Evidence-based Practice Center Systematic Review Protocol

Project Title: *Telehealth for Women*

I. Background and Objectives for the Systematic Review

Background

In 2016, the Health Resources and Services Administration (HRSA) partnered with the American College of Obstetrics and Gynecology (ACOG) under a cooperative agreement to support the Women's Preventive Services Initiative (WPSI) to develop evidence-based guidelines for women's preventive health care services. Currently, the services informed by the WPSI guidelines are covered without cost sharing under the Affordable Care Act (ACA)[1] resulting in a range of preventive services available to women, including contraception, counseling for sexually transmitted infections (STI), and screening for interpersonal violence (IPV), among others. Implementation of these services is guided by health equity to ensure "quality preventive health care for women at every stage of life."[2] Evaluating approaches to care that are inclusive, accessible, and sustainable are important to optimize women's health and reduce disparities. Effective approaches must appeal to both patients and clinicians. Thus, shared decision making and patient preferences are central to care models that can improve efficacy, patient and clinician satisfaction, and help reduce health disparities.[3] Telehealth is one promising model. However, coverage, reimbursement, and regulation of telehealth services have been slow to evolve.[4,5]

Traditionally, preventive services for women are either integrated into well woman visits[6,7] focusing on screening and prevention, or offered opportunistically in the context of managing health conditions. Recent research has found that telehealth may improve some obstetric and gynecologic outcomes[8] and may be effective for contraceptive care.[9-11] "Telehealth" includes services that utilize information and telecommunications technology in health care delivery for a specific patient involving a clinician across distance or time, such as remote real-time clinical visits and remote monitoring. Virtual health technologies, also considered telehealth services, may include mobile health applications (apps) or devices that collect patient-generated health data and interventions provided over the internet, such as screening questionnaires and education. Telehealth platforms for family planning, contraceptive services, and safety decision aids for survivors of IPV[12-14] show promise as a way to make these services more inclusive, accessible, and cost-effective. Telehealth services have been offered for contraception[15] to facilitate access for more geographically distant patients.[16] Digital health platforms for IPV services[17-19] have demonstrated acceptability and feasibility for violence prevention and decision support for those in abusive relationships.

Telehealth may improve access for underserved populations and those facing barriers to care.[20] However, telehealth could also widen disparities due to the differences in internet access and digital literacy; equity considerations including age and language barriers;[21-23] system factors such

as access to care or provider shortages; and social determinants of health including transportation barriers, food insecurity, and trauma. Bias and structural racism[24] further exacerbate health disparities.[25] Given this context, questions remain about how to best promote access and equity while streamlining health care delivery for populations[26] with unacceptable, ongoing disparities in health outcomes.[27,28] Updating the approach to preventive services and reproductive health care to include remote counseling, monitoring, and telehealth may present opportunities to close the gap on these disparities.[29] Yet, research has not definitively addressed whether telehealth increases access to care nor whether it results in similar or better outcomes compared with in-person care for reproductive health and IPV in women.

The coronavirus (COVID-19) pandemic led to rapid adoption of telehealth as a strategy to provide health services while reducing the risk of coronavirus exposure.[29-32] The pandemic has highlighted existing health disparities and placed a spotlight on a concerning rise in incidence of IPV against women and girls.[33-37] Intervention efforts for IPV must consider limitations in accessing the usual channels of support, particularly as many women have been unable to leave abusive or unstable environments due to stay at home mandates and increasing hardship, likely resulting in increased rates of IPV[38-40] and creating new barriers to reporting.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act[41] provided federal funding to increase telehealth access and provide infrastructure to increase capability and capacity for services for women including provision of family planning.[42] However, questions remain about whether some services can, or should, continue to occur remotely after the pandemic, given issues of patient perceptions, preferences, and barriers to virtual versus in-person care. Changes in regulatory and payment policies that supported the increases in telehealth during the pandemic may inform patient and clinician preferences. Furthermore, it is also important to identify the disadvantages telehealth may pose in effectively delivering preventive services to specific underserved populations.

