

Commentary

The View from the National Institutes of Health: A Decade with the Office of Research on Women's Health

Vivian W. Pinn, MD

*Associate Director for Research on Women's Health
Director, Office of Research on Women's Health
National Institutes of Health
Bethesda, Maryland*

When I became the director of the newly created Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH) in 1991, I excitedly assumed my post. A new world of health and medicine, reflecting the unique concerns of girls and women, was just beginning to develop. I was fully engaged by this powerful opportunity to contribute to women's health research through scientific leadership, the establishment of national priorities and objectives, and grant support to gifted investigators in women's health and medicine. I also saw an opportunity to create a national "clearinghouse" for the fresh ideas and new directions that I believed women's health would come to embody. As ORWH's first director, I viewed my role as a chance to help the clinical and research communities reach a much broader appreciation and recognition of the significant aspects of women's health and physiology, as revealed by effective—and effectively directed—research.

The most immediate concern facing the ORWH in 1991 was to change conventional wisdom about women's health, biology, and biochemistry. We embraced the objective of furthering scientific perspectives in sex and gender, female aging, hormonal medicine, female adolescence and development, and sex and gender variations in clinical conditions, from arthritis and musculoskeletal disorders to heart disease and infectious diseases and immunity, as well as behavioral and psychological disorders. We welcomed the task of promoting and supporting research initiatives that would provide scientific answers to women's health issues—answers that did not simply respond to any political or social pressures along the way.

The Major Obstacles

To realize ORWH's initial goals, 3 interrelated obstacles had to be met and surmounted. As is often the case with obstacles, these concerns were also central opportunities for ORWH to establish a new scientific basis—which I now term the "new mosaic"—for women's health.

In the early 1990s, voices in the scientific and clinical communities asserted that the establishment of ORWH represented, at least potentially, wasted money and wasted expertise. Those critics were convinced that the biomedical concerns of women would, as a matter of course, be revealed through ongoing research. Concern was voiced as well that an office dedicated to women's health research was simply a bow to popular notions and public pressure, as opposed to a legitimate new endeavor with a proper scientific pedigree. These objections have been overcome by accomplishing precisely what we set out to do: supporting and supervising scientific, research-oriented, evidence-based initiatives and investigations that operate within the same context as legitimate research in any other area of medical science.

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Objections were also fueled by the fear that an independent NIH office focused on women's health might create undue competition with those health and medical concerns commonly identified with boys and men. The past decade has demonstrated, however, that the greater part of women's health research has shed new light on men's health and, indeed, has brought insight to and benefited both men's and women's health. More recently we have come to understand that men's health research applies the templates of women's health in examining the links between gender and health care, and that the health of both men and women is not, and has never been, confined solely to reproductive characteristics.

Along with these other obstacles was the concern that our very existence would promote a "men versus women" atmosphere in research. Some investigators and advocates were apprehensive of turf battles, ownership of ideas, and the possible risks posed to successful scientific partnerships. In response, ORWH established at the outset a commitment to scientific and institutional collaboration. Today we enjoy numerous partnerships within and beyond the NIH community, across multiple organizations, among researchers, with advocacy groups and the nonprofit sector, as well as with international medical and research institutions and research. We have been able to facilitate collaboration and support around broad-based issues, be it priorities and objectives for research, assisting and furthering educational and career development programs, or promoting national leadership in women's health.

The Landscape of Women's Health

In the years since I came aboard as ORWH's director, we have realized a number of achievements that mark critical points of passage on the new landscape of women's health. Each milestone represents a pivotal concept or arena from which the science of women's health continues to grow and develop.

Interdisciplinary Collaborations

Perhaps most important to ORWH's success is a multi- and interdisciplinary "crosscutting" approach to the science of women's health. Based on its original commitment to cooperative and collabo-

orative outreach, ORWH has forged pathways and laid groundwork on the premise that collaboration equals synergy, thereby potentiating the results of research. This equation of partnership and cooperation underlies my sense of women's health as a matrix of insights and tools that, together, are inevitably stronger and more useful than any single independent research conclusion. This sense of matrix—a fabric of research and applications—prompted us to join others in embracing the term "new mosaic of women's health."

