Perspectives from HHS Offices and Programs on Women’s Health: The NIH Perspective on Research

IOM Committee on Women’s Health Research
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WOMEN, RESEARCH & HEALTH CARE IN THE 21ST CENTURY

Advocacy Demand
(Inclusion of women in clinical research)

Attention of Women in Congress

Establishment of Federal Government Attention to Women’s Health & Scientific Design of Research
(To address women’s health issues & Sex/Gender factors in health and disease)
The Office of Research on Women’s Health (ORWH), established in September 1990 within the Office of the Director, NIH, (a) advises the NIH Director and staff on matters relating to research on women’s health; (b) strengthens and enhances research related to diseases, disorders, and conditions that affect women; (c) ensures that research conducted and supported by NIH adequately addresses issues regarding women’s health; (d) ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH; (e) develops opportunities for and supports recruitment, retention, re-entry, and advancement of women in biomedical careers; and (f) supports research on women’s health issues.
Women’s Health Research, Care & Health Leadership:

Benchmarks of the Continuum

- Expanded Concepts of Women’s Health (Lifespan)
- Male/Female or Sex/Gender Comparisons
- Health Disparities/Differences Among Populations
- Interdisciplinary Research & Health Care
- Women’s Roles in Health Research, Health Policy, and Health & Science Careers & Men and Women as Women’s Health Researchers
Major Areas for Discussion

I. Inclusion of women and minorities in clinical research
II. Research (women’s health & sex/gender emphasis)
III. Examples of progress
IV. Examples of NIH communication tools
V. Strategic planning for updated research agenda
NIH REVITALIZATION ACT OF 1993  
(PL 103-43)  
NIH Guidelines on Inclusion

NIH must:

- Ensure that women and members of minority groups and their subpopulations are included in all human subject research;
- For Phase III clinical trials, ensure that women and minorities and their subpopulations must be included such that valid analysis of differences in intervention effect can be accomplished;
- Not allow cost as an acceptable reason for excluding these groups; and
- Initiate programs and support for outreach efforts to recruit these groups into clinical studies.

It is the policy of NIH that women and members of minority groups ... must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes...that inclusion is inappropriate with respect to the health of the subjects or the purposes of the research...

Federal Register March 1994

Fiscal Year Data Reported

- Total No. of Participants
- Total No. of Female Participants
- Total No. of Male Participants

17 fold increase
19 fold increase
15 fold increase
ORWH Publications on the Inclusion of Women and Minorities as Subjects in Clinical Research

Updated guidelines and information can be found at: http://orwh.od.nih.gov/inclusion.html
Complying with the NIH Inclusion Policy

Remaining issues include:

- Law/Policy does **not** allow for exclusions to implementation, i.e., for foreign populations, etc., and issues related to OMB categories of race/ethnicity

- Continuing to emphasize importance of analyses by sex/gender

- Publication of sex/gender results in scientific journals

- Recruitment & retention of diverse populations
Online Course:
http://sexandgendercourse.od.nih.gov

- Developed by the NIH and FDA to provide a basic scientific understanding of the major physiological sex differences, the influence of these differences on health, and the policy, research and health care implications
- Online course with six 30-40 minute lessons
- Self-paced with quizzes to measure mastery
- Up to four AMA PRA Category I Credits™ can be awarded for successful completion
The requirement that the SCOR necessarily include both basic science and clinical (interdisciplinary) projects should advance scientific discoveries out of the lab and into a clinical environment (administered through NIAMS).
SCORs FY 2008
11 ORWH Specialized Centers of
Research on Sex and Gender Factors
Affecting Women’s Health

CURRENT TOPICS of RESEARCH INTEREST

- Substance Abuse
- Pain (IBS and IC)
- Urinary Tract
- Reproductive Issues
- Depression
- Osteoporosis
Advancing Novel Science in Women’s Health Research (ANSWHR)

ORWH-developed, new research program that utilizes R21 and R03 grant mechanisms for 2 years of funding (Investigator-initiated, small grants program)

