Evidence-based Practice Center Systematic Review Protocol

Project Title: *Postpartum Care for Women Up to One Year After Pregnancy*

I.   Background and Objectives for the Systematic Review

In recent decades, the U.S. has witnessed a considerable rise in maternal morbidity and mortality.[1] In 2018, the maternal mortality ratio was 17.4 per 100,000 live births (the highest among industrialized countries), with wide racial and ethnic gaps (e.g., Black: 37.3 deaths per 100,000 live births, White: 14.9, and Hispanic: 11.8).[2] Approximately half (52%) of the deaths occurred in the postpartum period (defined as up to 1 year after giving birth).[2,3] Additionally, up to 70,000 individuals per year in the U.S. experience severe postpartum morbidities, including cardiac events, cerebrovascular events, postpartum hemorrhage, kidney failure, and postpartum depression, anxiety, and posttraumatic stress disorder.[4] Those who experience complications, such as cardiac and cerebrovascular events, are at approximately twice the risk of dying postpartum compared with those who do not experience complications.[4] The postpartum period, therefore, is not only a critical time for postpartum individuals and their families to recover from birth, transition to parenthood, and consider future family planning, but also to mitigate immediate and lifelong health risks by addressing pregnancy-related, mental health, and chronic conditions, and promoting healthy behaviors.

More than 60 percent of pregnancy-related deaths are considered preventable.[3,5] Various interdependent factors have been implicated in causing deaths: systems of care factors (e.g., lack of coordination among providers), provider factors (e.g., misdiagnoses, ineffective treatment), and patient and family factors (e.g., lack of knowledge about warning signs). These factors play a particularly important role in the postpartum period, during which access to care and insurance coverage of care may be suboptimal. Global reimbursement models, in which providers receive bundled payments for postpartum care during the perinatal period (regardless of how many postpartum visits occur),[6] may disincentivize healthcare centers from providing adequate postpartum care.[7,8] Additionally, new parents may struggle to balance the demands of caring for a newborn with managing their own health. Given this confluence of factors, up to half of postpartum individuals in the U.S. do not receive routine healthcare after giving birth.[9-12] In addition, federal Medicaid coverage for pregnant individuals currently ends after 60 days postpartum, limiting longer-term postpartum care. With the goal of improving health outcomes and reducing disparities, the American Rescue Plan Act of 2021 allows States to request a waiver so that postpartum Medicaid coverage can extend postpartum care for up to 1 year after giving birth.[13] As of December 16, 2021, five States have been approved and an additional 19 States are in the process of making requests.[14] Approved States may extend coverage beginning April 1, 2022.[13]

Another factor that needs improvement is the coordination of care for postpartum individuals, which is often suboptimal. Healthcare is often fragmented among multiple providers, each of whom focus on specific aspects of maternal health (e.g., breastfeeding education, contraception, chronic health conditions, mental health) and do not address holistic needs.[15] These factors may exacerbate existing disparities by race, ethnicity, education level, socioeconomic position, geographic location, and immigrant status, for postpartum individuals who face the greatest barriers to care.[16] Finally, the design of current postpartum care delivery may not meet postpartum individuals' needs. Many postpartum concerns, such as difficulty with breastfeeding and postpartum mood changes, occur within 1 to 2 weeks postpartum, but postpartum visits are commonly scheduled relatively late (e.g., at 4 to 6 weeks after giving birth). Additionally, most postpartum visits are delivered in-person, though many concerns may be more easily addressed through virtual modalities. Postpartum visits often suffer from low attendance (below 60% among Medicaid enrollees[11]); this may reflect a mismatch between how services are delivered and the preferences of postpartum individuals.

Among the 52 percent of pregnancy-related deaths occurring in the postpartum period, 19 percent occur in the first 6 days after birth, 21 percent between 7 and 42 days, and 12 percent between 43 days and 1 year.[17] A 2018 American College of Obstetricians and Gynecologists (ACOG) Committee Opinion recommends an initial interaction with the clinical care provider within 3 weeks postpartum, followed by ongoing care as needed and a comprehensive postpartum visit no later than 12 weeks postpartum.[18] However, most postpartum deaths occur before 12 weeks postpartum, and therefore having the comprehensive visit at 12 weeks may be too late. ACOG also recommends that postpartum individuals with chronic medical conditions (e.g., hypertensive disorders, diabetes) be further counseled regarding the importance of timely followup for ongoing care.[18] However, ACOG does not provide details regarding what constitutes "timely followup" for postpartum individuals with chronic medical complications.

