

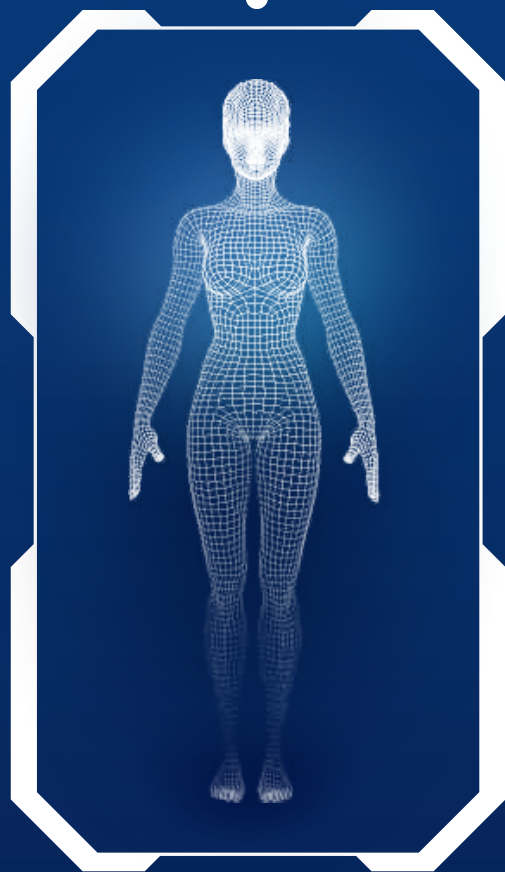


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NSF Engineering Research
Visioning Alliance

Transforming Women's Health Outcomes through Engineering

Executive Summary





Executive Summary

Women experience a range of health issues across the lifespan that affect how they live their daily lives and impact the health and resilience of society as a whole. Diseases and conditions that exclusively impact women represent a significant burden; hysterectomy and breast cancer are all too common, and the effects of menopause impose a costly health, financial, and career burden across families, workplaces, and communities. Other health challenges simply affect women differently or disproportionately, adding to the societal cost. Many of these conditions are challenging to study using traditional research techniques due to a complex mix of factors: timescales associated with chronic diseases can be far longer than those achievable in laboratory experiments; mimicking complex human hormonal cycling and the sexual development time course is challenging in cell- and animal-based experiments; and human reproductive tissues are often unavailable for experimentation due to ethical concerns.

Engineering may hold the key to overcoming these seemingly intractable women's health challenges, offering the potential to mitigate socio-cultural impacts and broaden health access. The engineering toolkit encompasses laboratory-based and computer-based methodologies, spanning fundamental research to clinical medicine.

The Engineering Research Visioning Alliance (ERVA), an initiative funded by the U.S. National Science Foundation, convened experts from across engineering, clinical medicine, technology enterprises, and startup companies to evaluate the landscape for novel solutions across the range of women's health conditions. Four engineering-based technology areas were examined:

Machine learning and artificial intelligence (AI), including applications in medical image interpretation and natural language processing;

***In silico* computational models**, including digital twins, multi-scale models, and systems-level biological modeling;

***In vitro* experimental approaches**, including tissue engineering, organoids, and microphysiological systems;

Patient-facing medical devices and therapeutics, including novel point-of-care diagnostics and wearables.

It was immediately apparent from the meeting that engineering research can play a key role in the women's health arena. Broad communication on how engineering research and collaborations contribute to health research and development will accelerate productive interactions and outcomes.

Key research opportunities that emerged from the event, considering a broad umbrella of women's health from *in utero* through post-menopause, are described in the table on the following page.

Key Engineering Research Priorities

<p>#1 Data, AI, and Medical Imaging Technologies</p>	<ul style="list-style-type: none"> • Methods and data standards to integrate patient-generated biometric data into clinician records and workflows • New data transport and mobile phone-based technologies to improve accuracy and enhance privacy and security (particularly for patient-generated data from wearables) • Multimodal AI-based image analysis for diagnosis and prediction • Imaging modalities that improve speed and accuracy of diagnosis
<p>#2 Computational Models (Fast models for real-time decision-making; slow models for disease prediction)</p>	<ul style="list-style-type: none"> • Novel biophysics and data-driven analysis models that can be tailored to a woman's complex physiology • New digital twin computational models based on interactive machine learning • Advanced modeling to disentangle the effects of aging from the effects of menopause
<p>#3 <i>In Vitro</i> Models</p>	<ul style="list-style-type: none"> • Organoids/microphysiological systems and biomimetic models that mimic female reproductive organs • Sex-specific models of organs and tissues (both healthy and diseased) • Engineered microphysiological systems to improve diagnosis and intervention • Personalized medicine tools for uterine fibroids and other conditions • Tissue engineering to create living devices that monitor health and enable study of a range of biological processes • <i>In vitro</i> digital tissue twins using a patient's own cells
<p>#4 Patient-facing Devices and Therapeutics</p>	<ul style="list-style-type: none"> • Wearables for at-home monitoring and diagnosis of many parameters (e.g., health broadly, eating disorders, osteoporosis, benign diseases of the reproductive system, menopause modeling, birth injuries) • Sensors sensitive to subtle physiological changes and signals spatially distributed within the body • Injectable biomaterials to regenerate damaged pelvic floor tissues • Other diagnostic devices for clinical deployment • Engineering research enabling personalized therapies to address various conditions and symptoms • Novel materials and biofabrication techniques for therapeutic use, as well as to create customizable breast implants • Novel drug delivery mechanisms, including next-generation drug delivery devices for birth control • Novel protective devices