ORWH and its NIH scientific partners are interested in encouraging extramural investigators to undertake new interdisciplinary research to advance studies on how sex and gender factors affect women's health

Two PAs active through FY2010

21 IC partners, plus OBSSR and ODS

Promotes innovative WHR & sex/gender analysis

First round of awards made in July, 2008
Women’s Health and the Research Agenda for the 21st Century

Priorities for 2008
Revised research agenda, the result of collaboration among scientists, health care providers, advocates, public health and policy decision-makers and the wider health community, but kept relevant yearly…
Women’s Health Research Priorities

‘The broad concept of what constitutes women's health has led to the recognition that research priorities in women's health must be comprehensive and interdisciplinary and should include not only clinical studies but also the full spectrum of research, from molecular and genetic studies to those of prevention, behavior, outcomes of interventions, and clinical translation of newly proven hypotheses.’

Pinn, JAMA, 2005
Women’s Health Research Priorities
2008 Overarching Themes

- Lifespan
- Sex/Gender Determinants
- Health Disparities/Differences and Diversity
- Interdisciplinary Research
Women’s Health Research Priorities, 2008
Areas of Research Interest

- **Methodological Advances:** statistical analysis methodology that addresses ethical and study design issues specific to studies of women/females in basic & clinical research; develop new methodologies for animal model studies of diseases and normal development of women, including use of female animals

- **Education and Career Development of Women in Science:** explore factors that affect the selection and advancement of women’s careers

- **Diseases and Conditions that Affect Women:** including, but not limited to, metabolic, inflammatory, endocrine, autoimmune, gastrointestinal, liver, urologic, ophthalmic, oral, reproductive, musculoskeletal, neurological, psychiatric, addictive, and cardiovascular diseases.

- **Quality of Life:** Develop approaches to management of disease and promotion of wellness that are directed at women and their unique issues.
NIH Research Efforts on Women’s Health

• Approximately $3.5 billion spent each year (FY 2005 and FY 2006) on sex/gender-specific research related to women’s health.

• More than $22.5 billion spent on research benefiting both women and men as either basic or laboratory research or clinical studies that included both women and men.
NIH Funding Mechanisms Employed by ORWH

- RFAs (SCOR-P50s, BIRCWH-K12s),
  - co-sponsored with ICs
- PAs (ANSWHR-R21s, R03s)
  - co-sponsored with ICs
- Investigator-initiated research mechanisms
  - submitted by ICs (R01s, R21s, R03s), cooperative agreements (U01s, U10s)
- Contracts - such as for OAI, Sjogren’s syndrome
- REAP- submissions from the ICs
- Conference grants (R13s, U13s)
- Reentry supplements
In conclusion, the Evaluation of ORWH’s First Ten Years was a comprehensive assessment of the progress that was made from FY 1991 to FY 2000 in achieving ORWH’s intermediate and long-term goals. The findings were generally positive and quite remarkable for a relatively small program office. The extensive amount of data collected for the evaluation will serve as a valuable resource in tracking ORWH’s future progress. In addition to contributing to program accountability, the study included the development of new analytical methodologies designed to be useful to ORWH as well as other IC administrators and researchers interested in assessing changes in an NIH research portfolio over a specified time period. It is hoped that all those who manage, fund, or provide other support for projects involving women’s health will be encouraged by the evaluation results and find them helpful in developing and improving a variety of interdisciplinary research programs.
WOMEN’S HEALTH RESEARCH:

Examples of a few current areas of focus
Cervical Cancer Vaccine

- **June 8, 2006: FDA approved use of Gardasil®**
  - Based on laboratory research and technology developed at the National Cancer Institute (NCI).
  - Can potentially save more than 5,000 U.S. women’s lives each year.
    - Targets two HPV types (HPV-16 and HPV-18)
      - Responsible for approx. 70 percent of cases worldwide.
    - Two other HPV types (HPV-6 and HPV-11) cause approx. 90 percent of the cases of genital warts.
The WHI cohort is still being followed:

- Combined E+P use after 5 yrs about doubles subsequent annual breast cancer risk