The abovementioned document from ACOG in 2018 was a Committee Opinion. In other words, it was based on consensus and not on a systematic review (SR). Updated clinical practice guidelines (CPGs) that, at least in part, address aspects of care *and* are explicitly evidence-based, are needed to ensure that postpartum care is effective and meets the needs of postpartum individuals, their families, and the healthcare system. There are several important aspects of postpartum care to examine, including managing postpartum care volume (e.g., optimal visit timing and frequency), providers (e.g., obstetricians and gynecologists [OB/GYNs], midwives, doulas), communication technology (e.g., telemedicine), content of postpartum care (e.g., recommended medical care and psychosocial support), and health education (e.g., pelvic floor function, breastfeeding). To improve postpartum care, there is an urgent need for a SR to address these issues to inform future CPGs.

Purpose of Review

This SR will assess the healthcare strategies for postpartum individuals. Specifically, the review will address the (comparative) benefits and harms of:
- Alternative strategies for postpartum healthcare delivery (Key Question [KQ] 1)
- Extension of postpartum healthcare or health insurance coverage (KQ 2)

The intended audience for this SR includes CPG developers, policymakers, and OB/GYNs, midwives, maternal fetal medicine (MFM) specialists, family medicine clinicians, primary care physicians, nurse practitioners, and other providers of care or support for postpartum individuals. It is expected that the findings will inform clinical guidance for strategies to manage postpartum care.

II. Key Questions

Key Question 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?

Key Question 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?

III. Eligibility Criteria

The specific eligibility criteria provided below have been refined based on discussions with a panel of Key Informants (KIs) and a Technical Expert Panel (TEP). These stakeholders included perspectives from patient

advocacy, obstetrics and gynecology, MFM, rural family practice, social work, doula care, epidemiology, health services research, health disparities research, national policy, and public health insurance.

Note that for KQ 1, we have altered the traditional framework for defining KQ eligibility criteria (PICOTSD). Specifically, we have restructured the Interventions and Comparators elements to be Content of Interventions Provided, Delivery Strategies, and Comparator Delivery Strategies. We have adopted this approach because KQ 1 compares strategies to deliver interventions with comparator delivery strategies. The Content of Interventions Provided refers to the actual interventions prescribed or given to patients by their healthcare providers; these interventions are not the components of care ("interventions") being focused on in this review.

Key Question 1 (Strategies for Healthcare Delivery)

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**
  - <u>Predominantly health system-based care</u> – 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
  - <u>Predominantly community-based care</u> – 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)
- <u>Intermediate and healthcare utilization outcomes</u>
  - **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***
- <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)
- Harms
  - **Health inequities***
  - **Perceived discrimination***
  - Over-utilization of healthcare
  - Patient burden regarding postpartum care

Potential Effect Modifiers
- Patient-level factors
  - 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)

- o Racial/ethnic concordance between provider and patient
- o Language concordance between provider and patient

Timing
- *Delivery strategy and comparator delivery strategy*: antenatal or postpartum (or both)
  - o 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)
- *Exclude: 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*

Key Question 2 (Extension of Healthcare or Insurance Coverage)

Populations
- Individuals (of any age) who are in the postpartum period (defined as within 1 year after giving birth).
  - o 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
  - o Healthy individuals (general population)
  - o Individuals at increased risk of postpartum complications due to pregnancy-related conditions (e.g., hypertensive disorders of pregnancy, gestational diabetes)
  - o 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:*
  - o *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).*
  - o *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)
- Intermediate and healthcare utilization outcomes
  - **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***
- 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)
- Harms
  - **Health inequities***
  - **Perceived discrimination***
  - Over-utilization of healthcare
  - Patient burden regarding postpartum care

Potential Effect Modifiers
- Patient-level factors
  - 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)
- Setting factors
  - 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*

IV. Analytic Framework

KQ1: Interventions
- Counseling, support, and education regarding infant care/feeding, reproductive life planning/contraception, cardiometabolic disease, risk factors associated with poor postpartum health
- Screening/prevention of pregnancy complications, mental health conditions, and common chronic health/gynecologic/postpartum problems