Purpose of the Review

This systematic review will identify and synthesize current research on the use of telehealth for a subset of services and conditions included in the WPSI guidelines, specifically women's reproductive health (including family planning, contraception, and STI counseling), and IPV to inform HRSA program planning and identify research gaps. A comprehensive understanding of the current context (contextual question), effectiveness (Key Question [KQ] 1a and 2a), patient preferences and engagement (KQ1b,c and 2b,c), and implementation of telehealth in the context of COVID-19 (KQ1d and 2d) will be the foundation for the review. In addition, barriers to and facilitators of the use of telehealth in geographically isolated and underserved settings and populations (KQ1e and 2e), and evidence about the impact of COVID-19 on the use of telehealth and virtual health for these services, will be included. Harms (KQ1f and 2f) will also be addressed.

Evidence on the impact of COVID-19 on the use of telehealth will be particularly relevant.[43] Considerations for the equitable future use of telehealth as a supplement or replacement for some in-person care needs to consider patient-centered outcomes including patient preferences, content of services and frequency of visits, status of technology, and potential harms. Importantly, this review will address the decisional dilemma facing policy makers and practice leaders about the

uncertainty regarding the effectiveness of telehealth for delivering specific preventive services and how to best mobilize telehealth to address women's health care needs, particularly for those who are geographically isolated or in underserved settings or populations. We will also evaluate outcomes for populations adversely affected by disparities due to socioeconomic disadvantage, racial or ethnic minority status, rural location, or other factors as defined by the National Institute on Minority Health and Health Disparities.[44]

II. Key Questions

The KQs for this systematic review are based on questions provided in the scope of work that accompanied the Request for Task Order. The questions were reviewed, reorganized, and refined by the systematic review project team and were further revised after input from the Agency for Healthcare and Quality (AHRQ) Task Order Officer (TOO), HRSA partner, and the Technical Expert Panel (TEP).

The review is defined by two overarching key questions, the first focusing on evidence about women's **reproductive health** and the second focusing on **interpersonal violence** as they relate to telehealth services.

Key Questions for the Systematic Review

Key Question 1: For conditions related to women's reproductive health (including family planning, contraception, and STI counseling):

a) What is the evidence of effectiveness of telehealth as a strategy for delivery of health care services for reproductive health?
b) What are patient preferences and patient choice in the context of telehealth utilization?
c) What is the effectiveness of patient engagement strategies for telehealth?
d) What is the impact of COVID-19 on the effectiveness of telehealth and patient engagement?
e) What are the barriers to and facilitators of telehealth for women's reproductive health in low-resources settings and populations?
f) What are the harms of telehealth for women's reproductive health?

Key Question 2: For interpersonal violence (including intimate partner violence and domestic violence):

a) What is the evidence of effectiveness of telehealth as a strategy for screening and interventions for interpersonal violence?
b) What are patient preferences and patient choice in the context of telehealth utilization?
c) What is the effectiveness of patient engagement strategies for telehealth?
d) What is the impact of COVID-19 on the effectiveness of telehealth and patient engagement?
e) What are the barriers to and facilitators of telehealth for screening and interventions for interpersonal violence in low-resources settings and populations?
f) What are the harms of telehealth for screening and interventions for interpersonal violence?

Contextual Question: What guidelines, recommendations or best practices have been developed for the design and use of telehealth and virtual health technologies for women for any clinical

