National Strategy to Close the Women's Health Gap

An Investment in America

Vision: Mobilize Congress to make a $20 billion, 10-year strategic commitment to close the women's health gap.

This is the women's health moonshot.

Women comprise more than half the U.S. population, yet for decades their health needs across conditions and stages of life have been understudied and underserved. A comprehensive, congressionally directed framework for women's health offers a bipartisan needs-based path to better coordinate research, improve access to evidence-based care, and advance long-term prevention efforts. By advancing our understanding of women's health and translating that knowledge into clinical practice and public health action, Congress can help improve health outcomes for women, families, and communities while reducing long-term health care costs and strengthening the nation's economic productivity.

This framework provides a pathway and a vision:

- Women's health will be prioritized and integrated rather than overlooked and underfunded
- A complete, actionable evidence base will drive the next generation of discovery
- Regulatory policies will nurture sex-specific innovation and value women's health
- Health care professionals will have the evidence they need for more timely and accurate diagnoses for their patients
- Women will enter the health care system knowing more about their own biology and have access to the individualized treatments they need

Research and Innovation

Proposed Investment: $7 Billion

Robust investment and strengthened coordination across the federal research agencies will unlock new scientific discoveries to inform our understanding of sex differences and women's health.

- **Increase funding for women's health research across federal research agencies**
  Funding for women's health research should be increased across all federal research agencies, including NIH, VA, DoD, and the Advanced Research Projects Agency for Health. Increased funding should be paired with mechanisms to enable meaningful tracking of funding and outcomes.
- **Establish a Women's Health Research Interdisciplinary Fund**
  Establish a Women's Health Research Interdisciplinary Fund ("the Fund") at NIH to serve as a centralized funding mechanism to aid in the coordination and integration of women's health research across the agency. The Fund will support research related to progression of disease, screening, treatment, and prevention of diseases and conditions that uniquely, disproportionately, or differently affect women but currently lack adequate investment and research. Research will focus on a lifespan approach to women's health.
- **Establish national Women's Health Centers of Excellence**
  Establish a national network of Centers of Excellence to accelerate translation of women's health research into clinical care. The centers would be interdisciplinary, located across the country, and would include partnerships between research centers and community-based partners. They would serve as clinical trial hubs, advance implementation science to move research discoveries into practice, provide regional referral expertise, and serve as training sites for researchers and clinicians in women's health.

Regulatory Coordination and Modernization

Proposed Investment: $1 Billion

Accountability, transparency, and coordination of federal regulatory bodies will ensure that research design, drug and treatment approvals, and coverage and reimbursement decisions account for sex differences, integrating the health needs of American women in regulatory systems.

- **Improve coordination and collaboration across agencies**
  - Modernize and expand the HHS Coordinating Committee for Women's Health to ensure cross-agency collaboration. Institute an annual public meeting to enable public stakeholder engagement and create a pathway for federal agencies and stakeholders to collaborate and address sex differences and the needs of women's health to improve health outcomes.
  - Establish official liaisons across Institutes within the NIH and advance the visibility and accountability of existing internal coordinating committees and working groups across ICs.
- **Modernize pathways and policies to address sex differences and women's health needs**
  - HHS needs a pathway for regulatory bodies to collaborate, share information, and make recommendations that will address sex differences and the needs of women and women's health outcomes. This initiative should include, but is not limited to, clinical trials and research design; improvements in approval pathways; identification of and action to address gaps or needs in Medicare coverage; and engagement with private payers, hospital systems, and Medicaid programs to advance the health of women through improved regulatory pathways and better oversight.
  - Modernize the NIH system used to track NIH-funded projects to ensure accurate accounting of women's health research projects to enable a comprehensive understanding of investment in women's health, including evident areas of underinvestment.
  - Develop and implement publication standards that require authors to demonstrate how sex as a biological variable (SABV) was considered and incorporated throughout the research process, including study design, analysis, and reporting, or to provide a clear scientific justification when SABV is not relevant.
  - Develop an inclusion code for pregnant and lactating women to require investigators to include this population in NIH-funded clinical research unless a justified reason for exclusion exists, in accordance with the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

- **Address women's health coverage gaps and improve access to care**
  - Assess coverage gaps and differences between women and men to determine fair coverage and direct implementation of improvements for treatments, with an eye toward the fact that women have higher annual out-of-pocket costs and live 25% of their lives in poorer health than men.
  - Support and incentivize innovation in women's health coverage to ensure fair access to care.