KQ1: Delivery Strategies
- Where healthcare is delivered
- How healthcare is delivered
- When healthcare is delivered
- Who provides healthcare/support
- Healthcare coordination and management of care
- Information and communication technology
- Interventions targeted at healthcare providers or systems

KQ1: Comparator Delivery Strategies
- Standard delivery strategy
- Alternative delivery strategy

KQ2: Interventions and Comparators
Interventions
- More comprehensive or 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, less continuous, or no insurance coverage
- Worse, less continuous, or no access to healthcare

Population
Individuals (of any age) in the postpartum period (i.e., within 1 year after giving birth)

(KQ 1, 2)

Intermediate and Healthcare Utilization Outcomes
- Attendance at postpartum visits*
- Unplanned care utilization (e.g., readmissions, ER)*
- Adherence to condition-specific screening/testing or treatment*
- Transition to primary care provider for long-term care*

(KQ 1, 2)

Clinical Outcomes
- Maternal mortality*
- Symptoms/diagnosis of mental health outcomes (e.g., anxiety, depression, substance use)*
- Patient-reported outcomes (quality of life*, perceived stress*, pain, sleep quality, fatigue, sexual well-being/satisfaction, awareness of risk factors for long-term ill health)
- Physical health/medical outcomes (postpartum preeclampsia/hypertension, infections, severe maternal morbidity, e.g., cardiovascular disorders, cerebrovascular disorders, 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)

Harms
- Health inequities*
- Perceived discrimination*
- Overutilization of healthcare
- Patient burden regarding postpartum care

Potential Effect Modifiers
Patient-level factors
- Age, race, ethnicity
- Gender identity, sexual identity
- Physical disability status
- Socioeconomic status
- Immigration status
- Barriers to transportation to healthcare facility
- Paid family leave policies
- Access to internet (for KQ 1: virtual health)
- Substance use/substance use disorder
- Type of insurance coverage
- Presence versus absence of disorders of pregnancy or

peripartum complications that increase the risk of postpartum complications
- Preterm versus term delivery
- Number of infants (singleton versus twins/triplets, etc.)
- Presence versus absence of a supportive partner
- Infant health
Setting factors
- Country (U.S. versus other) (KQ 1 only)
- Geography (urban versus suburban versus rural)
- Different levels of neighborhood vulnerability
- Volume of facility/hospital (high versus low)
- Type of facility/hospital (private versus public)
- Racial/ethnic, language concordance

* Important outcomes that will be used when developing Strength of Evidence tables.
For KQ 1a, timing of interest for outcomes is within 3 months after giving birth. For KQ 1b, timing of interest for outcomes is 3 months to 1 year after giving birth (except interpregnancy interval, unintended pregnancies, and chronic diseases [e.g., diabetes, hypertension], which can be later). For KQ 2, ti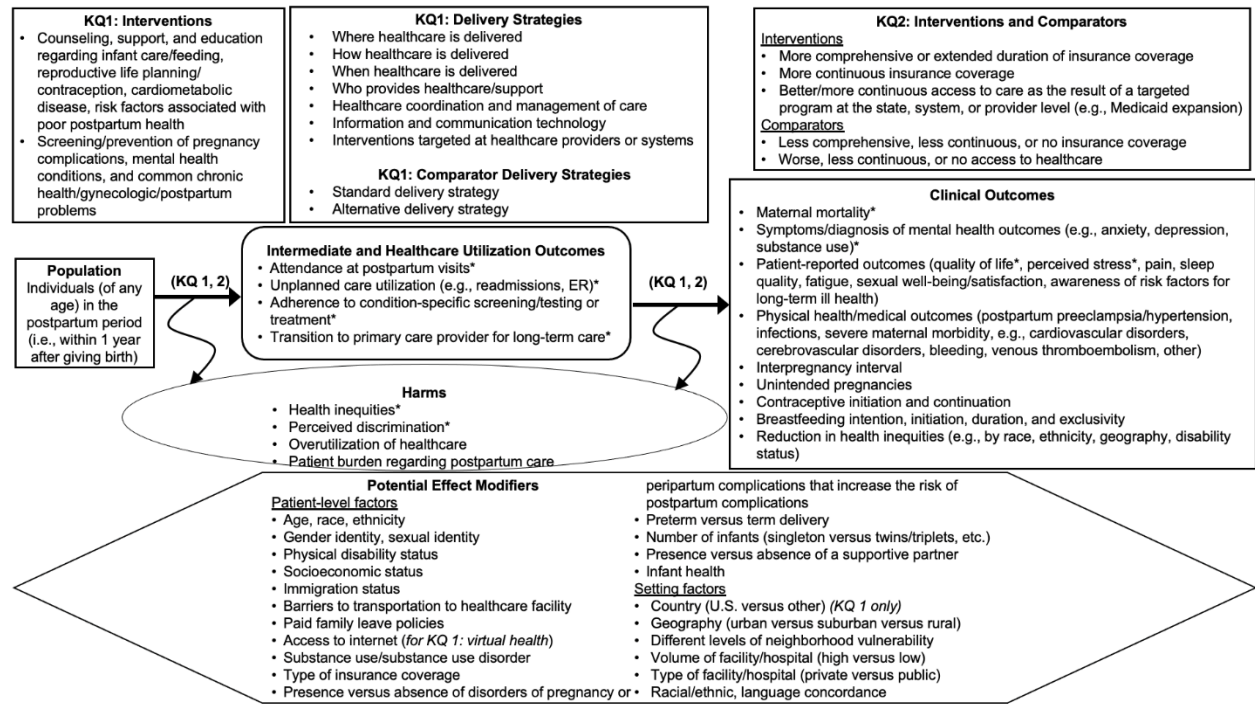ming of interest for outcomes is within 1 year after giving birth (except interpregnancy interval, unintended pregnancies, and chronic diseases [e.g., diabetes, hypertension], which can be later).
Abbreviations: ER = emergency room, KQ = Key Question, LARC = long-acting reversible contraception.