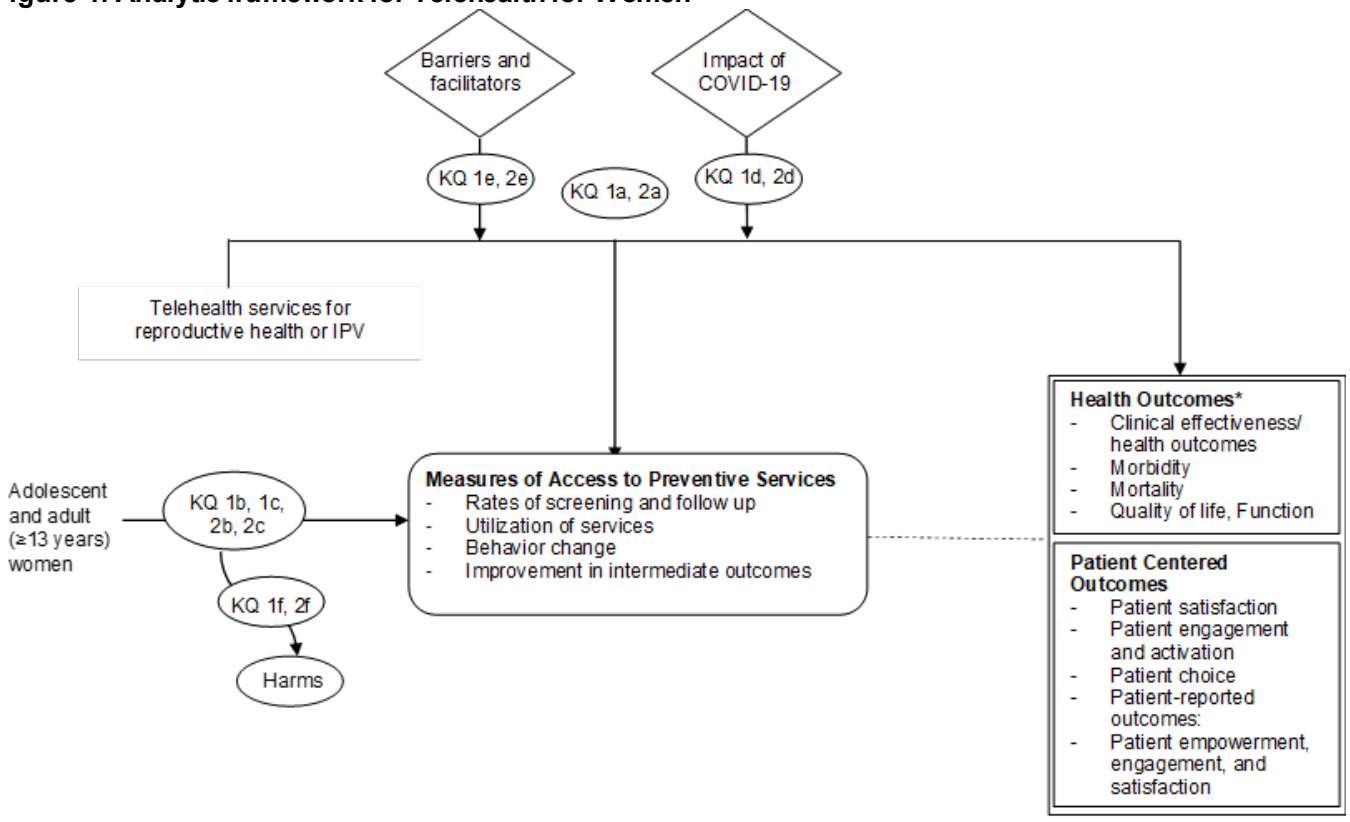
conditions, including on patient preferences, patient choice, patient engagement, and implementation in low-resource settings?

PICOTS

The populations, interventions, comparators, outcomes, and settings (PICOTS) of interest are described in **Tables 1 and 2**.

III. Analytic Framework

Figure 1. Analytic framework for Telehealth for Women



The analytic framework illustrates how the populations, interventions, and outcomes relate to the Key Questions (KQ) in the review.
[a] Outcomes vary by preventive service and are specified in Table 2.
Abbreviations: COVID-19 = novel coronavirus; IPV = interpersonal violence; KQ = key questions

IV. Methods

Criteria for Inclusion/Exclusion of Studies in the Review

The criteria for inclusion and exclusion of individual studies are based on the KQs and PICOTS described above and outlined in **Tables 1 and 2** below.

The term "telehealth" is used to define services that may include the use of information and telecommunications technology in health care delivery for a specific patient involving a clinician across distance or time, such as remote real-time clinical visits and remote monitoring. For this review we will refer to "telehealth" when considering interventions that use technology

to facilitate interactions at a distance between specific patients and clinicians. Interactions could occur over time (asynchronous) as well as over distance. We will consider telephone conversations, e-mail, and short message service (SMS) texts to be telehealth if they allow interaction between patient and clinician and could replace or supplement an in-person interaction. These interventions will not be included if they occur only in one direction or if they are not personalized (e.g., phone, email or text message notifications, generic messages sent to a group of patients).