Data and Evidence Infrastructure

Proposed Investment: $4 Billion

We cannot improve what we cannot measure. Silos must be broken down so that common data elements can be developed, existing data sets can be leveraged, and gaps can be better identified and closed.

- **Establish a public–private partnership for women's midlife health data**
  The partnership would focus on establishing a standardized process for safely collecting deidentified midlife health data and sharing, with a goal of achieving a true picture of what women are actively experiencing during midlife. The effort could leverage clinical data from the NIH and FDA, along with claims data from CMS, electronic health record data, and data from wearables.

- **Convene a public workshop to review women's health research data**
  NIH has recently undertaken efforts toward developing common data elements related to women's health. Recognizing the important data that exists from NIH-supported longitudinal studies, such as All of Us, the Study of Women's Health Across the Nation (SWAN Study), the Women's Health Initiative, and more, the Office of Research on Women's Health and the Office of Data Science Strategy should collaborate with relevant institutes, centers, and offices to review data that are currently available to…
    - Fill gaps in women's health research
    - Identify the best ways for NIH to curate and make the existing datasets widely available to the research community
    - Provide recommendations about future research opportunities and how to better support the women's health research data infrastructure

Bolstering the Women's Health Clinical and Research Workforce

Proposed Investment: $7 Billion

Women's health research has long suffered from a shortage of trained investigators, clinicians, and specialists who focus on the diseases, conditions, and biological factors that affect women uniquely or disproportionately. Without a robust and sustained workforce, even the best-funded research priorities stall and clinical gaps go unaddressed.

- **Create and expand pathways to support early- and mid-career investigators within the women's health research workforce**

  Augment existing NIH programs and create new ways to support career pathways and provide mentorship opportunities for scientists through all stages of the careers of women's health researchers. To develop and support the research workforce…

  - Create a new subcategory for investigators conducting research in women's health or sex differences for loan repayment
  - Create new and expand existing early-career grant mechanisms that specifically support growing and developing the women's health research workforce
  - Create new and expand existing mid-career investigator awards to support and promote the midcareer women's health research workforce
  - Provide mentorship support
  - Expand the Early-Career Reviewer program to enroll qualified individuals from underrepresented areas of expertise in women's health and include women's health, sex differences, and sex as a biological variable training for participants
  - Increase funding for the following programs at NIH:
    - **Building Interdisciplinary Research Careers in Women's Health (BIRCWH)**
    - **Specialized Centers of Research Excellence (SCORE)**
    - **Women's Reproductive Health Research (WRHR)**
    - **Research Scientist Development Program (RSDP)**

- **Establish a women's health clinical workforce loan repayment program**
  Model a new program on the National Health Service Corps that will target general ob-gyns and ob-gyn subspecialties, reproductive endocrinology, menopause specialists, and autoimmune specialists. The priority will be to support growing the workforce in rural and underserved areas and academic–community hybrid roles.
- **Support a Women's Health Centers of Excellence training pipeline**
  Direct funding to support fellowships, interdisciplinary training, and mid-career training/specialization at these centers across the country and support training modules on the diseases and conditions that are unique to or occur disproportionately or differently in women.

Public Awareness and Education

Proposed Investment: $1 Billion

Public awareness and health literacy are not merely complements to scientific investment; they are essential to ensuring that women can access, understand, and benefit from advances in research, prevention, diagnosis, and treatment. National public awareness and education campaigns will meet women where they are—to deliver clear, actionable information about the health conditions, life stages, screenings, and research opportunities that matter most to them—and they will support health care professionals in the clinic translating research findings into practice.

- **Plan and launch national women's health campaigns**
  Establish a series of national campaigns focused on women's health, using a combination of digital and traditional media tactics. Campaigns should raise awareness about key women's health issue areas to increase public knowledge, ultimately improving health and quality of life outcomes for women across the country. Campaigns must be created in consultation with members of the public and patient engagement organizations and representatives from industry, relevant medical societies, and organizations with subject matter expertise. They may involve…
    - Education on specific diseases, conditions and life stages that disproportionately, differently, or exclusively impact women
    - Education on the importance of women's health research, particularly the value of participating in research, including during pregnancy and lactation
    - Information about key health care screenings and preventive care
    - Medicare and health insurance information specifically geared toward what women need to know