EDITORIAL

Women's Health Research: Current State of the Art

女性健康研究：当前发展状况

Investigación sobre la salud de las mujeres: estado actual de la técnica

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It is remarkable that only a few years ago, discussions about women's health research often had to be prefaced with the expanded vision of what that concept should actually be in totality as the traditional approach to the health of women had focused on the reproductive system or "bikini medicine," as Dr Marianne Legato, an internationally recognized specialist in women's health, and others have characterized it. Today, there is an almost universal appreciation of the broader perception of women's health and that research on women includes not just clinical trials but also basic investigation from the molecular level of genes to the many aspects of behavioral and societal influences. This evolution over the past 25 years of what should and does constitute women's health research has been important in influencing the design of biomedical and behavioral research studies and in elucidating factors now implicit in diagnostic and therapeutic approaches to both males and females.[1] And examples of advances from research providing the foundation for public health policies and legislative initiatives only strengthen the understanding of the value of these efforts.[2]

In the first federal report on women's health, *Women and Health: United States 1980*, published as a supplement to Public Health Reports, it was noted that "Some research into problems which affect both women and men have used only male subjects; the resulting data often cannot be validly generalized to the female population."[3] A coalition of advocates, scientists, and legislators acted on this concern, eventually leading to an audit by the United States General Accounting Office of federally funded clinical trials through the National Institutes of Health (NIH) to determine if women were being systematically included in studies of diseases or conditions that affect both women and men.[4] The uproar from the results of that audit, documenting that the inclusion of women in clinical trials was not consistently required by the NIH of its investigators, led to the establishment of the NIH Office of Research on Women's Health (ORWH) to ensure the inclusion of women in clinical research—the first office within the US Department of Health and Human Services (HHS) to have women's health research as it primary mission. Taking this concern further, the Congressional Caucus on Women's Issues led Congress to include in the NIH Revitalization Act of 1993 (Public Law 103-43) the requirement that women and minorities must be included in clinical trials funded by NIH.

Implementing requirements for the inclusion of women in clinical research required a focus on scientifically based initiatives. The ORWH began its efforts of determining priorities for research parallel to implementing the strengthened inclusion policies by first establishing collaborative efforts with the institutes and centers of the NIH for application to the broad array of scientific priorities and funding pursuits. This was a directed effort by the ORWH in keeping with its full mission: to advise the NIH director on matters relating to research on women's health; strengthen and enhance research related to diseases, disorders, and conditions that affect women; ensure that research conducted and supported by NIH adequately addresses issues regarding women's health; ensure that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH; develop opportunities for and supporting recruitment, retention, re-entry, and advancement of women in biomedical careers; and support research on women's health issues.

While attention to women's health and research did not begin with the establishment of the ORWH, it should not be denied that the specific attention of the ORWH and other similar offices across the HHS provided a certain credibility to women's health as a legitimate field of study and also prompted scientists to rethink the design of their studies. The additional provision of federal funding specifically for studies of conditions that affect women and to determine if differences exist between men and women in response to various therapeutic interventions, in concert with Public Law 103-43 and the revised NIH inclusion policies to facilitate analyses of sex and gender differences, provided impetus to both experienced and new investigators to consider the pursuit of women's health research.

In the early surge of investigative attention to women's health research, the primary objectives included emphasizing the expanded concepts of women's health research beyond the traditional reproductive system to include the entire spectrum of conditions and diseases that may affect both men and women across the life span. For example, it had long been recognized that while heart disease was the leading overall cause of death in women, for a variety of reasons, much of the previous cardiovascular research had been conducted in men with the assumption that the results would be applicable to women.

Cardiovascular research became one of the most cited to demonstrate the need for a comprehensive approach to women's health with women as an integral and substantial component of study populations.[5] The attention to analyses of research outcomes by gender became a requirement with implementation of the law in 1994, supporting the recognition of what is now known as the science of sex and gender in human health. Recent years have evidenced a more expansive emphasis on the importance of gender-based studies and the need for reporting their outcomes in the scientific literature.[6]

To advance a robust research agenda signaling priorities for women's health research and to assist with funding initiatives, ORWH initially conducted two intensive initiatives for strategic planning in 1991 and again in 1998 to set the research agenda for the next decades. The first agenda redefined parameters of women's health to encompass a better understanding of sex and gender differences in development, health, and disease and to focus on populations of women that had been underrepresented in previous clinical research, ie, addressing health disparities. The second report, *Agenda for Research on Women's Health for the 21st Century*, expanded upon the initial scientific agenda for women's health research but added a call for interdisciplinary research and career development and for considerations of the importance of basic laboratory research on sex differences in translational implications for clinical applications. The latter emphasis was bolstered by the landmark Institute of Medicine (IOM) report of 2001, *Exploring the Biological Contributions to Human Health: Does Sex Matter?*, which documented sex differences across the life span and urged that exploration of sex differences should encompass even basic cellular and molecular levels of study.[7]

The NIH strategic agendas emphasized the relevance of the full spectrum of research from basic to clinical research and trials, epidemiological and population studies, clinical applications, and health outcomes applied to women's health. And they stressed more exacting scientific endeavors using the developing and innovative diagnostic or investigative tools and skills to further these areas of investigative pursuits.