For this review, the term *women* is used in a biological context, where applicable (e.g., individuals with potential for becoming pregnant without contraception), and can be applied to individuals of all gender identities, including cisgender, transgender, gender non-binary, or otherwise gender expansive for relevant services.

Reproductive health services considered for this review include family planning, contraception, and STI counseling. For this review, family planning services include preconception counseling (including birth spacing) and contraceptive care (screening, counseling, provision, and follow-up care). We will consider contraceptive care that can be delivered via telehealth by a broad range of health care workers (e.g., physicians, nurses, pharmacists, counselors). Telehealth services for interpersonal violence include screening, diagnosis, and treatment for intimate partner violence and domestic violence. **Tables 1 and 2** shows full eligibility criteria to identify studies that address the KQs.

Table 1. PICOTS and Corresponding Inclusion and Exclusion Criteria

	Include	Exclude
Population	Adolescent and adult women (age 13 years and older), including those who are pregnant, eligible for screening, counseling, or treatment for: KQ 1: Reproductive health services: (family planning, contraception, STI counseling) KQ 2: Interpersonal violence	• Men • Children under 13
Interventions	KQ1: Reproductive health services: • Family planning (preconception counseling and care) • Contraception (screening, counseling, provision, and follow-up care) • STI counseling KQ2: Interpersonal violence (intimate partner violence, domestic violence) KQ 1a, 1b, 1e, 1f, 2a, 2b, 2e, and 2f: Telehealth and virtual health, defined as: • Any two-way telehealth strategy intended to supplement or replace traditional in-person care (e.g. virtual visits, remote monitoring, mobile applications, at-home use of medical devices, use of a facilitator; use of patient-portal or electronic medical record) • Must include direct contact between a clinician or other provider and a patient or group of patients • Telehealth can be synchronous or asynchronous • Interventions may be comprised of a single telehealth strategy or may be delivered as telehealth packages, comprised of multiple telehealth strategies. KQ 1c, 1d, 2c, and 2d: Patient engagement strategies using telehealth and virtual health	• KQ1: Non-FDA-approved contraceptive devices, medications, and other methods that are not currently in clinical use in the U.S. as of 2021 • Telehealth clinician-to-clinician consults • Interventions without bidirectional communication between the patient and the health care team (e.g., one way email or text messages) • Peer-led interventions (no clinician involvement) • Maternity Care

	Include	Exclude
Comparators	• For effectiveness and harms (KQ 1a, 1c, 1d, 1f, 2a, 2c, 2d, 2f): Usual or in-person care or traditional care models (care provided without telehealth); telehealth + in-person care vs. in-person care alone (augmentation) • For barriers, facilitators, preferences (KQ 1b, 1e, 2b, 2e): Studies with or without comparison groups (i.e. patients' perceptions are based on comparisons of their own previous experiences) • KQ 1d and 2d: during COVID-19: Clinical services before and after COVID-19 pandemic	No comparison for effectiveness and harms
Outcomes	See Table 2.	• Outcomes not relevant to the KQs • Cost analyses • Patient knowledge/education
Clinical Setting	• Home, outpatient, primary care, or primary care-referable • Contact can be simultaneous (synchronous) or communicating across time (asynchronous) • Individuals providing care include a broad range of health care workers (physicians, nurses, pharmacists, counselors, etc.) • No geographic restriction: can be urban, suburban, or rural	Studies of health care services delivered outside of health care settings (e.g., social services, churches, schools, prisons)
Country Setting	Research conducted in the U.S. or in populations similar to U.S. populations, with services and interventions applicable to U.S. practice (i.e., countries with a United Nations HDI of "very high")	Countries with significantly different health care systems and fewer resources (e.g., low-income countries); not rated 'very high' on the 2018 HDI
Study types and designs	• RCTs • A best evidence approach will be used for considering inclusion of observational studies (non-RCT with some type of comparison): o Comparative studies including trial and observational studies, including prospective and retrospective cohort studies and before-after studies (i.e., natural experiments) o Qualitative studies that evaluate preferences, barriers/facilitators o Studies that specifically note that they were conducted during the COVID-19 pandemic (e.g. either specify they are assessing effects of COVID-19, or compare practices before and after March 2020) will be included. Studies with data that overlap this period will be considered only if results are stratified by pre-post pandemic.	Case reports, case series
Language	English language	Non-English