V. Methods

This SR will follow Evidence-based Practice Center (EPC) Program methodology, as described in its Methods Guide, particularly as it pertains to reviews of comparative effectiveness, diagnostic tests, and complex meta-analyses.

Criteria for Inclusion/Exclusion of Studies in the Review: See Study Eligibility Criteria in Section II.

Literature Search Strategies to identify primary studies for all KQs: We will search for primary studies and SRs in MEDLINE (via PubMed), Embase, The Cochrane Register of Clinical Trials, The Cochrane Database of Systematic Reviews, and CINAHL. Duplicate citations will be removed prior to screening. We will not employ any date or language restrictions to the search but will include filters to remove nonhuman studies and articles that are not primary studies or systematic reviews. We will include specific controlled vocabulary terms (MeSH or Emtree), along with specific free-text words, related to postpartum, healthcare strategies, and insurance coverage. The searches will be independently peer reviewed. Appendix A includes the search strategy for each database.

We will also run a search of the ClinicalTrials.gov registry for ongoing studies, unpublished study protocols, and unpublished study results. The reference lists of relevant existing SRs will be screened for additional eligible studies. Additional articles suggested to us from any source, including peer and public review, will be screened applying identical eligibility criteria. For non-English language articles, screening and data extraction will be done either by readers of the relevant languages or after translation via Google Translate (https://translate.google.com/), if possible.

A Supplemental Evidence and Data for Systematic review (SEADS) portal will be available for this review. Additional articles suggested to us from any source, including peer and public review, will be screened applying identical eligibility criteria.

We will update the search upon submission of the Draft Report for public review.

Screening Process: Citations from all searches will be deduplicated and then entered into Abstrackr software (http://abstrackr.cebm.brown.edu/) to enable title and abstract screening. The team will conduct two or more rounds of pilot screening. During each pilot round, we will all screen the same 100 abstracts and discuss conflicts, with the goal of training the team in the nuances of the eligibility criteria and refining them as needed. After the pilot rounds, we will continue abstract screening in duplicate. The Abstrackr software has machine learning capabilities that predict the likelihood of relevance of each citation. Daily, the list of unscreened abstracts will be sorted so that the most potentially relevant articles are presented first. This process will make screening more efficient and will enable us to capture almost all relevant articles relatively early in the abstract-screening process.