- The increased breast cancers seen with combined E+P use declines markedly after discontinuation and is unrelated to mammography utilization change

- These findings support the hypothesis that the recent reduction in breast cancer incidence is predominantly related to a decrease in combined E+P use
Diabetes Prevention Program (DPP)

• DPP: RCT comparing intensive lifestyle interventions vs. metformin
  – Both reduced the incidence of Type 2 diabetes, with lifestyle interventions being the most effective

• National Diabetes Education Program (a joint program of NIH and CDC, along with 200 other organizations) incorporated DPP results through Small Steps/Big Rewards, and is directed at public awareness, education for consumers and health professionals, and is being expanded internationally
Diabetes mellitus reaches epidemic proportions in the US

- Diabetes Prevention Project (DPP)- RCT demonstrated superior efficacy of lifestyle interventions over oral hypoglycemic in delaying or preventing DM
  - Both effective in women with h/o gestational diabetes

- Economic impact, quality of life, prevention of end organ damage (blindness, amputations, CVD morbidity)

• Helps guide women with diabetes through healthy pregnancies
• Includes information about
  – checking and controlling blood glucose
  – maintaining a healthy diet
  – staying physically active
  – taking tests and diabetes medications during pregnancy

(http://www.diabetes.niddk.nih.gov/dm/pubs/pregnancy/)
FY 2008 ORWH Research Highlights

- Comprehensive Uterine Fibroids Research
  - Fibroid Tissue Bank-with NICHD, on-going research, conferences and planning for 2009 3rd International Congress on Advances in Uterine Fibroid Research

- Menopause-related Research
  - Co-funding 2 RFA’s, MsFLASH launched in 9/08

- Autoimmunity Research
  - E.g. SLE, MS, Sjogren’s syndrome & ACE awards

- Prevention Research
  - E.g. Microbicide innovation programs (MIPs), Physical activity grants
FY 2008 ORWH Research Highlights

- Research on Chronic Pain Syndromes
  - TMJ, interstitial cystitis, fibromyalgia, vulvodynia
- Health Disparities Research
- Stillbirth Research Follow-Up Study - with NICHD
  - Subsequent maternal fetal outcomes post index case
- Long-term Research Partnerships:
  - Diabetes - DPP- OS with NIDDK
  - Ob-Fetal Pharmacology - with NICHD
  - ADD Health - with NICHD
WOMEN’S HEALTH RESEARCH:

Examples NIH Communication and Outreach
Active Communications From Across the ICs
New webpage at NLM devoted to women’s health research, launched March 10, 2008
One-stop resource for both consumers and researchers
Located on NLM’s Special Information Services website with a link on ORWH’s home page
Includes consumer information on health topics for women, based on the 2008 NIH Priorities for Women’s Health
ORWH and NLM plan to expand the site and welcome feedback from interested parties
NLM/ORWH Information Resource

Women’s Health Resources

This collaborative effort by the National Institutes of Health 27th Institutes and Centers provides:
- Topics based on the NIH Research Priorities for Women’s Health
- Clinical trials opportunities and research reports
- Easy to read, consumer health information
- Free publications and resources produced by the NIH Institutes and Centers


This resource was created in a partnership between the National Library of Medicine Special Populations and Outreach Branch and the National Institutes of Health Office of Research on Women’s Health. NIH Institutes and Centers input is provided through the Coordinating Committee on Research on Women’s Health at NIH.
Pinn Point on Women’s Health Podcast Series

The Office of Research on Women’s Health (ORWH) is broadcasting a series of podcasts, “Pinn Point on Women’s Health,” hosted by Dr. Vivian W. Pinn, Associate Director for Research on Women’s Health and the Director of the Office of Research on Women’s Health. The monthly podcast discusses the latest news in women’s health research and includes conversations with guests on a variety of subjects.

“Podcasting” is a relatively new method of distributing audio and video information through the Internet to iPods and other portable media players on demand. The main benefit of podcasting is that listeners can sync content to their media player and take it with them to listen whenever they want to. Because podcasts are typically saved in MP3 format, they can also be listened to on nearly any computer.