Mentoring New Careers

One facet of our work that will affect the future of science and research is ORWH's long-standing commitment to education, mentoring, and professional development. Women's health flourishes by its ability to engage and retain scientists and health care providers. Educational opportunity, leadership training, and career enhancement are only a few of the vitally important issues in supporting the development of biomedical careers. Of particular note is the Building Interdisciplinary Research Careers in Women's Health programs, offering career development and mentoring awards for junior faculty who have recently completed or are soon to complete clinical training or postdoctoral fellowships. These awards support research by emerging scientists who are investigating issues specific to sex and gender factors and women's health and illness at more than 20 universities throughout the nation. The SCOR (Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health) initiative is another form of support for careers in women's health, engaging investigators at sites nationwide in studies involving a gamut of concerns, from pharmacokinetics in women to incontinence, pain sensitivity, irritable bowel syndrome, and the roles of sex and gender in drug abuse.

Sex and Gender Research

ORWH established and now maintains a pivotal role in bringing sex and gender issues in biological research to the forefront of scientific discourse. Beginning with the clarification of terms and definitions—*sex* reflecting a male or female individual based on chromosomal complement and physical

characteristics, *gender* being an individual's self-representation shaped by biology as well as responses to environment, experience, and societal factors—ORWH remains committed to a comprehensive and inclusive approach to sex and gender factors in health status and outcomes across the lifespan.

Bench-to-Bedside Research Priorities

All ORWH programs and initiatives are keyed to the critical transfer of basic research to clinical research, and from clinical research to the hospital bedside and clinic. ORWH research priorities target the exploration of sex and gender differences in health and disease, and therapeutic interventions at genetic, cellular, molecular, and functional levels. In bringing these factors into focus, and making research results broadly applicable in the United States, ORWH has been able to drive, support, or endorse research agendas on health disparities, sex and gender differences, variations in biomedical interventions, and issues of diversity among varying populations or subpopulations of women.

From Women's Health to Gender Medicine— and Beyond

From its inception, ORWH sought to foster and facilitate the involvement of women in clinical trials. Our work has been consistently steered toward an expansion of rigorous clinical studies of women's health and their physical and psychological transitions across the lifespan. The normative standards derived from such studies have established new and more reliable parameters for conclusions, interventions, and applications in women's health.

The Nurses' Health Study I and II, launched in 1976 and 1989, respectively, involved more than 100,000 participants and cast new light on a number of health concerns among women. More recently, the Women's Health Initiative, launched in the mid-1990s, has observed more than 150,000 women and yielded important new information on cardiovascular disease, hormone physiology, and osteoporosis. These studies among others serve as clear examples of the necessity and utility of framing sex and gender hypotheses, thereby permitting

scientifically valid conclusions that apply uniquely to women.

This priority was reinforced by the passage of the NIH Revitalization Act of 1993 (Public Law 103-43), which stipulated that women and minorities must be included in all human subject research, notably in phase III clinical trials in numbers sufficient to allow for valid analyses of sex and gender differences. NIH was mandated to initiate and support the necessary outreach efforts to recruit and retain women as volunteers for clinical studies. Fueled both by the Act and by ORWH's existing mandate and established policy, a tracking system to monitor inclusion of women in research was initiated, in collaboration with several components of NIH including the Office of Extramural Research. For the first time in NIH history, it became possible to identify women's participation in human subject research, to accurately determine numbers of participants, and to productively analyze that data.

ORWH's commitment to the scientific study of women's health has witnessed, in little more than a decade, the transformation of a nascent effort to a complex research agenda, defined by a strategy devoted to the inclusion of women in all phases of biomedical research.

The ORWH experience continues to demonstrate that strength, value, and utility rise from our differences. The understanding of variations and specificities in health and disease among women and men has fueled fresh insight far more than it has minimized either research arena. Women's health research has amply demonstrated its ability to add to the pool of scientific knowledge while shedding a sometimes unexpected light on men's health issues.

Women's health, in the late 1980s and early 1990s, was an idea whose time had come. In the years since, ORWH has been and continues to be strongly positioned to take that idea forward—and to create a new kind of synergy in health care research. From my position at ORWH and NIH and as a participant in the exciting and ongoing expansion of women's health, I welcome the potential and promise of not only the next decade, but of the 21st century.