



February 23, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, D.C., 20001

Comments submitted electronically via www.regulations.gov.

Re: Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (RIN 0955-AA13)

Secretary Kennedy:

The Society for Women's Health Research (SWHR) is pleased to offer comments in response to the U.S. Department of Health and Human Services (HHS) Request for Information on Accelerating the Adoption and Use of Artificial Intelligence (AI) as Part of Clinical Care.

Founded in 1990, SWHR is a national nonprofit dedicated to advancing women's health through science, policy, and education while promoting research on sex differences to optimize women's health. SWHR is guided by our goal to close the women's health gap. Women may live longer than men on average, but "women spend 25% more of their lives in debilitating health."¹ Furthermore, women spend \$15.4 billion more on out-of-pocket on health care annually – a disparity that is not exclusively due to costs related to maternity care² – and remain under researched and underprioritized across clinical studies. Women also account for 60% of the unpaid caregiving population, leading to both short and long-term health impacts.³ Taken together, these realities highlight the need for exploring innovative ways to approach health care not only for women, but for all Americans.

SWHR recognizes that AI holds tremendous, unprecedented promise in transforming the delivery of clinical care. From being used to improve diagnostic methods to helping identify optimal personalized medicines and treatments, AI applications have potential to advance the quality and reliability of medical research, improve the quality of clinical care, and alleviate patient burdens in navigating the health care system. For women in particular, AI could help us better understand the role of sex differences in disease progression and presentation, potentially serving as a tool to improve women's health across the lifespan. SWHR is excited to consider how emerging technologies, such as AI, could improve health care delivery

¹ World Economic Forum. *Closing the Women's Health Gap: A \$1 Trillion Opportunity to Improve Lives and Economies*.; 2024. Accessed February 13, 2026. <https://www.weforum.org/publications/closing-the-women-s-health-gap-a-1-trillion-opportunity-to-improve-lives-and-economies/>

² Deloitte. *Hiding in Plain Sight: The Health Care Gender Toll*.; 2023. Accessed February 13, 2026. <https://www.deloitte.com/us/en/Industries/life-sciences-health-care/articles/womens-health-equity-disparities.html>

³ Caputo, J., Pavalko, E. K., & Hardy, M. A. (2016). The Long-Term Effects of Caregiving on Women's Health and Mortality. *Journal of marriage and the family*, 78(5), 1382–1398. <https://doi.org/10.1111/jomf.12332>

across the country in a way that benefits women and communities and, ideally, help to close the women's health gap.

As HHS considers the use of AI in its approaches to regulation, reimbursement, and research and development, SWHR urges the agency to utilize AI as a supplementary tool, preserving human oversight and the ethical implementation of AI across its agencies. Importantly, any AI use must be guided by and rooted in existing evidence as it relates to sex and gender differences and how such factors influence health care delivery and outcomes. This stance was established in our [July 2025 comment](#) to the National Institutes of Health RFI NOT-OD-25-117, and we reiterate it in our comment here.

Below, we offer comments relevant to two key areas of inquiry posited by the RFI: areas of AI research that HHS should prioritize and challenges within health care that patients and caregivers may wish to see addressed by the adoption and use of AI in clinical care.

Prioritizing SABV and Gender Considerations

SWHR strongly urges that HHS center women's health considerations – including sex as a biological variable (SABV) and social and cultural determinants of health, including gender – into the regulation and application of AI across clinical use.

SABV is fundamental to scientific rigor, reliability, and reproducibility. Biological sex is associated with well-evidenced differences in genetics, physiology, endocrinology, and molecular signaling that influence health and disease processes. Males and females exhibit distinct patterns in metabolism, immune function, reproductive biology, neurobiology, cardiovascular physiology, and skeletal regulation, among other systems. These sex-based differences affect disease susceptibility, pathophysiology, clinical presentation, progression, and therapeutic response. Accordingly, integrating SABV into research design and analysis is fundamental to improving clinical care.

To illustrate the above, heart disease is one case where the role of SABV is evident. In heart disease, there are key differences in biology, hormones, and physiology, which impact heart disease progression and treatment response. For example, women's hearts tend to be smaller than men, making women more vulnerable to plaque development. Further, the protective qualities of estrogen can influence women's susceptibility to heart disease after undergoing menopause.⁴ These differences mean that women may present with different symptoms than men and therefore, may require a clinical approach that is mindful of how to recognize and treat symptoms.

Key biological sex differences are also evident in Alzheimer's disease, autoimmune diseases, and bone diseases, to name a few.

