Women's Health Stakeholder Recommendations
White House Initiative on Women's Health Research

The undersigned group of stakeholders in the women's health space is pleased to provide consensus recommendations to the White House Gender Policy Council for consideration by the White House Initiative on Women's Health Research. As a group we support continued dedicated research and development of technologies and procedures to address women's health conditions, to include those conditions that are experienced only by women, those that disproportionately impact women, and those that may impact women differently than men, and to raise awareness and reduce inequities related to the need to diagnose, include in research, and improve health outcomes for women.

Recommendations

1) Empower women's engagement in health research through amplifying their voices.

- Host and/or sponsor "Demo Day" events to highlight women's health innovations that have been developed and ongoing research into women's health conditions.
- Engage the attention and interest of policymakers, care providers, and the general public through deployment of Public Health Announcements (PHAs) that target women's health issues. Federal agencies can use PHAs to provide education or focus messaging on specific health issues (e.g., cardiovascular disease, menopause, mental health, autoimmune conditions).

- Conduct PHAs that address the need to understand and recognize differences in symptoms experienced by women for disease states and conditions that may present differently in men.
- Require education and training for health care providers and those training to become health care providers, emergency response personnel, and those engaged in training these individuals on health issues that specifically impact women or that differently affect women, including symptoms common to women.
- Fund or support PHAs and media campaigns to educate women on the importance of participation in clinical trials for lifesaving and innovative treatments, including emphasizing that trial participation provides access to the gold standard of care and can help increase the number of women participating in clinical research.
    - Research protocols and training should emphasize that data collected during research is private and protected to address concerns of women who are reluctant to share their personal data.
    - Support education on appropriate conduct of clinical research, to include protection of sensitive and confidential health data.
- Conduct PHAs that address the need to hear, believe, and address women's health concerns.
    - Educate researchers and caregivers on treating all women and all patients in accordance with treatment guidelines and reevaluating guidelines to ensure they are equitable.

- Products should be developed with empathy in mind.

2) Increase understanding of women's health and existing care gaps that impact the survival, well-being, and quality of life for women.

    - Promote research into the leading causes of morbidity and mortality for women to garner increased development of treatments and/or prevention strategies.
    - Improve health outcomes through advancing research for women with specific health conditions to include sex and gender differences as well as on diseases that impact women over the course of their lives.
        - We support the recommendations included in the President's budget to examine a range of conditions, even beyond those articulated, and recommend that adequate funding be allocated to facilitate research into these conditions and subsequent product development to address them.
    - The final report of the National Academies of Sciences, Engineering, and Medicine (NASEM) Committee on the Assessment of NIH Research on Women's Health could be a helpful guiding document for the Administration to determine which areas within women's health are most in need of dedicated research investments.

3) Increase investment in women's health research to include increased diversity, consistent study funding, and improved technology/procedure payment.

- Organizations (e.g., private foundations, investors) and agencies that fund research need to incentivize the equitable inclusion of women in studies through earmarked funds for women's health research.
- There should be increased efforts to engage more diverse populations in women's research. Diversity encompasses many characteristics, including but not limited to race, ethnicity, socioeconomic status, geography, age, and ability (e.g., physical, mental, and intellectual). Engagement with a broader range of care facilities, including those serving underrepresented and large populations of minority and low socioeconomic status (SES) patients (e.g., disproportionate share facilities, historically Black colleges and universities (HBCU) medical schools and their affiliated hospitals, health professional schools, and facilities in rural areas) can contribute to better representation of all women in research.
    - Institutions that service underrepresented populations and communities need the infrastructure to conduct research; additional support may further enable them to serve as a research site.
    - Efforts could include more funding to establish and support the clinical research infrastructure within hospitals and medical schools that treat these patients, including those affiliated with HBCUs, to include the ability to conduct research and/or to serve as secondary sites to augment research being conducted at other locations.
    - Data from this research should be disaggregated to assess the design and effectiveness/impact of this and future research.
    - Support the education of health care providers, clinical and physician specialty societies, and of Institutional Review Boards on the importance of recruitment of diverse populations including women in clinical trials.
- Improve and/or accelerate the process by which devices navigate Federal agency approval processes.
- Willingness to engage in research is in part predicated upon the ability to gain reimbursement and coverage once a product goes to market. Establishing more predictability in how women's health products will be cleared/approved, covered, and paid will influence product development.
    - If new innovative women's health technologies, once FDA-approved, are not reimbursed at appropriate levels, providers and/or hospitals are not incentivized to use them, and patients will not have access to them.
    - Improving the reimbursement landscape to make it easier to get coverage and payment for women's health technologies will encourage increased innovation in this space.
- Increase communication and collaboration across the Offices of Women's Health within the various Federal agencies to promote improved research practices, policies, and alignment, where applicable.
    - Prioritize and publicize the information coming out of these offices.

