



Evidence-based Practice Center Systematic Review Protocol

Project Title: *Respectful Maternity Care: Dissemination and Implementation of Perinatal Safety Culture to Improve Equitable Maternal Healthcare Delivery and Outcomes*

I. Background and Objectives for the Systematic Review

Background

Despite sizeable resources invested in US maternity care, severe maternal morbidity and death is worse in the US than in all comparable countries,¹⁻⁴ with the greatest impact on Black women.^{5,6} Emerging research suggests that one key part of this problem relates to disrespectful care during childbirth. From 2018 to 2019, just ahead of the COVID-19 pandemic, maternal mortality rates in the US increased from 17.4 to 20.1 per 100,000 live births. In 2020, rates increased to 23.8 per 100,000 live births,^{7,8} and statistically significant differences in maternal mortality continued for non-Hispanic Black women (55.3/100,000 live births) compared to non-Hispanic White women (19.1 per 100,000 live births).⁸ Disparities in maternal mortality rates persist for non-Hispanic Black women even when controlling for education, income, or socioeconomic characteristics.^{6,7,9}

Access to high-quality maternal health care is associated with reduced maternal and perinatal morbidity and mortality because it can help identify conditions that increase the risk for poor outcomes and facilitate appropriate and timely interventions for prevention or treatment.¹⁰ Although maternity care, including prenatal screening, is currently covered without cost sharing under the Affordable Care Act,^{11,12} inequities persist in the receipt and delivery of care. Emerging models such as remote monitoring and alternative prenatal care schedules^{13,14} to deliver care may present opportunities to improve access, efficacy, promote collaborative care,¹⁵ optimize patient safety,^{16,17} and improve patient satisfaction to help close the health disparities gap.¹⁷ Integrated care delivery models that promote the use of multidisciplinary teams (e.g., midwives, doulas, physicians) and care approaches¹⁸⁻²⁰ such as telehealth and remote monitoring, support a paradigm shift towards reorganizing care to successfully reach populations facing barriers and could address the diversity of contributors to maternal death.¹

While many factors contribute to these maternal health disparities between the US and other high-resource countries and within the US, particularly between White vs. Non-Hispanic Black women, there is increasing attention to the role that respectful maternity care (RMC) may play in shaping these outcomes. Lack of RMC, or disrespectful care,

has been identified as part of systems' failures leading to worse outcomes among those who are the most vulnerable during childbearing.^{21,22} A large uptick in community births within many US communities may reflect patients who did not feel safe or respected in hospitals, or because their support networks were not permitted in hospitals during the pandemic.^{23,24} Shared decision making²⁵ and patient preferences²⁶ are central considerations for updated maternity care approaches that are appealing to pregnant individuals and create safe birthing environments. These factors signal the need for careful consideration of standard RMC practices and opportunities for innovation in the care of all childbearing individuals, with particular attention to racial inequity and disadvantaged groups, to inform culturally competent care.

In 2020, the US Department of Health and Human Services (HHS) launched a department-wide effort to improve equity in maternal health and safety outcomes in response to the ongoing recognition of growing maternal health disparities, particularly among groups already at risk. This included funding of maternal mortality review committees and efforts to address implicit bias and racial gaps in pregnancy and childbirth related deaths.²⁷ Through a partnership with HRSA's Maternal Child Health Bureau and the Alliance for Innovation on Maternal Health (AIM), AHRQ worked to integrate the Safety Program in Perinatal Care (SPPC) with the existing AIM maternal safety bundle framework^{28,29} by emphasizing teamwork and communication to improve patient safety and the culture of obstetric care. HRSA, AIM, and AHRQ have focused on updating the existing AIM Maternal Safety Bundle "4 R framework" (Readiness, Recognition, Response, Reporting) to include a 5th R: respectful maternity care (RMC) in an effort to improve person-centered and equitable care and incorporate pregnant and postpartum individuals and their identified support networks as part of the multidisciplinary care team.^{30,31}

Defining RMC and its components, understanding fundamental aspects of RMC, and identifying validated tools to measure and implement safe and respectful care, is paramount to informing future program goals and addressing these dilemmas.³² Careful attention to these key components of RMC is important during labor and delivery, when women may experience pain or insecurity and are particularly vulnerable to experiences of disrespect or abuse.³³ Implementing evidence-based practices³⁴ to train those delivering care may help reduce variations in care and promote effective and respectful delivery of care, while discouraging ineffective, inequitable, or potentially harmful interventions. Since there is no single tool to identify or measure RMC, recognizing the themes,³⁵ domains,³⁶ and key principles of RMC may facilitate a clearer understanding of target metrics for evaluation. Key measurements include the impact on maternal health outcomes and identifying care disparities that consider patient experiences.

Purpose of the Review

The purpose of this review is to address the uncertainty in measuring and identifying respectful maternity care (RMC), disrespect or abuse³⁷⁻³⁹ during childbirth, and identify effective strategies for implementing RMC in order to improve outcomes, particularly for disadvantaged populations.⁴⁰ The goal is to define, identify, and evaluate key components of RMC, how it may be measured, and to synthesize current research on strategies to deliver RMC to inform an update of the AIM Maternal safety bundle. Specifically, this systematic review aims to inform policy makers and practice leaders by identifying and evaluating appropriate metrics and tools to assess RMC. When data are available, we will also assess the differential impact of RMC on populations adversely affected by disparities due to geography, race/ethnicity, age, language, education, socioeconomic status, disability, or other factors as defined by the PROGRESS-plus framework.⁴¹

II. Review Questions

The systematic review questions are based on those provided in the scope of work that accompanied the Request for Task Order. A topic refinement document that included the key questions (KQ), Contextual Question (CQ), and description of patients, interventions, comparators, outcomes, timing, settings, and study design (PICOTS), and analytic framework for this topic was posted on the Agency for Healthcare Research and Quality (AHRQ) Website from August 19th to September 9th, 2022. Public comments included concerns about excluding care during the prenatal period; recognizing additional disparities faced by persons with disabilities; and incorporating examples and working definitions of published, existing RMC frameworks.⁴² While we acknowledge that there are opportunities for the delivery and receipt of both disrespectful and respectful care throughout the prenatal period, this review will focus on RMC during labor and delivery in an effort to maintain a narrower scope and better focus on areas for future intrapartum research. There were no other comments specific to the KQs or other PICOTs. The questions, analytic framework and PICOTS table were reviewed, organized, and refined by the project team, with input from the AHRQ Task Order Officer (TOO), partners, Key Informants (KIs), public comments, and will be reviewed by a Technical Expert Panel (TEP). Additional modifications may be made based on feedback and input from the TEP.