We will train the machine learning algorithm as follows: (1) We will include references of known existing potentially relevant studies for each KQ. (2) We will confirm this set of potentially relevant citations was successfully captured by our PubMed search and add the ones that aren't. (3) Based on recently published work by Sampson et. al.,[19] we will select the top 500 articles from our search using PubMed's best-match algorithm. (4) The abstracts from steps (1) and (3) will be entered into Abstrackr and screened by all team members, with resolution of all conflicts in conference. (5) Subsequently, citations found by the full literature searches will be added to the already-screened citations in Abstrackr, and abstract screening will continue in duplicate, with conflicts adjudicated in conference or by a third screener. (6) As screening progresses, the pretrained Abstrackr machine learning algorithm will continue to adapt and will sort the list of unscreened abstracts such that the most potentially relevant articles are presented first. This process will make screening more efficient and will enable us to capture the preponderance of relevant articles relatively early in the abstract screening process. (7) We will stop double screening when the predicted likelihood of the remaining unscreened papers being relevant is very low. We typically use a threshold for the prediction score of the unscreened citations of 0.40 (this threshold is based on experience with several dozens of screening projects and an analysis in preparation for publication but may be lowered depending on whether we continue to find eligible abstracts near the threshold). To confirm that the selected prediction score threshold is appropriate for this literature base, when the maximum prediction score is <0.40, we will double screen at least 400 additional consecutive citations (this sample size is chosen because the upper 97.5% confidence interval bound for a proportion of 0/400 is less than 1%). If any of the 400 citations are screened in (at the abstract level), we will repeat the process (restart counting an additional 400 citations) until we have rejected at least 400 consecutive citations. At that stage, we plan to stop abstract screening.

Potentially relevant citations will be retrieved in full text. All these articles will be rescreened in duplicate.

Data Extraction and Data Management: Data from eligible studies will be extracted into the Systematic Review Data Repository Plus (SRDR+) software (https://srdrplus.ahrq.gov). Each article will be extracted by one researcher, and entered data will be confirmed by a second, independent researcher. Individual studies with multiple publications will be extracted as a single study (with a single entry in SRDR-Plus). Each study will be entered into SRDR-Plus separately, even if two or more studies are reported within a single publication.

For each study, we will extract publication identifying data, study design features, population characteristics, intervention and comparator names and descriptions, relevant outcomes and their definitions, results, and funding source. We will extract, as available, data on the effect modifiers that are relevant to the KQ(s) being addressed by each study.

Assessment of Methodological Risk of Bias of Individual Studies: We will evaluate each study for risk of bias and methodological quality.

Because we anticipate including a variety of study designs, we will incorporate items from three different existing commonly used tools and will tailor the set of items for each study design. The three tools will include the Cochrane Risk of Bias Tool,[20] the Risk of Bias in Nonrandomized Studies (ROBINS-I) Tool,[21] and the National Heart, Lung, and Blood Institute (NHLBI) Quality Assessment Tool.[22]

For RCTs, we will use all the items from the Cochrane Risk of Bias Tool,[20] which addresses issues related to randomization and allocation concealment methodology; blinding of patients, study personnel/care providers, objective outcome assessors, and subjective outcome assessors; incomplete outcome data; selective outcome reporting; and other issues that could be related to bias. We will also use items from the NHLBI Tool focusing on the adequacy of descriptions of study eligibility criteria, interventions, and outcomes.[22]

For NRCSs, we will use the specific sections of the ROBINS-I Tool[17] that pertain to confounding and selection bias. Because NRCSs, like RCTs, can be impacted by the lack of blinding and by participant loss to followup, we will also use the items from the Cochrane Risk of Bias Tool[16] that focus on issues related to blinding of patients, study personnel/care providers, objective outcome assessors, and subjective outcome assessors; incomplete outcome data; selective outcome reporting; and other issues that could be related to bias. We will also use items from the NHLBI Tool that pertain to the adequacy of descriptions of study eligibility criteria, interventions, and outcomes.[22]

Data Synthesis: We will summarize the evidence both qualitatively and, when feasible and appropriate, quantitatively (i.e., by meta-analysis). Each study included in the SR will be described in summary and evidence tables presenting study design features, study participant characteristics, descriptions of interventions, outcome results, and risk of bias/methodological quality. Summary tables will briefly describe the studies and their findings.

We anticipate heterogeneity among interventions within a particular delivery strategy, in terms of the content, intensity, and complexity. For example, home visiting programs may range from a single home visit in the early postpartum period to dozens of home visits over the first 2 years of life. We will detail these features in evidence tables and summarize them in the text of the Report to allow readers to compare the resources required to implement various delivery strategies.

