absence, different durations of leave)
- Substance use/substance use disorder
- Type of insurance coverage (insured versus uninsured, private versus public [e.g., Medicaid], insurance coverage of postpartum care, Medicaid insurance coverage extension or expansion)
- Presence versus absence of disorders of pregnancy (e.g., hypertensive, cardiovascular, gestational diabetes mellitus) or peripartum complications that increase risk of postpartum complications
- Preterm versus term delivery
- Live birth versus stillbirth/spontaneous abortion/induced abortion
- Number of infants (singleton versus twins/triplets, etc.)
- Presence versus absence of a supportive partner
- Infant health (e.g., neonatal intensive care unit [NICU] admission, congenital anomalies)

- <u>Setting factors</u>
  - Geographic location (urban versus suburban versus rural)
  - Different levels of neighborhood vulnerability (e.g., social vulnerability index)
  - Volume of facility/hospital (high versus low)
  - Type of facility/hospital (private versus public)
  - Racial/ethnic concordance between provider and patient
  - Language concordance between provider and patient

Timing

- *Interventions and Comparators*: within 1 year after giving birth
- *Outcome measurement*: up to 1 year after giving birth (except interpregnancy interval, unintended pregnancies, and chronic diseases [e.g., diabetes, hypertension], which can be later)

Settings

- U.S. only
- Outpatient care
- *Exclude: Institutionalized settings (e.g., prisons)*

Design

- Randomized controlled trials (N ≥10 participants per group)
- Nonrandomized comparative studies, longitudinal (prospective or retrospective) or cross-sectional (N ≥30 participants per group)
- Case-control studies (N ≥30 participants per group)
- *Exclude: Single-group (noncomparative) studies, comparative cross-sectional studies (without a discernable time-period between intervention and measurement of outcomes), qualitative studies*

Dated: March 7, 2022.

Marquita Cullom,

Associate Director.

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