Key Questions

Questions for the Systematic Review:

KQ1. Which components of RMC have been examined using validated measures? Are there validated tools to measure RMC?

KQ2. What is the effectiveness of strategies to implement respectful maternity care?

KQ3. What is the effectiveness of respectful maternity care on maternal health and utilization outcomes?

- a. How does effectiveness vary among disadvantaged pregnant persons?
- b. Which components of RMC are associated with effectiveness?
- c. Which (non-patient) factors are associated with effectiveness?

KQ4. What is the effectiveness of respectful maternity care on infant health outcomes?

- a. How does effectiveness vary among infants of disadvantaged pregnant persons?
- b. Which components of RMC are associated with effectiveness?
- c. Which (non-patient) factors are associated with effectiveness?

For KQ 3a and 4a, ‘disadvantaged pregnant persons’ may be defined by geography, race/ethnicity, age, disability, language, education, SES, etc., as described in Cochrane’s PROGRESS-Plus framework.⁴¹ In KQ 3c and 4c, ‘non-patient factors’ could be related to setting (type of hospital, rural/urban, staffing ratios) or intervention characteristics.

Contextual Question

CQ1. How is respectful maternity care during labor and delivery, and the immediate postpartum period defined in the literature? Does the literature define the essential/critical components of RMC? For example, is teamwork and communication (amongst providers, staff, patients and families) an essential element of RMC?

PICOTS

Table 1 describes the populations, interventions, comparators, outcomes, and settings (PICOTS).

Table 1. PICOTS: Inclusion and exclusion criteria

	Inclusion	Exclusion
Population	KQ 1-4: Pregnant adolescents and adults admitted for labor through discharge after delivery <u>Subgroups of interest:</u> • KQ 3a and 4a: Disadvantaged individuals ^a	Non-pregnant populations
Interventions	KQ 1: Validated measures of respectful care KQ 2: Implementation strategies for RMC (eg, patient/provider education, policies, payment, doula/patient advocate, practice facilitation) KQ 3-4: Respectful maternity care (any definition) KQ 3b and 4b: Specific component of RMC	Non-validated RMC measures
Comparators	KQ 1: Other tool(s), reference/gold standard or no tool to measure respectful care	No tool, measure, or comparison

	<p>KQ 2: Other implementation strategies for RMC</p> <p>KQ 3-4: Routine maternity care</p> <p>Absence of a specific RMC component</p>	
Outcomes	<p>KQ 1:</p> <ul style="list-style-type: none"> • Respectful care as measured by a validated tool <p>KQ 2</p> <ul style="list-style-type: none"> • RMC provider knowledge and/or practices • Rates of procedures and interventions <p>KQ 3:</p> <ul style="list-style-type: none"> • Health outcomes for pregnant persons <ul style="list-style-type: none"> ○ Maternal morbidity ○ Maternal mortality ○ Mental health outcomes ○ Function, quality of life, patient satisfaction using validated measures ○ Mental health outcomes based on validated measures (eg, anxiety, depression) ○ Harms • Utilization outcomes for pregnant persons <ul style="list-style-type: none"> ○ Length of stay ○ Healthcare utilization post-discharge ○ Rates of procedures <p>KQ 4:</p> <ul style="list-style-type: none"> • Health outcomes for infants <ul style="list-style-type: none"> ○ Infant morbidity ○ Infant mortality ○ Harms • Utilization outcomes for infants <ul style="list-style-type: none"> ○ Length of stay ○ Healthcare utilization post-discharge 	<p>KQ4: Infant health outcomes >1 year</p>
Timing	<ul style="list-style-type: none"> • Intervention: Admission for labor through discharge after delivery • Outcomes: from admission through one year postpartum 	<p>Interventions: before labor, during prenatal care</p> <p>Outcomes: More than one year postpartum</p>
Settings	<ul style="list-style-type: none"> • KQ1, CQ: All countries in a hospital or birthing facility setting (eg, birth centers) • KQ 2-4: hospital or birthing facility in US or US relevant countries • KQ 3c and 4c: hospital or birthing facility in US or US relevant countries 	<p>Home births</p>
Study designs and publication types	<ul style="list-style-type: none"> • KQ1-4: Trials (randomized and comparative nonrandomized), comparative observational studies 	<p>KQ 1: Studies that do not describe psychometric properties/methods of determining validity of measures or components</p>