There is no doubt that the introduction of interdisciplinary research and career development programs as the first of the ORWH's own primary funding initiatives set the stage for many institutional advancements in women's health research over the previous decade and has helped it to become embedded into the future of this field of endeavors. The concept of "interdisciplinary" programs based upon the idea of bringing together the many scientific, health professional, behavioral, and other related areas of expertise in a synergy of effort grew out of the appeal from those in healthcare as well as in advocacy to lessen the fragmentation of women's healthcare; these programs were introduced with the idea of a more collegial and collaborative research partnership facilitating such institutional approaches to providing care as well as building a cadre of interdisciplinary women's health researchers who would have experience in the many aspects of such research and its possible expansiveness. A more detailed description of one of these programs, "Building Interdisciplinary Careers in Women's Health Research," is included in this issue.[8] The interdisciplinary research centers in women's health and sex differences further demonstrate the important role of women's health research in examining basic laboratory hypotheses and the eventual translation of their outcomes into clinical applications—a very basic theme of the importance of human scientific investigation in general.

As more has been learned about women's health and sex-based factors and recognizing that the results of scientific investigations usually stimulate the search for more truths to be discovered and more scientific initiatives to be undertaken, a third strategic planning effort provided a collaboratively and purposefully developed foundation for future research priorities and programmatic initiatives: *A Vision for 2020 for Women's Health Research: Moving Into the Future With New Dimensions and Strategies*.[9]

Five regional workshops and public hearings ensured the participation of women and men who are scientists, practitioners, educators, advocates, public health officials, or members of an interested and invested public constituency to provide insight into the future of women's health research and that the future of this research would be on the cutting edge of science, address the questions that are foremost in today's scientific milieu, be based upon the most advanced and evolving techniques and methodologies, and have the results more rapidly translated into clinical care and communicated with better clarity to the scientific and lay communities of the nation and the world.[10] This new strategic plan made clear that while our understanding of what constitutes women's health research and efforts to expand scientific knowledge about women's health have grown extensively over the previous 20 years, there are still remaining questions and developing areas of discovery that need further exploration. A similar conclusion was reached by another IOM committee that focused its review of the progress in reducing mortality or morbidity of conditions that affect women's health over the 20 years following Congressional attention to women's health and research with the resulting changes in federal organizational efforts and offices.[11]

More than 400 specific recommendations for women's health research and career priorities were recorded during these discussions. Those recommendations were reduced to six succinct overarching goals that could universally apply to broad or specific priorities, further nurture the field of research on women's health and sex-specific factors, and enhance multidisciplinary careers as well as interdisciplinary approaches to pursue these goals in the coming decade. The major goals identified are as follows:

1. Increase the study of sex and gender differences in basic biomedical and behavioral research;
2. Incorporate findings of sex and gender differences into the design and application of new technologies, medical devices, and therapeutic drugs;
3. Actualize personalized prevention, diagnostics, and therapeutics for women and girls;
4. Create strategic alliances and partnerships to maximize the domestic and global impact of women's health research;
5. Develop and implement new communication and social networking technologies to increase understanding and appreciation of women's health and wellness research; and
6. Employ innovative strategies to build a well-trained, diverse, and vigorous women's health research workforce.

While some of the broad areas defined by these goals build on existing initiatives, others invoke new insights and pathways for the future of this field. ORWH already has begun to work on the implementation of these new research priorities with enthusiastic trans-NIH participation, and those efforts are described in some detail in the article in this issue by Tingen et al.[12] Therefore, it is expected that even more exciting and important advances in women's health and sex differences research and career development programs can be anticipated during the years to come.

Women's health and sex/gender differences research is better appreciated today as a scientific and valid field of pursuit, but the challenges from 20 years ago, including the need to continue to direct investigational attention to women's reproductive health and diseases, have not all been eliminated. With legislative and advocacy concerns related to the inclusion of women in clinical research having provided the incentive in 1990 for federal programs and designated funds specifically for women's health research, today there is still not an assurance that journal editorial policies will encourage the publication of these analyses, although progress has been made in that arena. Further, especially in times when budgetary reductions for biomedical research may be lessened, it is essential that the research community continue to develop and submit proposals that will advance the science. Recognizing that progress has been made in research contributing to both basic and clinical appreciation of the health of girls and women across the life span and how that may differ from or be similar to that of boys and men should not lead to complacency. The attention of the scientific, professional, legislative, and advocacy communities continues to be important so that probing pursuits of new revelations is still considered a priority for the full research community.

This issue of *Global Advances in Health and Medicine* contains reports on encouraging advancements in women's health research and career objectives through the goals and priorities of research agendas resulting from thoughtful and dedicated contributions of many. Now is the time to move the science forward toward valuable new discoveries and their clinical applications for the totality of our national and global populations but with better definition to those specific to women and girls. Now is also the time to implement pioneering and novel mechanisms and programs that will ensure a future with women and men who have the desire and the capability to be successful contributors through research and that the diversity of women will find their opportunities for career success to be as attainable as it is for their male colleagues.

As the 2010 IOM report *Women's Health Research: Progress, Pitfalls, and Promise* concluded,

> *The considerable investment in women's health research of the past two decades has yielded much to improve the health and well-being of women in the U.S. Despite this important investment, much work remains in all aspects of research. Given the multiple and significant roles women play in our society, maintaining support for women's health research and enhancing its impact are not only in the interest of women, they are in the interest of us all.*[12]

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