        - Encourage these offices to have more direct communication and authority within their respective agency's approving offices to ensure understanding of the need to advance women's health issues with other agencies, divisions, and policymakers.
    - Agencies such as the National Institutes of Health, National Science Foundation, and Department of Defense fund the development of technology through Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program grants. These agencies could allocate some portion of existing funds via these grant programs for the development of technologies to address women's health needs —thereby spurring innovation without the need for new money.
        - If these technologies, once commercialized, are found to be useful in addressing the condition for which they were developed, the agency should coordinate with other Federal agencies (e.g., Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), etc.) to undertake efforts to expand technology access to more women. A mechanism should exist for sharing information regarding the technologies developed through SBIR/STTR programs, and their potential for more widespread use.
        - Agencies funding the development of women's health products via SBIR/STTR grants should regularly communicate to better understand the range of technologies and to facilitate access to and dissemination of those found to be effective.
        - Support for appropriations to conduct women's health research is needed (e.g., adding money to the Defense Appropriations bill within the Congressionally Directed Military Research Program (CDMRP) Women's Health Research Program.
    - Women often face barriers in seeking treatment, and participating in clinical trials, including missing work, childcare, and transportation costs. This is especially true for women identified as having low SES and/or those living in rural areas. Consideration should be given to supporting policies that enable women to have leave from work to participate in research.
    - Make remote and telehealth payment permanent and create payment for Primary Care Providers and others to discuss clinical trial participation and to perform supplemental care to support clinical research.
    - As was proven during the COVID-19 pandemic, remote visits and telehealth provided patients with a more convenient method of interacting with their providers and avoiding missed appointments.
        - All payers, including Medicare and Medicaid, should continue to reimburse providers for providing care remotely, when appropriate.
        - Digital, remote, and telehealth technologies can also accommodate collection of data from persons enrolled in clinical research. However, the care providers (e.g., physicians, physician assistants, nurses, nurse practitioners, other allied health professionals) should be reimbursed for this data collection.
        - Support passage of the Connect for Health Act (S. 2016).

- Medicaid should be urged to support access to medical device clinical trials to mitigate hurdles/barriers to participation in clinical trials by their insured populations. Medicaid has already done this for drugs; the same policy, for parity, should apply to devices.
- To address shortages in the diversity of and the number of trained researchers consideration should be given to engaging other types of care providers (e.g., nurses, nurse practitioners, physician assistants) in research and allowing some aspects of research to be conducted in alternate environments (i.e., decentralized clinical trials) which could enable increased participation by women who may be limited in their ability to routinely seek care at a research site that may not be conveniently accessed.

4) Improve the research environment for women's health technologies.