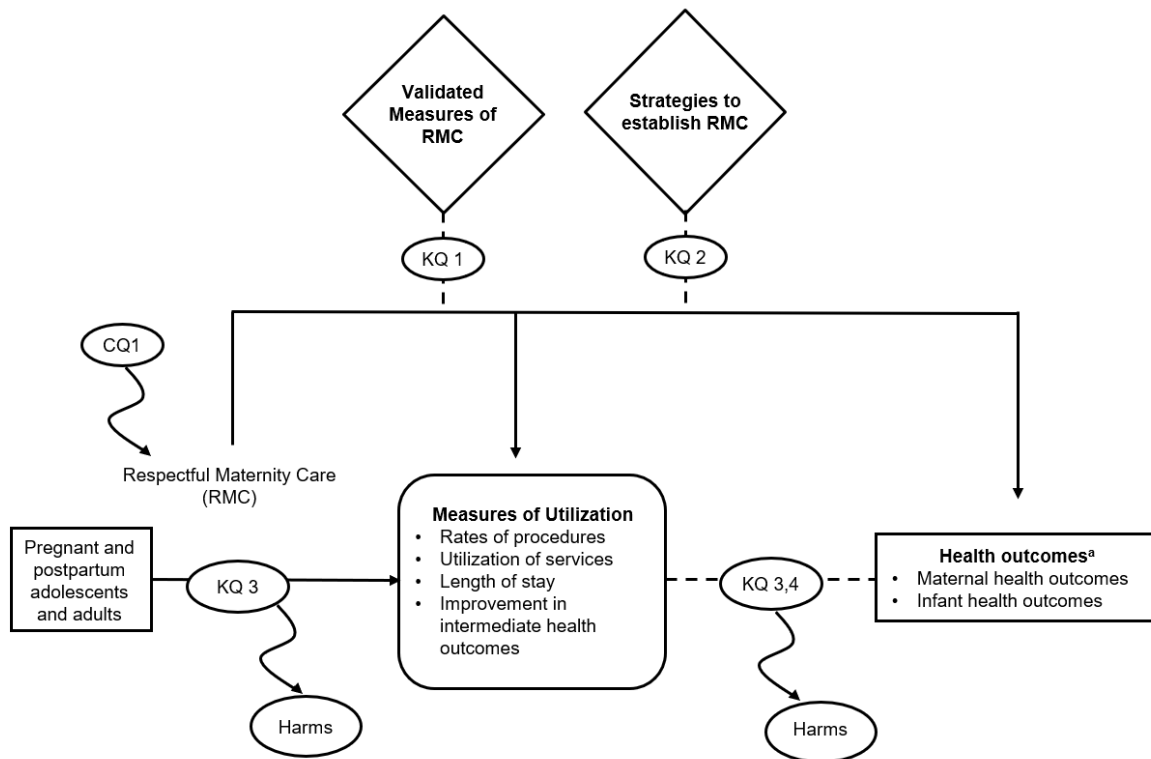
		<p>KQ2-4: Case reports, case series (or similar single-arm designs) Publication types: Conference abstracts or proceedings, editorials, letters, white papers, citations that have not been peer-reviewed, single site reports of multi-site studies</p>
--	--	---

Abbreviations: CQ, contextual question; KQ, key question; RMC, respectful maternity care

^a “Disadvantaged persons” as defined by PROGRESS-plus framework⁴¹

III. Analytic Framework

Figure 1. Analytic Framework



The analytic framework illustrates how the populations, interventions, and outcomes relate to the Key and Contextual Questions (KQ, CQ) in the review.

^a Outcomes vary by KQ and are specified in Table 2.

IV. Methods

Respectful maternity care (RMC) may include several different strategies or models designed for various settings, patients, or clinical conditions. We worked with the TOO,

partners, KIs, and will work with the TEP to identify definitions, criteria, principles, and domains to define and evaluate RMC strategies for this review.

Criteria for Inclusion/Exclusion of Studies in the Review

Table 1 includes specific details of the eligibility criteria for the overall review based on PICOTS framework. Additional details on key criteria are further defined below.

Key Question 1: Our working definition for “validated” tools and measures will consider studies that include studies of RMC that incorporate measures that have been implemented, evaluated, or reported in the literature. We will also review and evaluate existing conceptual frameworks such as the MADM,⁴³ MIST,¹² and MOR⁴⁴ index tools, AWHONN guidelines,⁴² Birth Place Lab’s RMC measurement registry.⁴⁵ We will consider COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments)⁴⁶ criteria to facilitate descriptions of measurement validation.

Key questions 2,3,4: We will evaluate studies of comparative effectiveness of strategies to implement RMC. We will consider studies that report the effect of RMC on maternal and infant health outcomes, in addition to outcomes related to utilization. We aim to evaluate how the effective delivery and strategies to implement or provide RMC varies among disadvantaged persons as defined by the PROGRESS-plus framework,⁴¹ including populations that may vary by geographic location or residence, race/ethnicity/culture, language, disability, age, gender/sex, and others. We will also intend to represent patient perspectives, including patient satisfaction, as outcomes, when reported, although these may be less precise to capture.

Contextual Question: This question aims to identify definitions and components of RMC described in the literature. Descriptive and hypothetical studies will not be included.

Study Designs: Randomized controlled trials (RCTs) will be prioritized for all key questions. However, based on our preliminary review of the literature, the majority of the available evidence is unlikely to be randomized controlled trials (RCTs) with patient-level randomization that assess effectiveness. Rather, most will be observational studies that are likely to have limitations that must be considered. For example, issues related to confounding or selection bias may limit the validity and interpretation of results from observational studies. In the absence of evidence from RCTs, we will include prospective, comparative trials. Nonrandomized, controlled studies of interventions will also be considered for harms.

Non-English-Language Studies: We will restrict to English language articles but will review English language abstracts of non-English language articles to identify studies that would otherwise meet inclusion criteria, in order to assess for the likelihood of language bias.

Settings: While RMC approaches may be very different in other countries, we will not limit the search to the United States but will evaluate and include what is most relevant by considering the context. For example, countries outside the US will be considered for

KQ1 and the CQ as these questions do not evaluate effectiveness of RMC and would not pose an issue for applicability. Rather, these questions aim to identify key components and validated measures of RMC, which may not primarily be from US relevant settings and would not affect applicability. Low- or middle-income countries will not be considered for questions of effectiveness (KQ 2,3,4).

Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

Literature Databases: Ovid® MEDLINE®, EMBASE®, and the Cochrane Library will be searched. Appendix A contains our sample MEDLINE® search strategy, which will be adapted to search the other databases. In order to capture all relevant literature, searches will include additional sources beyond PubMed, when evidence from peer-reviewed literature is lacking. This will include human rights, legal, psychology, sociology (SocIndex) and medical anthropology literature as well as work from reproductive justice leaders outside of the academic space (eg, National Birth Equity Collaborative). These sources may be more apt to inform the contextual question.

Search Strategy. During topic refinement, Key Informants provided input on approaches that we will translate into our initial search strategy. Examples of studies of interest will be used to validate our search strategy. Search strategies were developed by a research librarian with expertise in conducting searches for systematic reviews. Search strategies will be reviewed by the TEP. Searches will be peer reviewed by a second librarian.