Abbreviations: COVID-19 = novel coronavirus; FDA = U.S. Food and Drug Administration; HDI = human development index rating; KQ = key question; RCT = randomized controlled trial; STI = sexually transmitted infection; US= United States

Table 2. Table of Outcomes

Category	Included outcomes
All conditions/services	KQ 1a and 2a: • Clinical effectiveness, patient health outcomes (see specific outcomes) • Quality of life, function KQ 1b, 1c, 1d, 2b, 2c, and 2d: Measures or descriptions of patient satisfaction, patient engagement and activation, patient choice KQ 1e and 2e: Measures or descriptions of barriers and facilitators in low-resource settings • Patient-reported outcomes: patient empowerment, engagement, and satisfaction • Measures of health care access, equity, and utilization o Rates of screening and follow up; adherence; no-shows o Utilization of services • KQ 1f and 2f: Harms (e.g. missed diagnosis, incorrect diagnosis, overdiagnosis, delay in treatment, increase in redundant testing or in low-value care, mental health outcomes, stress, anxiety, loss to follow up)
Family planning	• Desired pregnancy; unwanted/unintended pregnancy • Interpregnancy interval • Resource utilization
Contraception	• Reduced unintended or unwanted pregnancy and births • Increased contraceptive use/uptake • Change in contraceptive method • Reproductive health outcomes • Harms associated with contraceptive care (e.g., complications of contraceptive methods; delayed method start; unable to start method of choice; reproductive coercion)
STI counseling	• Health outcomes: o STI incidence (based on testing/biologic confirmation) o STI complications • Behavioral outcomes: o Changes in STI risk behaviors (e.g., multiple sexual partners, concurrent sexual partners, sexual partners with high STI risk, unprotected sexual intercourse or contact, sex while intoxicated with alcohol or other substances, sex in exchange for money or drugs) o Changes in protective behaviors (e.g., sexual abstinence; mutual monogamy; delayed initiation of intercourse or age of sexual debut; use of condoms, other barrier methods, or chemical barriers; or other changes in sexual behavior) • STI harms: o Health care avoidance o Psychological harms (e.g., anxiety, shame, guilt, stigma)
IPV	• Health outcomes o Reduced exposure to IPV as measured by a validated instrument (e.g., Community Composite Scale), self-report frequency of abuse (e.g., number of physical/sexual assaults), or discontinuation of an unsafe relationship o Physical morbidity caused by IPV, including acute physical trauma (e.g., fractures, dislocations) o Mental health morbidity caused by IPV, including acute mental morbidity (e.g., stress, nightmares) and chronic mental health conditions (e.g., posttraumatic stress disorder, anxiety, depression) o Sexual trauma, unintended pregnancy, pregnancy loss, and sexually transmitted infections o Health care utilization attributed to physical or mental effects of IPV (e.g., rates of emergency room visits); o Social isolation • Harms o Increased abuse or other forms of retaliation; and other reported harms of screening or identification

Abbreviations: IPV = interpersonal violence; KQ = key question; STI = sexually transmitted infections

Study Designs: We will include comparative studies of any design including comparative trials and observational studies. We will include observational cohort studies, as well as pre-post

designs (i.e., the comparison can be across time points). We will include qualitative studies that evaluate preferences, barriers/facilitators. For the key questions we will exclude descriptive studies with no outcome data or studies that include only data from one point in time (cross-sectional), although these may be considered for the contextual question. We will also exclude modeling studies or studies that use synthetic data. 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 also exclude commentaries, letters, and articles that describe telehealth systems or implementation strategies but do not assess impact.

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.

Literature Search Strategies to Identify Relevant Studies to Answer the Key Questions:
Literature Databases: Ovid MEDLINE®, CINAHL®, EMBASE, and Cochrane CENTRAL will be searched to capture both published and gray literature. The search strategies will be developed by a librarian with expertise in conducting searches for systematic reviews. Searches will be peer reviewed by a second librarian.