In women's health, the key stakeholders are many—women themselves, along with researchers, health care clinicians, start-up companies, and the investors who fund them—and there are many opportunities for engineers to work collaboratively to advance the field in significant ways. According to a recent McKinsey report, bringing new engineering technologies to market and to the clinic to address large problems offers a \$1 trillion potential for societal benefit by 2040. Beyond the market opportunities, improving women's health outcomes holds the promise of reducing morbidity and mortality across a substantial portion of the U.S. population. There are intangible benefits as well; since a large fraction of the women's health gap affects working-age women, the effects are both economic and socioeconomic; closing the gap may help address the "leaky pipeline" for women seeking senior management positions.

ERVA workshop participants were uniformly positive about the potential for transformative engineering research, development, and implementation of technologies with unique contributions from engineering to advance the field of women's health. Keeping engineering research priorities as the focus of discussion, three cross-cutting threads emerged:

Thread 1: Addressing Challenges in Women's Health Across the Lifespan

- Undertake comprehensive engineering research that encompasses the breadth of related conditions that impact distinct life stages in women's health: prenatal to puberty, puberty to menopause, and beyond menopause.
- Design safe, secure, reliable, and trustworthy engineering tools for improving prevention, diagnosis, and treatment of women's health conditions.
- Treat the whole woman and her complex physiology instead of focusing on a single disease, tissue, or organ.
- Ensure health data is secure and interoperable so it captures events across the lifespan to improve clinical decision-making.
- Harness technology to assist women as they move between medical discipline silos for care.
- Consider dietary and environmental factors that are often dissociated from medical tests and treatment plans.
- Realize the potential for consumer device-based personalized medicine.

Thread 2: Engineering Women's Health Data, Ethics, Privacy, and Security

- To enable comprehensive research on women's health challenges, develop large multimodal datasets, incorporating Big Data across millions of women and including adequate female-specific sources.
- Require engineering research for human health to be sex-stratified and enforce sex as a biological variable in policies uniformly.
- Ensure data and image standardization, including uniform collection methodology, data storage field codes, privacy and security, and sufficient metadata to encourage safe sharing and re-use.
- Consider rural-urban and other disparities in engineering research for women's health.

Thread 3: Re-imagining Approaches to Women's Health Engineering Research Funding and Collaboration

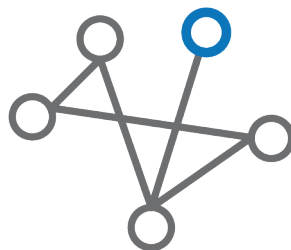
- Encourage and incentivize cooperation between academic researchers and companies in the emerging female technology (femtech) sector.
- Create consortia-based mechanisms for joint research that is inter-, multi-, and transdisciplinary, as these are necessary to improve effectiveness and impact.
- Establish dedicated research institutes for women's health and engineering.
- Create new education and training programs for women's health and engineering.

Taking Action

This report sets a vision for applying engineering research to overcome historic research barriers and create a forward path toward solutions that address women’s health challenges. Advances across engineering disciplines, from systems engineering to materials and biomechanics, to the application of AI and machine learning tools, hold the potential for a new engineering research framework that could positively impact the health of more than half the U.S. population. Success relies on overcoming challenges in how we integrate a longitudinal approach to women’s health; secure and standardize data collection and aggregation; and create incentives and mechanisms to leverage large interdisciplinary consortia that include the nascent female technology (femtech) industry as part of the foundational research enterprise.



In the near term, there is an urgent need to apply robust research standards regarding data and broad adoption of sex-specific research models, a critical step to enable computational modeling and training for AI algorithms. Beyond this, there are myriad targets for women’s health engineering research across the lifespan. This report underscores the urgent need for engineering research to create solutions addressing women’s health issues that have been historically under-researched. The full report provides specific directions for engineering researchers and funding bodies to pursue that have the potential to transform women’s health outcomes through engineering and unleash the vast opportunities to improve women’s lives and health.





NSF Engineering Research
Visioning Alliance

Our mission is to identify and develop bold and transformative new engineering research directions and to catalyze the engineering community's pursuit of innovative, high-impact research that benefits society.



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