Literature identified during the updated search will be assessed using the same process of dual review as all other studies considered for inclusion. If any pertinent new literature is identified for inclusion in the report, it will be incorporated before the submission of the final report.

Gray Literature. Sources for gray literature will include reports produced by federal and state agencies, healthcare provider organizations, or others. We will search for clearinghouses that aggregate, or reports that summarize perspectives or research across different organizations. We will follow up on the suggestions made by KIs and TEP members and will track publications and organizations cited in included studies and reports. These sources may be considered when evidence from RCTs is lacking.

Hand Searching: Reference lists of included articles and relevant systematic reviews will also be searched for includable literature.

Supplemental Evidence and Data for Systematic review (SEADS): AHRQ will publish an announcement in the Federal Register to notify stakeholders about the opportunity to submit information via the SEADS portal on the Effective Health Care Website.

Publication Date Range: For key questions that define, measure, and evaluate effectiveness of RMC, we will search databases for studies published after 2013. There was general agreement that we should focus on relatively recent literature from the last 5

to 10 years. The AIM program was established in 2014, which changed the policy context. The use of the term “respectful maternity care” was also not cited in the peer reviewed, indexed literature prior to 2013, so searches dating back prior to 2013 may not be informative or relevant. Electronic literature searches will be updated while the draft report is posted for public comment and peer review to capture any new publications.

Process for Selecting Studies

In accordance with the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*,⁴⁷ we will use the pre-established criteria described in Table 1 to screen citations (titles and abstracts) identified through our searches to determine eligibility for full-text review. To ensure accuracy, all excluded abstracts will be dual reviewed. We will retrieve full text articles for all abstracts deemed appropriate for consideration by at least one of the reviewers. Each full-text article will be independently reviewed for eligibility by two team members, including any articles suggested by the TEP or peer reviewers, or that result from the public posting process. Any disagreements will be resolved by consensus among investigators. A record of studies excluded at the full-text level with reasons for exclusion will be maintained and made available as an appendix to the final report. We will review existing systematic reviews, and include their results if appropriate. At a minimum, we will use systematic reviews to identify studies. We will maintain a record of studies excluded at the full-text level with reasons for exclusion.

Data Abstraction and Data Management

For studies meeting inclusion criteria, data will be abstracted, including elements such as study design, year, setting, country, sample size, patient characteristics, clinician types and characteristics (e.g., training/background/scope of practice), and results relevant to each question (e.g. maternal/infant health, patient reported, utilization outcomes) as outlined in Table 1. We will create tailored, detailed data abstraction tools for each key question after full text review which will be discussed with the AHRQ TOO, and the TEP. All extracted study data will be verified for accuracy and completeness by a second team member.

Assessment of Methodological Risk of Bias of Individual Studies

We will use predefined criteria to assess the risk of bias, or internal validity, of included studies. Controlled trials and observational studies will be assessed using a priori established criteria consistent with the approach recommended in the chapter, *Assessing the Risk of Bias of Individual Studies*, described in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.^{47,48} These criteria will include methods of patient selection (e.g., consecutive patients, use of an inception cohort) and appropriate control for confounding of relevant factors.^{49,50} We will downgrade studies that do not provide randomization, allocation, and/or blinding details, have a high rate of study loss to followup, or demonstrate selective reporting or other bias accordingly. To address the potential for publication bias, we will conduct appropriate statistical tests (e.g., funnel plots, statistical tests for Egger’s small sample effects) when we have sufficient (≥ 10)

studies.⁵¹ These criteria and methods will be used in concordance with the approach recommended in the chapter, *Assessing the Risk of Bias of Individual Studies When Comparing Medical Interventions*,⁴⁸ from the *AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.⁴⁷ Studies will be rated as being “low,” “moderate,” or “high” risk of bias as described below in Table 2. Each study will be independently evaluated for risk of bias by two team members. Any disagreements will be resolved by discussion and consensus. Team members who were involved in the conduct of a study will not be involved in data abstraction or risk of bias assessment for that study.

Table 2. Criteria for grading the risk of bias of individual studies

Rating	Description and Criteria
Low	<ul style="list-style-type: none"> • Least risk of bias, results generally considered valid • Employ valid methods for selection, inclusion, and allocation of patients to treatment; report similar baseline characteristics in different treatment groups; clearly describe attrition and have low attrition; use appropriate means for preventing bias (e.g., blinding of patients, care providers, and outcomes assessors); and use appropriate analytic methods (e.g., intention-to-treat analysis)
Moderate	<ul style="list-style-type: none"> • Susceptible to some bias but not enough to necessarily invalidate results • May not meet all criteria for low risk of bias, but no flaw is likely to cause major bias; the study may be missing information related to attrition, blinding, or analytic methods, making it difficult to assess limitations and potential problems • Category is broad; studies with this rating will vary in strengths and weaknesses; some studies rated moderate risk of bias are likely to be valid, while others may be only possibly valid
High	<ul style="list-style-type: none"> • Significant flaws that imply biases of various kinds that may invalidate results; “fatal flaws” in design, analysis or reporting; large amounts of missing information; discrepancies in reporting; or serious problems with intervention delivery • Studies are at least as likely to reflect flaws in the study design or execution as the true difference between the compared interventions • Considered to be less reliable than studies rated moderate or low risk of bias when synthesizing the evidence, particularly if discrepancies between studies are present

Data Synthesis

Key Question 1: Approaches to data synthesis may differ across key questions. For Key Question 1, recent frameworks, including those referenced in the background above, will be used to develop functional and/or conceptual categories to describe the strategies, measures, and approaches we identify and provide the basis for qualitative

synthesis. A table or evidence map may facilitate the synthesis of various categories corresponding to leading domains and measures of RMC.

Key Questions 2, 3, 4: We will construct evidence tables identifying the study characteristics and results of interest, and risk of bias/quality ratings for all included studies. Summary tables will highlight the main findings. We will review and highlight studies by using a hierarchy-of-evidence approach, where the best evidence will be the focus of our synthesis for each question.