Search Strategy: The Ovid MEDLINE® search strategy is included in Appendix A. This will be refined or augmented as needed based on the results. Search, and triage results will be reviewed with the TEP and AHRQ TOO. Additional search strategies will be considered in consultation with these two groups if needed.

Publication Date Range: Searches will begin in July 1, 2016. This will capture studies of systems that rely on more current technology and will follow searches from a recent report that provided an evidence map of telehealth services for women (search end date December 2016).[45] We will review the studies included in the evidence map for consideration in this review and will include information on the dates the studies were conducted and the technologies used, as well the dates of publication.

Initial searches will be conducted through June 2021. These searches will be updated during the public comment period of the draft report to capture any new publications. Literature identified during the updated search will be assessed by following the same process of dual review as all other studies considered for inclusion in the report. If any pertinent new literature is identified for inclusion in the report, it will be incorporated before the final submission of the report.

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.

Gray Literature: Sources for gray (unpublished) literature will include reports produced by government agencies, health care provider organizations, or others. We will contact the federal government community of practice on telehealth, and other appropriate organizations including, but not limited to the American Telemedicine Association, The Society for Education and the Advancement of Research in Connected Health (SEARCH) and AcademyHealth to make initial

inquires, and we will also followup on any suggestions made by TEP members. Preprints will be monitored as a way to identify studies that may be published during the period between the draft and final report or inform our discussion of future research needs. However, data from preprints will not be included as evidence in accordance with National Institutes of Health (NIH) policy.

Hand Searching: Reference lists of included articles, selected excluded articles (e.g., narrative reviews), and systematic reviews will be reviewed for includable literature.

Contacting Authors: In the event that information regarding methods or results appears to be omitted from the published results of a study, or if we are aware of unpublished data, we will attempt to contact the authors to obtain additional information.

Process for Selecting Studies: Pre-established criteria as presented in Table 1 will be used to determine eligibility for inclusion and exclusion of abstracts in accordance with the AHRQ *Methods Guide for Effectiveness and Comparative Effectiveness Reviews.*[46] To ensure accuracy, all excluded abstracts will be dual reviewed. Full text for all citations deemed appropriate for inclusion by at least one of the reviewers will be retrieved. Each full-text article will be independently reviewed for eligibility by two team members, including any articles suggested by peer reviewers or that arise 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.

Data Abstraction and Data Management: After studies are deemed to meet inclusion criteria, data will be abstracted, such as: study design, year, setting, country, sample size, patient and providers types and characteristics (e.g., age, sex, race, reason for presentation, diagnosis, provider training/background/scope of practice and primary care or specialty type), intervention characteristics (e.g., mode of delivery, duration or frequency, function) and results relevant to each KQ as outlined in the previous PICOTS section. Data abstraction forms will be developed after full text review and the data to be included in evidence tables will be discussed with the AHRQ TOO and the TEP. All study data will be verified for accuracy and completeness by a second team member.

Risk of Bias of Individual Studies: Predefined criteria will be used to assess the risk of bias (also referred to as quality or internal validity) for each individual included study, using criteria appropriate for the study designs. 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*.[46] Studies will be rated as "low risk of bias," "medium risk of bias," or "high risk of bias."

Studies rated "low risk of bias" are considered to have the least risk of bias, and their results are generally considered valid. "Low risk of bias" studies include clear descriptions of the population, setting, interventions, and comparison groups; a valid method for allocation of patients to treatment; low dropout rates and clear reporting of dropouts; appropriate means for preventing bias; and appropriate measurement of outcomes.

Studies rated "medium risk of bias" are susceptible to some bias, though not enough to invalidate the results. These studies may not meet all the criteria for a rating of low risk of bias, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems. The "medium risk of bias" category is broad, and studies with this rating will vary in their strengths and weaknesses. The results of some medium risk of bias studies are likely to be valid, while others may be only possibly valid.