For both KQs, we will compare interventions with their comparators for their effects. As reported data allow, we will primarily evaluate odds ratios (ORs) for dichotomous outcomes (e.g., mortality), net mean differences (NMDs) (i.e., difference in differences or between-intervention comparisons of within-intervention changes) for continuous outcomes with both pre- and postintervention data (e.g., quality of life scales), and differences (between interventions) in continuous outcome data postintervention (e.g., patient satisfaction). For NRCSs, we will consider excluding unadjusted analyses or at the least prioritize adjusted over unadjusted analyses. Where there are at least three studies that compare sufficiently similar interventions (or strategies) and report sufficiently similar outcomes at sufficiently similar time points, we plan to conduct pairwise meta-analyses using random-effects models. We will search for opportunities to evaluate outcomes by effect modifiers both from within-study data and across studies.

Grading the Strength of Evidence (SoE) for Major Outcomes and Comparisons: We will evaluate the SoE addressing each major comparison or evaluation for each KQ. We expect that these will include the following comparisons for postpartum individuals:
- Relative intermediate and healthcare utilization outcomes associated with various healthcare delivery strategies
- Relative clinical outcomes associated with various healthcare delivery strategies
- Relative harms of various healthcare delivery strategies
- Relative intermediate and healthcare utilization outcomes associated with various levels of insurance coverage
- Relative clinical outcomes associated with various levels of insurance coverage
- Relative harms of various levels of insurance coverage
- Relative intermediate and healthcare utilization outcomes associated with various degrees of continuity in insurance coverage
- Relative clinical outcomes associated with various degrees of continuity in insurance coverage
- Relative harms of various degrees of continuity in insurance coverage
- Relative intermediate and healthcare utilization outcomes associated with various degrees of access to healthcare

- Relative clinical outcomes associated with various degrees of access to healthcare
- Relative harms of various degrees of access to healthcare

We will grade the strength of the body of evidence as per the Agency for Healthcare Research and Quality (AHRQ) Methods Guide on assessing SoE.[23] We will assess SoE for each of the important clinical outcome categories. We determined the relative importance of the outcomes with input from the TEP.

For each SoE assessment, we will consider the number of studies, their study designs, the study limitations (i.e., risk of bias and overall methodological quality), the directness of the evidence to the KQs, the consistency of study results, the precision of any estimates of effect, the likelihood of reporting bias, other limitations, and the overall findings across studies. Based on these assessments, we will assign a SoE rating as being either high, moderate, low, or insufficient evidence to estimate an effect.

Outcomes with imprecise estimates or inconsistent findings across studies that preclude a conclusion or with data from only one study will be deemed to have insufficient evidence to allow for a conclusion (with the exception that a particularly large, low-risk of bias, well-generalizable single study could provide at least low SoE). This approach is consistent with the concept that for imprecise evidence "any estimate of effect is very uncertain," the definition of Very Low quality evidence per GRADE.[24]

We will summarize the data sources, basic study characteristics, and each SoE dimensional rating in a "Summary of Evidence Reviewed" table. This table will detail our reasoning for arriving at the overall SoE rating.

Assessing Applicability: For each KQ, we will assess the applicability of the included studies to the general population of postpartum individuals in the U.S. based primarily on the studies' eligibility criteria and their included participants, specifically related to such factors as age, postpartum risk status, and country.