Contextual Question: We will organize the contextual question according to the sub-questions, and qualitatively synthesize the data. In our synthesis, we will prioritize U.S. national or regional studies over local reports or data from other countries, if we determine they are more relevant. We will summarize the strengths and limitations for each of the included reports for these questions, with a focus on elements such as the extent the sample represents the population of interest and the completeness and reliability of the data, and prioritize the studies that are more rigorous and complete. The specifics of how we synthesize the data will be driven by the types and quantity of data available. Once inclusion decisions have been made and key information abstracted, we will identify existing frameworks, models or measures that can be used to organize and categorize the finding for this question.

Qualitative data will be summarized in summary tables, including ranges and descriptive analysis and interpretation of the results. If sufficient data are available, meta-analyses will be conducted to summarize data and obtain more precise estimates of outcomes across any subgroups of methodologically comparable studies.^{52,53} The feasibility of a quantitative synthesis will depend on the number and completeness of reported outcomes and a lack of significant heterogeneity. To determine whether meta-analysis could be meaningfully performed, we will consider the risk of bias for each of the studies and the heterogeneity among studies in design, patient population, interventions, and outcomes, and may conduct sensitivity analyses. If meta-analysis is performed, randomized controlled trials will be analyzed separately from observational studies. Meta-regression may be conducted to explore statistical heterogeneity using additional variables for methodological or other characteristics (e.g., risk of bias, randomization or blinding, outcome definition, and ascertainment) given enough number of studies. Applicability to U.S. practice settings will be assessed based on the Evidence-based Practice Center (EPC) Methods Guide, using the PICOTS framework.⁵⁴ See section on Applicability below.

Grading the Strength of Evidence (SOE) for Major Comparisons and Outcomes

Grading the strength of evidence (SOE) only applies to questions of effectiveness and therefore will only be conducted for Questions 2, 3, and 4. Similar to the approach for assessing risk of bias for individual studies, the strength of evidence (SOE) for each Question or Quality will be initially assessed by one researcher for selected outcomes (see PICOTS) by using the approach described in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.⁴⁷ We will involve the TEP, Partners and TOO in

the prioritization of the outcomes for SOE after the included studies are identified. We will provide a suggested list of relevant outcomes based on preliminary searches to help define and prioritize key outcomes for consideration. To ensure consistency and validity of the evaluation, the initial assessment will be independently reviewed by at least one other experienced investigator using the following criteria:

- Study limitations (low, medium, or high level of study limitations)
- Consistency (consistent, inconsistent, or unknown/not applicable)
- Directness (direct or indirect)
- Precision (precise or imprecise)
- Reporting bias (suspected or undetected)

The strength of evidence will be assigned an overall grade of high, moderate, low, or insufficient (**Table 3**) by evaluating and weighing the combined results of the five primary domains.

Table 3. Description of the strength of evidence grades

Strength of Evidence	Description
High	Very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies. The findings are stable, i.e., another study would not change the conclusions.
Moderate	Moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies. The findings are likely to be stable, but some doubt remains.
Low	Limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both). Additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	Investigators are unable to estimate an effect, or have no confidence in the estimate of effect for this outcome. The body of evidence has unacceptable deficiencies, precluding reaching a conclusion. If no evidence is available, it will be noted as “no evidence”

The strength of the evidence may be downgraded based on the limitations described above. There are also situations where the observational evidence may be upgraded (e.g., large magnitude of effect, presence of dose-response relationship or existence of plausible unmeasured confounders), if there are no downgrades on the primary domains, as described in the AHRQ Methods Guide.^{47,48} Where both RCTs and observational studies are included for a given intervention-outcome pair, we follow the additional

guidance on weighting RCTs over observational studies, assessing consistency across the two bodies of evidence, and determining a final rating.⁴⁷

Assessing Applicability

Applicability will be assessed in accordance with the AHRQ’s Methods Guide,⁴⁷ using the PICOTS framework. We will use the PICOTS framework to consider the applicability of the evidence base for each question, for example, examining the characteristics of the patient populations (e.g., clinical condition) and study setting. These characteristics of the studies may limit the ability to generalize the results to other populations and settings.

Review of abstracted information on these factors will be used to assess situations for which the evidence is most relevant and to evaluate applicability to real-world clinical practice in typical U.S. settings. We will provide a qualitative summary of our assessment.

V. Definition of Terms

Abbreviation	Definition
AWHONN	Association of Women’s Health, Obstetric, and Neonatal Nurses
AHRQ	Agency for Health Research and Quality
CQ	CQ, Contextual Question
EPC	Evidence-based Practice Center
KI	Key Informant
KQ	Key question
MADM index	Mothers Autonomy in Decision Making scale
MIST	Mistreatment index
MOR index	Mothers on Respect index
PICOS	Populations, interventions, comparators, outcomes, timing, and setting
PROGRESS-Plus	Disadvantaged pregnant persons are defined according to the PROGRESS-Plus framework, which includes place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status, and social capital.
RCT	Randomized controlled trial
RMC	Respectful Maternity Care
SEADS	Supplemental Evidence and Data for Systematic review
SOE	Strength of evidence
SUD	Substance use disorder
TEP	Technical Expert Panel
TOO	Task Order Officer

VI. Summary of Protocol Amendments

None

VII. Review of Key Questions

The Agency for Healthcare Research and Quality (AHRQ) posted the Key Questions for on the AHRQ Effective Health Care Website for public comment August 19-Sept 9, 2022. The Evidence-based Practice Center (EPC) refined and finalized the Key Questions after review of the public comments, and input from Key Informants. Further refinement will occur after discussions with the Technical Expert Panel (TEP). All input is intended to ensure that the key questions are specific and relevant.

VIII. Key Informants

Key Informants are the 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 Key Informant role is to provide input into identifying the Key Questions for research that will inform healthcare decisions. The EPC solicited input from Key Informants when developing questions for the systematic review. Key Informants are not involved in analyzing the evidence or writing the report. They do not review the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants 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 Key Informants and those who present with potential conflicts may be retained. The AHRQ Task Order Officer (TOO) and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

IX. 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. They are 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 results in 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 nor 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.

TEP input will be sought to hone and re-affirm methods in the draft protocol, including perspectives on proposed KQ and PICOTS changes and managing challenges and reporting to enhance usability and inform meaningful presentation of the report.