Studies rated "high risk of bias" have significant flaws that imply biases of various types that may invalidate the results. They have a serious or "fatal" flaw in design, analysis, or reporting; large amounts of missing information; discrepancies in reporting; or serious problems in the delivery of the intervention. In general, observational studies that do not perform adjustment for potential confounders will be assessed as "high risk of bias." This is because it is likely the results of these studies are at least as likely to reflect flaws in the study design as the true difference between the compared interventions. We will not exclude studies rated high risk of bias a priori, but high risk of bias studies will be considered to be less reliable than low or medium risk of bias studies when synthesizing the evidence, particularly if discrepancies between studies are present.

Each study evaluated will be independently reviewed for risk of bias by two team members. Any disagreements will be resolved by 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.

Applicability of Individual Studies: Applicability of individual studies will be considered according to the approach described in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[46] Information relevant for assessing applicability includes the number of patients randomized/eligible for inclusion in an observational study relative to the number of patients enrolled; or the number and diversity of settings or locations as well characteristics of the population, telehealth intervention or implementation strategy, and administrating personnel.

Data Synthesis: We will construct evidence tables identifying the study characteristics (as discussed above), results of interest, and risk of bias ratings for all included studies, and summary tables to highlight the main findings. We will review and highlight studies by using a hierarchy-of-evidence approach, where the best evidence is the focus of our synthesis for each key question.

Quantitative data will be summarized in summary tables and ranges and descriptive analysis and interpretation of the results will be provided. If sufficient data are available, meta-analyses will be conducted to summarize data and obtain more precise estimates for outcomes when studies are homogeneous enough to provide a meaningful combined estimate. 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 studies. When meta-analyses cannot be performed, our approach

will be to qualitatively synthesize by creating categories of results based primarily on the direction of the effect, whether there is statistical significance or not, with less emphasis on the magnitude of the effect (e.g., large difference in benefits, no difference in harms), reporting findings according to risk of bias ratings, and summarizing results across studies grouped by preventive service and/or telehealth function/modality.

For synthesis of qualitative data on barriers, facilitators, and patient preferences (KQ1b, e and KQ 2b, e), we will extract key statements from each study and categorize them according to theme and type of preventive service (family planning, contraception, STI counseling, IPV). Some issues may be common to all preventive services, while others may be unique to the service. For example, improved access to care and flexibility could be facilitators common to all preventive services, but concerns about safety may be a specific barrier for IPV telehealth screening. Main themes and frequencies of occurances across studies will be summarized in tables to determine patterns and interpretations. These results will be compared with results of quantitative studies reporting barriers, facilitators, and preferences as available to determine coherence of findings across all sources in the systematic review.

If sufficient data are available for any of the KQs, we will conduct an additional analysis of populations particularly affected by potential barriers to preventive care services and telemedicine. This analysis would focus on populations in geographically rural areas or underserved settings regardless of where the clinicians are located. For this analysis, rural is broadly defined by any commonly used or endorsed definition. In addition, health equity, access, utilization, and disparities will be analyzed if possible according to the PROGRESS-Plus Framework (place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, socioeconomic status and social capital, while the "plus" captures other characteristics that may indicate a disadvantage, such as age and disability).[47]

Grading the Strength of Evidence (SOE) for Major Comparisons and Outcomes: The strength of evidence (SOE) for each Key Question will be initially assessed by one researcher for each clinical outcome (see PICOTS). For KQ1a, c, d (effectiveness) we will use the approach described in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[46] To ensure reliability and validity of the evaluation, the body of evidence will be assessed for the following criteria as they are defined in the Methods Guide:

- 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)

KQs 1b, d, e and 2b, d, e are descriptive and a formal SOE assessment will not be conducted. We will prioritize reports of U.S. national or regional studies over local reports or data from other countries. We will summarize the strengths and limitations of the data collection and analyses 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.

