

Focus on Women's Health



OCTOBER 18, 2021

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HHS Continues Focus on Women's Health: AHRQ Calls for Data on Telehealth for Women

The Department of Health and Human Services ("HHS") is continuing its focus on women's health, this time through its research arm, the Agency for Healthcare Research and Quality ("AHRQ"). If the COVID-19 pandemic has shown us anything, it is that necessity is indeed the mother of invention. Over the past 18 months, telehealth and other digital health tools have emerged as important tools in both clinical care and clinical research—minimizing congestion in waiting rooms and keeping patients safe from potential exposure.

Significantly, much of the innovation has emerged in the women's health space. It has been reported that funding for women-focused digital health start-ups in 2020, fueled by the pandemic, rose 105% to \$418 million. The increase in attention and utilization of women-focused digital health products is no surprise, given that according to the Department of Labor, women make 80% of healthcare decisions in the U.S. and spend 29% more on healthcare than men.

Now, AHRQ is hoping to evaluate the potential benefits and risks of telehealth strategies focused on women. Specifically, in its recent [Federal Register notice](#), AHRQ called for data and information related to telehealth offerings focused on either reproductive health care for women or screening for interpersonal violence (including domestic and intimate partner violence).¹ [AHRQ previously solicited requests](#) for information concerning telehealth for routine antenatal care services.²

KEY QUESTIONS AND INCLUSION/ EXCLUSION CRITERIA

In its Federal Register notice, AHRQ requested information from clinical studies focused on two areas involving telehealth and women:

1. Reproductive health (including family planning, contraception, and sexually transmitted infection ("STI")): AHRQ specifically



requested information concerning the effectiveness of telehealth as a strategy for delivery of services for reproductive health, patient preferences and patient choice in the context of telehealth utilization, patient engagement strategies for telehealth, the impact of COVID-19 on the effectiveness of telehealth and patient engagement, barriers to and facilitators of telehealth for patients in low-resource areas, and any harms for women's reproductive health from telehealth.³

Inclusion Criteria: Adolescent and adult women 13 years and older, including pregnant women, who are eligible for screening counseling, and treatment for family planning, contraception, and STI. Any two-way health strategy intended to supplement or replace traditional in-person care is eligible, but the strategy must include direct contact between a clinician or other provider and a patient or group of patients. Telehealth may be synchronous or asynchronous and interventions may be comprised of a single or multiple telehealth strategies.⁴

Exclusion Criteria: Men and children under 13 years of age; non-FDA-approved contraceptive devices, medications, and other methods that are not currently in clinical use in the U.S.; clinician to clinician consults; interventions without bidirectional communication; peer-led interventions; maternity care; patient knowledge/education; studies of services delivered outside of health care settings; cost analyses; and studies derived from countries with significantly different health systems and fewer resources.⁵

2. **Interpersonal violence (including intimate partner violence and domestic violence):** AHRQ also requested information concerning the effectiveness of telehealth as a strategy for screening and interventions for interpersonal violence, patient preferences and patient choice in the context of telehealth utilization, the effectiveness of patient engagement strategies for telehealth, the impact of COVID-19 on the effectiveness of telehealth and patient engagement, barriers to and facilitators of telehealth for low-income women, and the harms of telehealth for screening and interventions for interpersonal violence.⁶

Inclusion Criteria: Adolescent and adult women 13 years and older, including pregnant women, who are eligible for screening counseling, and treatment for interpersonal (intimate partner and domestic) violence. Any two-way health strategy intended to supplement or replace traditional in-person care is eligible, but the strategy must include direct contact between a clinician or other provider and a patient or group of patients. Telehealth may be synchronous or asynchronous and interventions may be comprised of a single or multiple telehealth strategies.⁷

Exclusion Criteria: Men and children under 13 years of age, clinician to clinician consults, interventions without bidirectional communication, peer-led interventions, patient knowledge/education, studies of services delivered outside of health care settings, cost analyses, and studies derived from countries with significantly different health systems and fewer resources.⁸

CONCLUSION

We expect that AHRQ's collection of clinical data regarding the use and effectiveness of women-focused digital health tools in clinical research and patient care will pave the way for greater acceptance and utilization of these tools in medical product development and the marketplace. The data collection may also help to establish best practices and guidelines for use of telehealth that can help future companies design increasingly efficient and far-reaching clinical studies, and it may ultimately help improve access to improved care for women.



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¹ See HHS, Agency for Healthcare Research and Quality—Supplemental Evidence and Data Request on Telehealth for Women, 86 Fed. Reg. 56708 (Oct. 12, 2020), https://www.govinfo.gov/content/pkg/FR-2021-10-12/pdf/2021-22074.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=subscription+mailing+list.

² See HHS, Agency for Healthcare Research and Quality-- Supplemental Evidence and Data Request on Schedule of Visits and Use of Telemedicine for Routine Antenatal Care, 86 Fed. Reg. 47310, 47310, <https://www.govinfo.gov/content/pkg/FR-2021-08-24/pdf/2021-18125.pdf>.

³ See 86 Fed. Reg. at 56708 – 56709.

⁴ For the full list of inclusion criteria, please refer to the tables in the Federal Register notice. See *id.* at 56709 – 56710.

⁵ For the full list of exclusion criteria, please refer to the tables in the Federal Register notice. See *id.*

⁶ See 86 Fed. Reg. at 56708 – 56709.

⁷ For the full list of inclusion criteria, please refer to the tables in the Federal Register notice. See *id.* at 56709 – 56710.

⁸ For the full list of exclusion criteria, please refer to the tables in the Federal Register notice. See *id.*