X. 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 and technical briefs will be published three months after the publication of the evidence 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.

XI. 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. No conflicts were reported by any team members.

XII. Role of the Funder

This project was funded under Contract No. 75Q80120D00006 from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The AHRQ Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

XIII. Registration

This protocol will be registered in the international prospective register of systematic reviews (PROSPERO).

XIV. References

1. Declercq E ZL. Maternal Mortality in the United States: A Primer Fund TC; December 16, 2020 2020.
<https://www.commonwealthfund.org/publications/issue-brief-report/2020/dec/maternal-mortality-united-states-primer> Accessed April 16, 2022.
2. Declercq E ZL. Severe Maternal Morbidity in the United States: A Primer Fund TC; October 28, 2021 2021.
<https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/severe-maternal-morbidity-united-states-primer> Accessed April 16, 2022.
3. Gunja MZ SS, Zephyrin L, Williams, RD II. Health and Health Care for Women of Reproductive Age: How the United States Compares with Other High-Income Countries Fund TC; April 5, 2022 2022.
<https://www.commonwealthfund.org/publications/issue-briefs/2022/apr/health-and-health-care-women-reproductive-age> Accessed April 16, 2022.
4. MacDorman MF, Thoma M, Declercq E, et al. Racial and Ethnic Disparities in Maternal Mortality in the United States Using Enhanced Vital Records, 20162017. *Am J Public Health*. 2021 Sep;111(9):1673-81. doi: 10.2105/AJPH.2021.306375. PMID: 34383557.
5. Collaborators GBDMM. Global, regional, and national levels of maternal mortality, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016 Oct 8;388(10053):1775-812. doi: 10.1016/S0140-6736(16)31470-2. PMID: 27733286.
6. 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.
7. Hoyert D. Maternal mortality rates in the United States, 2019 National Center for Health Statistics. *Prevention CfDca*; April 2020 2021.
<https://stacks.cdc.gov/view/cdc/103855>
<http://dx.doi.org/10.15620/cdc:103855>
8. Hoyert D. Maternal mortality rates in the United States, 2020 National Center for Health Statistics. *Prevention CfDca*; February 2022 2022.
<https://stacks.cdc.gov/view/cdc/113967>
<https://dx.doi.org/10.15620/cdc:113967>.
9. Tucker MJ, Berg CJ, Callaghan WM, et al. The Black-White disparity in pregnancy-related mortality from 5 conditions: differences in prevalence and case-fatality rates. *Am J Public Health*. 2007 Feb;97(2):247-51. doi: 10.2105/AJPH.2005.072975. PMID: 17194867.
10. Allen J, Gibbons K, Beckmann M, et al. Does model of maternity care make a difference to birth outcomes for young women? A retrospective cohort study. *Int J Nurs Stud*. 2015 Aug;52(8):1332-42. doi: 10.1016/j.ijnurstu.2015.04.011. PMID: 25952336.
11. Initiative WsPS. Recommendations for preventive services for women: final report to the US Department of Health and Human Services, Health Resources &

- Services Administration. 2016. <https://www.hrsa.gov/womens-guidelines-2016/index.html>.
12. Vedam S, Stoll K, Taiwo TK, et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. *Reprod Health*. 2019 Jun 11;16(1):77. doi: 10.1186/s12978-019-0729-2. PMID: 31182118.
 13. Butler Tobah YS, LeBlanc A, Branda ME, et al. Randomized comparison of a reduced-visit prenatal care model enhanced with remote monitoring. *Am J Obstet Gynecol*. 2019 Dec;221(6):638 e1- e8. doi: 10.1016/j.ajog.2019.06.034. PMID: 31228414.
 14. Dowswell T, Carroli G, Duley L, et al. Alternative versus standard packages of antenatal care for low-risk pregnancy. *Cochrane Database Syst Rev*. 2015 Jul 16(7):CD000934. doi: 10.1002/14651858.CD000934.pub3. PMID: 26184394.
 15. Rubashkin N, Warnock R, Diamond-Smith N. A systematic review of person-centered care interventions to improve quality of facility-based delivery. *Reprod Health*. 2018 Oct 10;15(1):169. doi: 10.1186/s12978-018-0588-2. PMID: 30305129.
 16. AHRQ. AHRQ Safety Program for Perinatal Care: Experiences From the Frontline. 17-0003-23-EF. Rockville, MD: Quality AfHRa; October 30, 2016 2016. www.ahrq.gov/perinatafsafety Accessed April 16, 2022.
 17. ASTHO. The Impact of COVID-19 Telehealth Flexibilities on Maternity Care Association of State and Territorial Health Officials. September 2020 2020. <https://www.astho.org/globalassets/brief/the-impact-of-covid-19-telehealth-flexibilities-on-maternity-care.pdf>.
 18. Carlson NS, Neal JL, Tilden EL, et al. Influence of midwifery presence in United States centers on labor care and outcomes of low-risk parous women: A Consortium on Safe Labor study. *Birth*. 2019 Sep;46(3):487-99. doi: 10.1111/birt.12405. PMID: 30414200.
 19. Neal JL, Carlson NS, Phillippi JC, et al. Midwifery presence in United States medical centers and labor care and birth outcomes among low-risk nulliparous women: A Consortium on Safe Labor study. *Birth*. 2019 Sep;46(3):475-86. doi: 10.1111/birt.12407. PMID: 30417436.
 20. Smith DC, Phillippi JC, Lowe NK, et al. Using the Robson 10-Group Classification System to Compare Cesarean Birth Utilization Between US Centers With and Without Midwives. *J Midwifery Womens Health*. 2020 Jan;65(1):10-21. doi: 10.1111/jmwh.13035. PMID: 31553129.
 21. Chinn JJ, Martin IK, Redmond N. Health Equity Among Black Women in the United States. *J Womens Health (Larchmt)*. 2021 Feb;30(2):212-9. doi: 10.1089/jwh.2020.8868. PMID: 33237831.
 22. Logan RG, McLemore MR, Julian Z, et al. Coercion and non-consent during birth and newborn care in the United States. *Birth*. 2022 Jun 23doi: 10.1111/birt.12641. PMID: 35737547.
 23. DeJoy SB, Mandel D, McFadden N, et al. Concerns of Women Choosing Community Birth During the COVID-19 Pandemic: A Qualitative Study. *J Midwifery Womens Health*. 2021 Sep;66(5):624-30. doi: 10.1111/jmwh.13290. PMID: 34596940.