- Support the establishment of programs that encourage greater numbers of women to pursue careers in clinical practice and research.
- Deficits in the volume and types of women's health research may, in part, be influenced by an absence of knowledge regarding where research into diseases and conditions that impact women is needed. Support for research into outcome gaps that can be used to undergird development of treatments and technologies for women's health conditions is an important first step in advancing this knowledge base. The Federal government could identify women's health areas where there are existing gaps in the pre-clinical research. This will assist in identifying areas where new/additional research is needed.
  - The Department of Health and Human Services and/or other Federal entities can work with and train community-based organizations (e.g., Community Health Centers, Federally Qualified Health Centers, faith-based organizations, social service programs, patient advocate groups, disease specific research organizations, and non-profit entities) to serve as a resource in helping to increase diverse patient participation in clinical research.
- Historically, women have been excluded from some research because of safety concerns. This is particularly true at certain stages of life, such as during pregnancy or post-partum, when lactating, and during menopause. The exclusion of these women from clinical trials ignores the need to determine whether products are as safe and effective for a range of women patients relative to men, or for women at varied stages of life. Clinical investigators should include a diverse range of women in research, across their lifespans, to understand the impact of new products, absent a compelling reason to exclude them. Women from varied racial and ethnic backgrounds should be included in Investigational Device Exemptions (IDEs) and Non-Significant Risk (NSR) studies to be more representative of the general population. This is especially critical for conditions that are more prevalent in younger women, as younger generations tend to be more racially and ethnically diverse than older generations.[1] To facilitate inclusion of diverse women in clinical research:

[1] Early Benchmarks Show 'Post-Millennials' on Track to Be Most Diverse, Best-Educated Generation Yet, https://www.pewresearch.org/social-trends/2018/11/15/early-benchmarks-show-post-millennials-on-track-to-be-most-diverse-best-educated-generation-yet/ (Pew Research Center; Richard Fry, Kim Parker (November 15, 2018)).

        - Encourage technology developers and the FDA to provide a clear and compelling rationale for clinical trial inclusion/exclusion criteria for women.
        - FDA should develop guidance to assist device sponsors in understanding the criteria FDA will use when reviewing IDEs vis a vis inclusion/exclusion criteria for women at all life stages. FDA should also develop guidance for Institutional Review Boards (IRBs) for their review of IDEs and of NSR studies vis a vis inclusion/exclusion criteria for women at different life stages, including pregnancy and postpartum.
        - Once guidance has been finalized, FDA should train reviewers on the recommended inclusion/exclusion criteria vis a vis women at all life stages. FDA should also develop and share guidance for IRBs on this topic.
    - Improve the ability of organizations/companies/persons conducting research to accommodate the inclusion of women by clarifying statutory and regulatory requirements governing the ability to obtain reimbursement and/or cover participation related expenses.
        - Clarifying Stark (42 U.S. Code § 1395nn) and Anti-Kickback Statute (AKS) (42 U.S.C. § 1320a-7b) requirements
            - Women bear a disproportionate share of household and familial responsibilities and the ability to appropriately compensate them for participation in clinical research could assist in improved recruitment and retention rates.
            - Lack of clarity regarding appropriate levels of compensation and/or accommodations that can be offered to trial participants compromises the ability to recruit and retain a diverse pool of subjects. Given the costs associated with participation (e.g., time missed from work, transportation, parking, childcare, etc.) it is important to permit payment of a reasonable amount that could help offset some of these costs.
        - The Secretary's Advisory Committee on Human Research Protections (SACHRP) has responsibility for recommending changes to the human subject guidance and provides expert advice and recommendations to the Secretary of HHS on issues pertaining to the protection of human subjects in research. Health and Human Services should work with the SACHRP to modernize human subject protection guidance and regulations to reflect current views on payments to human subjects.
            - Current remuneration strategies do not adequately motivate people from different race and ethnic groups to participate in clinical research and concerns about paying people to participate in trials are outdated and unsupported by evidence.[2]

[2] See *A Framework for Ethical Payment to Research Participants* (New England Journal of Medicine, Volume 378; Number 8 February 22, 2018, Pages: 766-771).

- Improving clinical trial participation numbers requires an understanding of the reasons women agree to join and/or remain in clinical trials (or not). A government or other study of this topic could help researchers and others better understand these decisions.