To listen to Dr. Pinn’s podcasts, visit the ORWH homepage at http://orwh.od.nih.gov/ and select the option of your choice under the section ORWH Presents: Pinn Point on Women’s Health.
NIH Podcast and Vodcasts

• In March 2007, the Office of Research on Women’s Health began podcasting “Pinn Point on Women’s Health.” The monthly podcast discusses the latest news in women’s health research.

• Recent WebTrends reports show that each podcast gets roughly 1,500 visits per month, each radio/audio report roughly 40 visits per week, and each vodcast roughly 100 visits per month.
NIH Women’s Health Campaigns

Powerful Bones/Beautiful Girls, ORWH

Sudden Infant Death (SIDS), NICHD

(Upcoming) National Eye Institute campaign encouraging women to have eye examinations

Special 5th Anniversary Edition Red Dress Pin, part of the Heart Truth National Wear Red Day, NHLBI
Sponsored by the NIH Office of Research on Women’s Health (ORWH)
Vivian W. Pinn, M.D., Associate Director for Research on Women’s Health and Director, ORWH

Vulvodynia Awareness Campaign Quick Facts

The Vulvodynia Awareness Campaign, led by the Office of Research on Women’s Health (ORWH) at the National Institutes of Health (NIH), and other NIH components, including the National Institute of Child Health and Human Development, the National Institute of Neurological Disorders and Stroke, the National Library of Medicine, and the NIH Pain Consortium, was developed in response to a Congressionally recognized need to bring more attention to this chronic pain syndrome of women. The campaign targets health care professionals and consumers.

Vulvodynia has been described as chronic burning in the lower genital tract or knifelike pain or pain on contact that lasts in excess of three months. Researchers estimate that up to 18 percent of women will experience symptoms consistent with vulvodynia. These symptoms have been reported by a diverse population. The lack of health care provider education about vulvodynia may lead to multiple doctor visits resulting in delayed diagnosis and treatment.
Office of Research on Women’s Health
Office of the Director
National Institutes of Health

20th Anniversary: Facing New Horizons

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est. September 1990
First National Agenda on Research on Women’s Health

‘Hunt Valley Report Revisited’
1997-2000 - Second National Agenda on Research on Women’s Health
STRATEGIES FOR ADDRESSING WOMEN’S HEALTH IN THE 21ST CENTURY: The Next Decade???

- Consider what we have learned from research
- Address continuing or emerging gaps in knowledge through expanded research
- Integrate new knowledge into health professions education
- Increase public awareness & consumer education
- Implement into health practices and public health policies
The Advisory Committee shall--
advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to--
(i) research on women's health;
(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;
(iii) research on gender differences in disease etiology, course, and treatment;
(iv) research on obstetrical and gynecological health conditions, diseases, and treatments; and
(v) research on women's health conditions which require a multidisciplinary approach.
OFFICE OF RESEARCH ON WOMEN’S HEALTH
LEGISLATIVELY MANDATED COMMITTEES
NIH Revitalization Act of 1993

COORDINATING COMMITTEE ON RESEARCH ON WOMEN’S HEALTH
(NIH IC Directors or their representatives)

With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in
(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;
(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;
(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;
(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and
(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.
Setting a National Research Agenda: Strategic Planning 2009

- Continuing Gaps & Emerging Science about Women’s Health & Sex/Gender Factors
- Application of New Technologies
- Basic Research to Clinical Translation: Molecular to Societal Factors
- Translation of Advocacy Concerns to Science-Based Initiatives
- Advancing and Sustaining Careers of Women in Science & Engineering Careers

Science Driven Initiatives
REVISING the NIH WOMEN’S RESEARCH AGENDA for the 21st CENTURY: The Next Decade

- Regional Meeting
  - Wash. Univ. – St. Louis
  - March 2009

- Regional Meeting
  - UCSF – May 2009

- Regional Meetings
  - Women & Infants Hospital, Providence - September
  - Northwestern - October

NIH Town Meeting

CCRWH

ACRWH

Revised Research Agenda