24. MacDorman MF, Barnard-Mayers R, Declercq E. United States community births increased by 20% from 2019 to 2020. *Birth*. 2022 Feb 25;doi: 10.1111/birt.12627. PMID: 35218065.
25. Megregian M, Emeis C, Nieuwenhuijze M. The Impact of Shared Decision-Making in Perinatal Care: A Scoping Review. *J Midwifery Womens Health*. 2020 Nov;65(6):777-88. doi: 10.1111/jmwh.13128. PMID: 32767740.
26. Baker A. Crossing the Quality Chasm: A New Health System for the 21st Century. *British Medical Journal*. 2001;323;doi: 10.1136/bmj.323.7322.1192.
27. National Academies of Sciences E, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice. *Advancing Maternal Health Equity and Reducing Maternal Morbidity and Mortality: Proceedings of a Workshop* National Academies Press. Washington, D.C.: Press NA; October 28, 2021. <https://www.ncbi.nlm.nih.gov/books/NBK575266/>.
28. AHRQ. TeamSTEPPS. June 2019 ed: Agency for Healthcare Research & Quality.
29. Engineer L. SAFETY PROGRAM IN PERINATAL CARE-II PHASE 2. Center for Health Services and Outcomes Research: Agency for Healthcare Research & Quality.
30. Care AfIoMH. Severe Hypertension in Pregnancy. ACOG; 2022. <https://safehealthcareforeverywoman.org/aim/patient-safety-bundles/maternal-safety-bundles/severe-hypertension-in-pregnancy-aim-2/>. Accessed July 11 2022.
31. Health AfIoM. Obstetric Hemorrhage. ACOG; 2022. <https://safehealthcareforeverywoman.org/aim/patient-safety-bundles/maternal-safety-bundles/obstetric-hemorrhage-patient-safety-bundle/>. Accessed July 11 2022.
32. Downe S, Lawrie TA, Finlayson K, et al. Effectiveness of respectful care policies for women using routine intrapartum services: a systematic review. *Reprod Health*. 2018 Feb 6;15(1):23. doi: 10.1186/s12978-018-0466-y. PMID: 29409519.
33. Hajizadeh K, Vaezi M, Meedy S, et al. Designing a respectful maternity care guideline: a multiphase study. *Reprod Health*. 2022 Mar 28;19(1):81. doi: 10.1186/s12978-022-01389-8. PMID: 35346250.
34. ACOG. Alliance for Innovation on Maternal Health (AIM). . American College of Obstetricians and Gynecologists; 2022. <https://www.acog.org/practice-management/patient-safety-and-quality/partnerships/alliance-for-innovation-on-maternal-health-aim>. Accessed April 9 2022.
35. Jolivet RR, Gausman J, Kapoor N, et al. Operationalizing respectful maternity care at the healthcare provider level: a systematic scoping review. *Reprod Health*. 2021 Oct 1;18(1):194. doi: 10.1186/s12978-021-01241-5. PMID: 34598705.
36. Shakibazadeh E, Namadian M, Bohren MA, et al. Respectful care during childbirth in health facilities globally: a qualitative evidence synthesis. *BJOG*. 2018 Jul;125(8):932-42. doi: 10.1111/1471-0528.15015. PMID: 29117644.
37. Ishola F, Owolabi O, Filippi V. Disrespect and abuse of women during childbirth in Nigeria: A systematic review. *PLoS One*. 2017;12(3):e0174084. doi: 10.1371/journal.pone.0174084. PMID: 28323860.
38. Mengesha MB, Desta AG, Maeruf H, et al. Disrespect and Abuse during Childbirth in Ethiopia: A Systematic Review. *Biomed Res Int*. 2020;2020:8186070. doi: 10.1155/2020/8186070. PMID: 33150181.

39. Sando D, Kendall T, Lyatuu G, et al. Disrespect and abuse during childbirth in Tanzania: are women living with HIV more vulnerable? *J Acquir Immune Defic Syndr*. 2014 Dec 1;67 Suppl 4:S228-34. doi: 10.1097/QAI.0000000000000378. PMID: 25436822.
40. Dhakal P, Creedy DK, Gamble J, et al. Educational interventions to promote respectful maternity care: A mixed-methods systematic review. *Nurse Educ Pract*. 2022 Mar;60:103317. doi: 10.1016/j.nepr.2022.103317. PMID: 35245873.
41. O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin Epidemiol*. 2014 Jan;67(1):56-64. doi: 10.1016/j.jclinepi.2013.08.005. PMID: 24189091.
42. AWHONN. Respectful Maternity Care Framework and Evidence-Based Clinical Practice Guideline. *J Obstet Gynecol Neonatal Nurs*. 2022 Mar;51(2):e3-e54. doi: 10.1016/j.jogn.2022.01.001. PMID: 35101344.
43. Vedam S, Stoll K, Martin K, et al. The Mother's Autonomy in Decision Making (MADM) scale: Patient-led development and psychometric testing of a new instrument to evaluate experience of maternity care. *PLoS One*. 2017;12(2):e0171804. doi: 10.1371/journal.pone.0171804. PMID: 28231285.
44. Vedam S, Stoll K, Rubashkin N, et al. The Mothers on Respect (MOR) index: measuring quality, safety, and human rights in childbirth. *SSM Popul Health*. 2017 Dec;3:201-10. doi: 10.1016/j.ssmph.2017.01.005. PMID: 29349217.
45. Birth Place Lab. Respectful Maternity Care Measurement Registry. <https://www.birthplacelab.org/rmc-registry/>. Accessed September 16, 2022.
46. Prinsen CAC, Mokkink LB, Bouter LM, et al. COSMIN guideline for systematic reviews of patient-reported outcome measures. *Qual Life Res*. 2018 May;27(5):1147-57. doi: 10.1007/s11136-018-1798-3. PMID: 29435801.
47. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. Content last reviewed April 2022. Rockville, MD: Effective Health Care Program, Agency for Healthcare Research and Quality; February 23, 2018. Chapters available at: <https://effectivehealthcare.ahrq.gov/topics/ceer-methods-guide/overview>.
48. Viswanathan M, Patnode CD, Berkman ND, et al. Assessing the Risk of Bias in Systematic Reviews of Health Care Interventions. *Methods Guide for Comparative Effectiveness Reviews*. (Prepared by the Scientific Resource Center under Contract No. 290-2012-0004-C). AHRQ Publication No. 17(18)-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality; Dec 2017. Posted final reports are located on the Effective Health Care Program search page: <https://effectivehealthcare.ahrq.gov/>. doi: 10.23970/AHRQEPCCMETHGUIDE2. PMID: 30125066.
49. Furlan AD, Malmivaara A, Chou R, et al. 2015 Updated Method Guideline for Systematic Reviews in the Cochrane Back and Neck Group. *Spine (Phila Pa 1976)*. 2015 Nov;40(21):1660-73. doi: 10.1097/brs.0000000000001061. PMID: 26208232.
50. Higgins JPT, Savović J, Page MJ, et al. Chapter 8: Assessing risk of bias in a randomized trial. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). *Cochrane Handbook for Systematic Reviews of*

