Women’s Health Conference 2021

Janine Austin Clayton, MD, FARVO
NIH Associate Director for Research on Women’s Health
Director, Office of Research on Women's Health
National Institutes of Health

October 20, 2021 – Director’s Welcome and Opening
<table>
<thead>
<tr>
<th>Era</th>
<th>Movements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1960s – 1970s</td>
<td><strong>Civil Rights Movement</strong>, <strong>Women’s Rights Movement</strong>, <strong>Women’s Health Movement</strong></td>
</tr>
<tr>
<td>1970s</td>
<td><strong>NIH &amp; Scientific Community</strong></td>
</tr>
<tr>
<td>1980s</td>
<td><strong>Congress</strong></td>
</tr>
<tr>
<td>1990s</td>
<td><strong>ORWH</strong></td>
</tr>
</tbody>
</table>
Unidimensional Research Created Knowledge Gaps

Default human model was 70-kg male
- Fundamental biology assumed to include only shared molecular, biochemical and physiologic characteristics
- Protectionism, paternalism, menstrual cycle

Preponderant use of male animals in preclinical research

Unidimensional research: Yet knowledge generated applied to women; meds prescribed to women

NIH & Congress require inclusion of women, others in clinical trials
- In 1993 the NIH Revitalization Act directed the establishment of guidelines for the inclusion of women and minorities in clinical research
- In 2016, the 21st Century Cures Act:
  - Required NIH-defined applicable phase III CTs to report results disaggregated by sex/gender, race, and ethnicity into ClinicalTrials.gov
  - Implemented NIH Policy on Sex as a Biological Variable (SABV) “expects that [SABV] will be factored into research designs, analyses, and reporting in vertebrate animal and human studies”.
- In 2017, NIH’s Research, Condition, and Disease Categorization reports publish inclusion data by sex/gender, race, and ethnicity
2021-2025 NIH-Wide Strategic Plan recognizes women’s health

This new plan continues to advance the vision for biomedical research direction, capacity, and stewardship through five cross-cutting themes:

- Improving Minority Health and Reducing Health Disparities
- Enhancing Women’s Health
- Addressing Public Health Challenges Across the Lifespan
- Promoting Collaborative Science
- Leveraging Data Science for Biomedical Discovery

Broad Input Through Paths That Converge Along the Way

Public Stakeholders

ACRWH WHC Working Group

Form, Guide, and Participate

Plan, Lead, Manage, and Host

Inform the development of conference report

Data Harmonization
Maternal Morbidity and Mortality
Cervical Cancer
Chronic Debilitating Conditions

CCRWH WHC Planning Comm.

ORWH

ICOs & HHS SMEs

Women’s Health Conference/ACRWH Meeting

Conference Report (Dec 2021)
Incorporating sex and gender across the research continuum advances rigor, discovery, innovation, and equity
Multidimensional Framework represents intersection of factors affecting the health of women

HEALTH OF WOMEN ACROSS THE LIFE

Women in Context – **External** Factors
Such as *social determinants of health* including *gender*, environment, & policies

Preconception  
*In Utero*  
Childhood  
Adolescence  
Adulthood

Biological Perspective – **Internal** Factors
such as *sex* influences at genetic, molecular, cellular, & physiological levels
An Integrated Life Course Perspective is Required to Understand the Health of Women
Seize this Moment to Advance Health of Women

• How do we move beyond policy and programs to drive fundamental change?
• What checks and balances need to be built into the research ecosystem?
• How can we incentivize cross sector innovation to drive discovery?
• Which part are you going to play?