If AI models are trained predominantly on male-centered datasets, they may exhibit reduced sensitivity to sex-specific manifestations of disease in women, potentially leading to higher rates of false negatives and misdiagnosis. For example, sex differences in symptom presentation, biomarker profiles, and disease trajectories in cardiovascular disease may be under-recognized when training data lack adequate female representation. Similar risks extend to other conditions that disproportionately affect or present differently

⁴ Betai, D., Ahmed, A. S., Saxena, P., Rashid, H., Patel, H., Shahzadi, A., Mowo-Wale, A. G., & Nazir, Z. (2024). Gender Disparities in Cardiovascular Disease and Their Management: A Review. *Cureus*, 16(5), e59663. <https://doi.org/10.7759/cureus.59663>

in women. Failure to incorporate balanced and representative data may therefore exacerbate diagnostic disparities and compromise clinical accuracy across diverse patient populations.

In addition to biological sex, social context plays a significant role in shaping health outcomes. Cultural expectations, social roles, and lived experiences associated with being male or female influence risk exposure, access to care, health behaviors, and interactions within clinical settings.⁵ Because these influences evolve over time and can vary across cultural contexts, these dynamics should be accounted for alongside biological factors in clinical care.

In summation, systematic evaluation and use of preclinical and clinical research that is aided by AI can help identify whether biological and gender-related factors have been appropriately integrated, while also detecting gaps such as underrepresentation, mischaracterization of sex differences, or implicit gender bias. As such, this information can be utilized to inform more precise and patient-centered health care delivery.

Centering Needs of Patients and Caregivers in Adoption and Use of AI in Clinical Care

Biological sex differences, gender roles, and the risk of biased or incomplete datasets are all challenges that will need to be addressed in order for AI to improve the experiences of women in the clinical setting. One 2023 study evaluating the records of more than 200 million Americans with more than 112 chronic diseases found that "women experience significantly longer diagnostic delays compared to men."⁶ If AI systems could explicitly incorporate SABV and be trained on balanced datasets, it could reduce false negatives, minimize diagnostic delay, and better capture atypical presentations.

AI could also improve existing gender biases in care delivery. Gender norms may influence symptom reporting, pain assessment, and clinician interpretation, sometimes resulting in minimization or misattribution of women's symptoms, such as in the area of endometriosis. Endometriosis – a condition which endometrial tissue grows outside the uterus and can lead to irregular, heavy, and even painful menstruation; diarrhea or constipation; notable fatigue; and, for some, infertility – is under-researched and under-recognized in clinical care. A woman's reported pain might be overlooked or disregarded entirely by a provider. AI-driven audits of clinical data could help identify patterns of undertreatment, delayed referral, or differential workup, thereby supporting quality improvement and accountability.

Conclusion

In implementing a strategy to accelerate the adoption and use of AI in clinical care under HHS leadership, SWHR urges the department to prioritize research and clinical considerations with respect to sex and gender. Women account for more than half of the U.S. population and are responsible for 80% of health care and medical decisions made within families. Yet women bear an undeserved burden of disparities when it comes to disease prevalence, treatment, and access to quality and evidence-based clinical care. AI has the potential to bridge some of these gaps to improve not only the health of all women but the health of all Americans. However, AI's implementation must be measured and scrutinized to ensure that it relies on scientifically-sound evidence, and human oversight – especially in clinical application and care – must remain paramount.

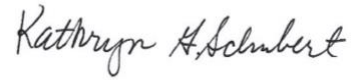
⁵ Mollborn, S., Lawrence, E. M., & Hummer, R. A. (2020). A gender framework for understanding health lifestyles. *Social science & medicine* (1982), 265, 113182. <https://doi.org/10.1016/j.socscimed.2020.113182>

⁶ Sun, T. Y., Hardin, J., Nieva, H. R., Natarajan, K., Cheng, R. F., Ryan, P., & Elhadad, N. (2023). Large-scale characterization of gender differences in diagnosis prevalence and time to diagnosis. *medRxiv : the preprint server for health sciences*, 2023.10.12.23296976. <https://doi.org/10.1101/2023.10.12.23296976>

Thank you for your time and consideration of these comments. We hope that HHS will take all necessary steps to ensure that women's unique health needs across lifespan are accounted for as it considers the application of these emergent technologies.

Please do not hesitate to reach out to me directly at Kathryn@swhr.org with any questions.

Sincerely,

A handwritten signature in cursive script that reads "Kathryn A. Schubert".

Kathryn Schubert, MPP, CAE
President and CEO
Society for Women's Health Research