The evidence for KQs 1b, d, e and 2b, d, e is likely to consist of studies that use qualitative methods (e.g., interviews, case studies, focus groups) as well as quantitative methods and the

studies may not be comparative. For these reasons the SOE approach planned for the other KQs is unlikely to be applicable. To address this, we will assess the fit of the GRADE-CERQual approach to our included studies for these questions.[49] If applicable to the body of literature, we will assess SOE based on the following domains from this framework:

- Methodological limitations
- Coherence
- Adequacy
- Relevance

For both approaches, the strength of evidence will be assigned an overall grade of high, moderate, low, or insufficient according to a four-level scale by evaluating and weighing the combined results of the included domains. The four levels are:

- 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—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—No evidence. Investigators are unable to estimate an effect, or have no confidence in the estimate of effect for this outcome. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

Assessing Applicability of Evidence Base: Applicability will be considered according to the approach described in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[46] We will use the PICOTS framework to consider the applicability of the evidence base for each key question, for example, examining the characteristics of the patient populations (e.g., clinical condition) and study setting. Variability in the studies may limit the ability to generalize the results to other populations and settings.

V. References

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VI. Definition of Terms

Abbreviation	Definition
ACA	Affordable Care Act
ACOG	American College of Obstetricians and Gynecologists
AHRQ	Agency for Health Research and Quality
CARES	Coronavirus Aid, Relief, and Economic Security
COVID-19	Novel Coronavirus Disease 2019
EPC	Evidence-based Practice Center
HRSA	Health Resources and Services Administration
IPV	Interpersonal violence
KQ	Key question
NIH	National Institutes of Health
PICOTS	Populations, interventions, comparators, outcomes, timing, and setting
SEADS	Supplemental Evidence and Data for Systematic review
SEARCH	Society for Education and the Advancement of Research in Connected Health

SMS	Short message service
SOE	Strength of evidence
STI	Sexually transmitted infection
TEP	Technical Expert Panel
TOO	Task Order Officer
WPSI	Women's Preventive Services Initiative

VII. Review of Key Questions

Key questions were refined by the Evidence-based Practice Center (EPC), then reviewed by Agency for Healthcare Research and Quality (AHRQ) staff and the HRSA partner to ensure they addressed the clinical questions driving the nomination of this topic. These reviews also aimed to make the key questions more explicit about the populations, interventions, comparisons, outcomes, treatment duration, settings, and study designs being considered.

VIII. 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, AHRQ, and HRSA 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.

IX. 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 preparing 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 3 months after 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 with any financial conflict of interest greater than $5,000 will be disqualified from peer review. Peer reviewers who disclose potential business or professional conflicts of interest can submit comments on draft reports through the public comment mechanism.

X. EPC Team Disclosures

EPC core team members have no financial conflicts of interest greater than $1,000 and any other relevant business or professional conflicts of interest. Direct financial conflicts of interest that cumulatively total more than $1,000 will usually disqualify an EPC core team investigator.

XI. Role of the Funder

This project is 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 the EPC response to 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 either the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

XII. Registration

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

Appendix A. Search Strategy

Database: Ovid MEDLINE(R) ALL 1946 to June 21, 2021

1 Telemedicine/

2 Mobile Applications/

3 (telemedicine or telemedical or telehealth or telephone or phone or (cell adj2 (phone or device)) or (cellular adj2 (phone or device)) or (text adj2 messag*) or "texting" or virtual or "remote monitor*" or "ehealth" or "e-health" or "mhealth" or "m-health" or (mobile adj2 health) or (digital adj2 health)).ti,ab,kf.

4 or/1-3

5 Women's Health/

6 exp Women/

7 Female/

8 (woman or women).ti,kf,sh.

9 (pregnant or pregnancy).ti,kf,sh.

10 or/5-9

11 Gynecology/

12 Family Planning Services/

13 exp Contraception/

14 exp Sexually Transmitted Diseases/

15 exp Domestic Violence/

16 exp Intimate Partner Violence/

17 ("reproductive health" or "family planning" or contraception or contraceptive or "sexually transmitted infection*" or "sexually transmitted disease*" or "STI*").ti,ab,kf.

18 (violent or violence or abuse or abused or abusive).ti,ab,kf.

19 or/11-18

20 4 and 10 and 19

21 (random* or control* or trial or systematic or "meta analysis" or "metaanalysis" or compar* or cohort or prospective or retrospective or "pre-post" or "before-after" or observational).ti,ab,kf,sh.

22 20 and 25