- Interventions version 6.3 (updated February 2022). Cochrane. 2022. Available from www.training.cochrane.org/handbook.
51. Sterne JA, Sutton AJ, Ioannidis JP, et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *Bmj*. 2011 Jul 22;343:d4002. doi: 10.1136/bmj.d4002. PMID: 21784880.
 52. Fu R, Gartlehner G, Grant M, et al. Conducting quantitative synthesis when comparing medical interventions: AHRQ and the Effective Health Care Program. *J Clin Epidemiol*. 2011 Nov;64(11):1187-97. doi: 10.1016/j.jclinepi.2010.08.010. PMID: 21477993.
 53. Morton SC, Murad MH, O'Connor E, et al. Quantitative Synthesis—An Update. *Methods Guide for Comparative Effectiveness Reviews*. (Prepared by the Scientific Resource Center under Contract No. 290-2012-0004-C). AHRQ Publication No. 18-EHC007-EF. Rockville, MD: Agency for Healthcare Research and Quality; February 2018. Posted final reports are located on the Effective Health Care Program search page: <https://effectivehealthcare.ahrq.gov/>. doi: 10.23970/AHRQEPCEMETHGUIDE3.
 54. Atkins D, Chang SM, Gartlehner G, et al. Assessing applicability when comparing medical interventions: AHRQ and the Effective Health Care Program. *J Clin Epidemiol*. 2011 Nov;64(11):1198-207. doi: 10.1016/j.jclinepi.2010.11.021. PMID: 21463926.

Appendix A. Sample Search Strategies: Cervical Degenerative Disease Treatment

Strategies will be adapted for databases to be searched.

Search Strategies

Overall

Database: Ovid MEDLINE(R) ALL <1946 to August 05, 2022>

Search Strategy:

-
- 1 ((respect* or disrespect*) adj3 (care or caring* or cares or cared) adj5 (matern* or mother* or obstetric*)).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (417)
 - 2 exp Maternal Health Services/ (56113)
 - 3 ((respect* or disrespect*) adj5 (care or caring* or cares or cared or wish* or prefer* or opinion* or desir* or patient* or matern* or mother*)).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (186150)
 - 4 2 and 3 (996)
 - 5 1 or 4 (1141)
 - 6 exp Human Rights/ (152811)
 - 7 exp cultural competence/ (6329)
 - 8 exp culturally competent care/ (2042)
 - 9 exp cultural diversity/ (12647)
 - 10 exp patient centered care/ (23421)
 - 11 6 or 7 or 8 or 9 or 10 (193112)
 - 12 2 and 11 (1557)
 - 13 exp "Attitude of Health Personnel"/ (167935)
 - 14 12 and 13 (236)
 - 15 exp Professional-Patient Relations/ (147587)
 - 16 12 and 15 (232)
 - 17 exp professional competence/ (127085)
 - 18 12 and 17 (49)
 - 19 exp Patient-Centered Care/ (23421)
 - 20 2 and 19 (347)
 - 21 exp decision making/ (226160)
 - 22 2 and 21 (1200)
 - 23 (respect* or appreciat* or consider*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (5196589)
 - 24 22 and 23 (297)
 - 25 5 or 14 or 16 or 20 or 24 (1910)

Measure exp "quality of health care"/ or measures.ti. or tools.ti. or measure.ti. or tool.ti. or (valid* adj3 stud*).mp.

Establishment of RMC (operationaliz* or operationalis* or strateg* or framework* or establish* or implement*).ti. or exp "implementation science"/

Maternal health outcomes (maternal or maternity or moms or mothers or mom or mother).ti. or exp mothers/

Infant health outcomes exp infant/ or infant.ti. or child.ti. or baby.ti. or babies.ti. or infants.ti. or children.ti.

Disadvantaged pregnant persons exp Social problems/ or exp socioeconomic factors/ or exp "health disparity, minority and vulnerable populations"/ or exp "homeless persons"/ or exp "medically uninsured"/ or exp "population groups"/ or exp prisoners/ or exp refugees/ or exp "sex workers"/ or exp "transients and migrants"/ or exp "working poor"/

Systematic Reviews Ovid limit applied = (systematic reviews pre 2019 or systematic reviews)

RCT (groups or trial or randomly).tw. or "Drug Therapy".fs. or placebo.tw. or randomized.tw. or "controlled clinical trial".pt. or "randomized controlled trial".pt.

Observational Studies exp "Cohort Studies"/ or "Controlled Clinical Trial".pt. or exp "Case-Control Studies"/ or ("Evaluation Studies" or "Comparative Study").pt. or ("Comparative Study".pt. or exp "Follow-Up Studies"/)