VI.   References

1. Petersen EE, Davis NL, Goodman D, et al. Racial/Ethnic Disparities in Pregnancy-Related Deaths - United States, 2007-2016. MMWR Morb Mortal Wkly Rep. 2019 Sep 6;68(35):762-5. doi: 10.15585/mmwr.mm6835a3. PMID: 31487273.
2. Centers for Disease Control and Prevention National Center for Health Statistics. Maternal Mortality. Atlanta, Georgia. https://www.cdc.gov/nchs/maternal-mortality/index.htm. Accessed on August 17, 2021.
3. Building U.S. Capacity to Review and Prevent Maternal Deaths. Report from nine Maternal Mortality Review Committees. . 2018. https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf. Accessed on August 17, 2021.
4. Ukah UV, Dayan N, Potter BJ, et al. Severe Maternal Morbidity and Risk of Mortality Beyond the Postpartum Period. Obstet Gynecol. 2021 Feb 1;137(2):277-84. doi: 10.1097/aog.0000000000004223. PMID: 33416296.
5. Howell EA. Reducing Disparities in Severe Maternal Morbidity and Mortality. Clin Obstet Gynecol. 2018 Jun;61(2):387-99. doi: 10.1097/grf.0000000000000349. PMID: 29346121.
6. Health Care Payment Learning & Action Network (HCP LAN). Clinical episode payment models. Chapter 4: Maternity Care.; 2016. http://hcp-lan.org/workproducts/maternity-whitepaper-final.pdf. Accessed on August 18, 2021.
7. Centers for Medicare & Medicaid Services. Medicaid and CHIP: Maternal and Infant Child Health Improvement. Lessons learned about payment strategies to improve postpartum care in Medicaid and CHIP. 2019. https://www.medicaid.gov/medicaid/quality-of-care/downloads/postpartum-payment-strategies.pdf. Accessed on August 18, 2021.
8. Applegate M, Gee RE, Martin JN, Jr. Improving maternal and infant health outcomes in Medicaid and the Children's Health Insurance Program. Obstet Gynecol. 2014 Jul;124(1):143-9. doi: 10.1097/aog.0000000000000320. PMID: 24901270.
9. Fabiyi CA, Reid LD, Mistry KB. Postpartum Health Care Use After Gestational Diabetes and Hypertensive Disorders of Pregnancy. J Womens Health (Larchmt). 2019 Aug;28(8):1116-23. doi: 10.1089/jwh.2018.7198. PMID: 30628865.

10. Herrick CJ, Keller MR, Trolard AM, et al. Postpartum diabetes screening among low income women with gestational diabetes in Missouri 2010-2015. BMC Public Health. 2019 Feb 4;19(1):148. doi: 10.1186/s12889-019-6475-0. PMID: 30717710.

11. Rodin D, Silow-Carroll S, Cross-Barnet C, et al. Strategies to Promote Postpartum Visit Attendance Among Medicaid Participants. J Womens Health (Larchmt). 2019 Sep;28(9):1246-53. doi: 10.1089/jwh.2018.7568. PMID: 31259648.

12. Thiel de Bocanegra H, Braughton M, Bradsberry M, et al. Racial and ethnic disparities in postpartum care and contraception in California's Medicaid program. Am J Obstet Gynecol. 2017 Jul;217(1):47.e1-.e7. doi: 10.1016/j.ajog.2017.02.040. PMID: 28263752.

13. American Rescue Plan Act of 2021. In: Congress tUS, editor.

14. Kaiser Family Foundation. Medicaid Postpartum Coverage Extension Tracker. https://www.kff.org/medicaid/issue-brief/medicaid-postpartum-coverage-extension-tracker/. Accessed on December 27, 2021.

15. Tully KP, Stuebe AM, Verbiest SB. The fourth trimester: a critical transition period with unmet maternal health needs. Am J Obstet Gynecol. 2017 Jul;217(1):37-41. doi: 10.1016/j.ajog.2017.03.032. PMID: 28390671.

16. The Commonwealth Fund. Maternal Mortality in the United States: A Primer. https://www.commonwealthfund.org/publications/issue-brief-report/2020/dec/maternal-mortality-united-states-primer. Accessed on August 17, 2021.

17. Davis NL, Smoots AN, Goodman DA. Pregnancy-Related Deaths: Data from 14 U.S. Maternal Mortality Review Committees, 2008-2017. . Atlanta, Georgia: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2019. https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief_2019-h.pdf. Accessed on August 17, 2021.

18. ACOG Committee Opinion No. 736: Optimizing Postpartum Care. Obstet Gynecol. 2018 May;131(5):e140-e50. doi: 10.1097/aog.0000000000002633. PMID: 29683911.

19. Sampson M, Nama N, O'Hearn K, et al. Creating enriched training sets of eligible studies for large systematic reviews: the utility of PubMed's Best Match algorithm. Int J Technol Assess Health Care. 2020 Dec 18;37:e7. doi: 10.1017/s0266462320002159. PMID: 33336640.

20. Higgins JP, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ (Clinical research ed). 2011 Oct 18;343:d5928. doi: 10.1136/bmj.d5928. PMID: 22008217.

21. Sterne JA, Hernan MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ (Clinical research ed). 2016 Oct 12;355:i4919. doi: 10.1136/bmj.i4919. PMID: 27733354.

22. National Heart, Lung, and Blood Institute. Study Quality Assessment Tools. https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools . Accessed December 5, 2020.

23. Berkman ND, Lohr KN, Ansari MT, et al. Grading the strength of a body of evidence when assessing health care interventions: an EPC update. J Clin Epidemiol. 2015 Nov;68(11):1312-24. doi: 10.1016/j.jclinepi.2014.11.023. PMID: 25721570.

24. Guyatt GH, Oxman AD, Kunz R, et al. Going from evidence to recommendations. BMJ (Clinical research ed). 2008 May 10;336(7652):1049-51. doi: 10.1136/bmj.39493.646875.AE. PMID: 18467413.

VII.   Abbreviations

AHRQ	Agency for Healthcare Research and Quality
ACOG	American College of Obstetricians and Gynecologists
CMS	Centers for Medicare & Medicaid Services
COI	conflicts of interest
CPG	clinical practice guideline
EPC	Evidence-based Practice Center
KI	Key Informant

KQ	Key Question
LARC	long-acting reversible contraception
MFM	maternal fetal medicine
NHLBI	National Heart, Lung, and Blood Institute
NICU	neonatal intensive care unit
NMD	net mean difference
NRCS	nonrandomized comparative study
OB/GYN	obstetrician-gynecologist
OR	odds ratio
PCORI	Patient-Centered Outcomes Research Institute
RCT	randomized controlled trial
ROBINS-I	Risk of Bias in Nonrandomized Studies of Interventions
SoE	strength of evidence
SR	systematic review
SRDR-Plus	Systematic Review Data Repository-Plus
TEP	Technical Expert Panel
TOO	Task Order Officer
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

VIII.   Summary of Protocol Amendments

If we need to amend this Protocol, we will give the date of each amendment, describe the change, and provide the rationale in this section.

IX.   Review of Key Questions

AHRQ posted the Key Questions on the AHRQ Effective Health Care Website for public comment. The EPC refined and finalized them after reviewing of the public comments and seeking input from KIs. This input is intended to ensure that the Key Questions are specific and relevant.

X.   Review of Key Questions

We included a panel of KIs during Topic Refinement. KIs are end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the KIs' role is to provide input into identifying and refining the Key Questions for research that will inform healthcare decisions. The EPC solicits input from KIs when developing questions for systematic review or when identifying high priority research gaps and needed new research. KIs are not involved in analyzing the evidence, writing the report, or reviewing the report, except as given the opportunity to do so through the peer or public review mechanism.

KIs must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as KIs and those who present with potential conflicts may be retained. The Task Order Officer (TOO) and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI.   Technical Experts

Technical Experts constitute a multi-disciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, or outcomes and identify particular studies or databases to search. The Technical Expert Panel (TEP) is selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that fosters a thoughtful, relevant systematic review. Therefore, study questions, design, and

methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and suggest approaches to specific issues, as requested by the EPC. Technical Experts do not do analysis of any kind; neither do they contribute to the writing of the report. They do not review the report, except as given the opportunity to do so through the peer or public review mechanism.

Members of the TEP must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The AHRQ TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XII.   Peer Reviewers

Peer reviewers are invited to provide written comments on the Draft Report based on their clinical, content, or methodological expertise. The EPC considers all peer review comments on the Draft Report in preparation of the Final Report. Peer reviewers do not participate in writing or editing of the Final Report or other products. The Final Report does not necessarily represent the views of individual reviewers. The EPC will complete a disposition of all peer review comments. The Disposition of Comments for systematic reviews will be published 3 months after the publication of the Final Report.

Potential peer reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Invited peer reviewers may not have any financial conflict of interest greater than $5,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on Draft Reports through the public comment mechanism.

XIII.   EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than $1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than $1,000 will usually disqualify EPC core team investigators.

XIV.   Role of the Funder

This project is funded by the Patient-Centered Outcomes Research Institute (PCORI) and executed under AHRQ, U.S. Department of Health and Human Services through Contract No. 75Q80120D00001. The TOO will review contract deliverables for adherence to contract requirements and quality. The authors of this report will be responsible for its content. Statements in the report should not be construed as endorsement by PCORI, AHRQ, or the U.S. Department of Health and Human Services.

XV.   Registration

This Protocol is being registered in the international prospective register of systematic reviews (PROSPERO).