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Broadening the Applicability of Clinical Research

Author(s)

Karin Ellison
Karen Wellner

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Description

In the field of clinical cardiology research, participants have mainly consisted of white males, ages 20 to 50 years. Years of cardiovascular research that excluded women reinforced the belief that coronary heart disease was a "man's" disease and development of medical treatments more effective for men than women. How can researchers advocate for change in a complex science and technology network when they are in the network themselves?

Body

- How can a basic approach to conducting research, such as mainly testing new medications in men, be changed?
- What kinds of people and groups would need to be involved to make changes to clinical research methodologies?

In the late 1980s and 1990s, Bernadine Healy, director the National Institutes of Health (NIH), and Florence Haseltine, director of the Center for Population Research at NIH, pushed American doctors to make the results of medical research more useful for women, children, and minorities. By the mid-1980s, the women's movement had prompted questioning of NIH policy and sought to overturn the norm of testing new drugs and medical interventions primarily in middle-aged white males. While change has been slow in coming, illustrating substantial technological momentum behind this research approach, individual scientists working within and through their employers, professional organizations, and advocacy groups began changing medical practice.

Healy and Haseltine used their expertise in women's health, and their understanding of science and technology as systems, to push women's health into the public spotlight. Their leadership proved instrumental in changing the overall strategies of the NIH, but they knew that they could not draw attention to social responsibility issues acting alone. Both directors worked collaboratively with others to hasten and increase their effectiveness in calling attention to a problem and rectifying it.

Changing NIH Policy

Healy and Haseltine represented the NIH and offered expert testimony before the U.S. Congress to provide guidance on legislative and regulatory matters on women's health. Their testimony persuaded the Government Accounting Office (GAO) to undertake a review of NIH policy recommendations in 1986 aimed at opening clinical trials to women. The 1990 GAO audit concluded that the NIH had poorly communicated the 1986 policy and researchers within NIH and in the research community at large had misunderstood it. Additionally, NIH had not collected data on study populations so it was hard to track just how many women and minorities participated in studies.

The audit led to the NIH Revitalization Act of 1993, where the Congressional Caucus on Women's Issues inserted the following provisions:

- All NIH-sponsored clinical trials were to include women and ethnic minorities as participants unless the condition under study was sex or ethnicity specific; cost was not an acceptable reason for exclusion.

- Researchers needed to design every NIH-funded clinical trial in a manner that would allow analysis of women and minority groups. NIH would no longer allow extrapolating results from white males to women or African-Americans.

Building Advocacy Organizations

In 1993, Haseltine also co-founded a nonprofit organization, Society for Women's Health Research (SWHR). The SWHR was instrumental in bringing awareness of women's health issues to the media and Congress.

Communicating through Professional Societies

Healy and Haseltine wrote and edited articles published by professional societies to address gender and minority issues:

- Haseltine acted as senior editor for the *Journal of Women's Health*, the journal of the American Medical Women's Association. Haseltine was responsible for helping publish research based on the premise that the biological differences between men and women extend beyond their reproductive systems. Haseltine coined the term "gender-specific biology."
- Healy wrote articles for *The New England Journal of Medicine*. One 1991 article, "The Yentl Syndrome" argued that doctors often failed to correctly diagnose and treat heart attacks in women. Healy, B. (1991). The Yentl syndrome. The New England Journal of Medicine, 325(4), 274-276. Media outlets picked up this article and soon the public was debating the issue of women and cardiology research. In the same issue of *The New England Journal of Medicine* were two articles that Healy drew upon to show disparities in post-heart attack management between men and women. Both articles reported that women with coronary artery disease received less aggressive treatment than men in the studies did.

Developing Programs at NIH

Healy and Haseltine were able to use their positions within NIH to make changes in how the agency studied women's health and research. They:

- Initiated the NIH's Reproductive Scientists Development Program, which places early career gynecologists and obstetricians in basic research laboratories
- Insisted that the NIH support women's health by conducting the Women's Health Study (1991-2009). This long-term study used women as participants and obtained results opposite those of the Physicians' Health Study – namely that low doses of aspirin do not help women over the age of 65 in preventing heart attacks. Levin, R. I. (2005). The puzzle of aspirin and sex. The New England Journal of Medicine, 352(13), 1366-1368. The study also examined cardiovascular disease, osteoporosis, and cancer.
- Established the Shannon Award, grants given to researchers for innovative biomedical research, including often-overlooked research in women's health

Both Healy and Haseltine also addressed their social obligations by giving scientific, public, and media presentations across the U.S. and internationally about women's health and research. The two NIH directors were quick to point out, however, that they could not have changed common practices in the conduct of clinical trials without the support from outside agencies and from the NIH departments for which they worked.

Additional resources

- Epstein, S. (2007). Inclusion: *The politics of difference in medical research*. Chicago: University of Chicago Press.
- Jones, D. A. (2000). Visions of a cure: Visualization, clinical trials, and controversies in cardiac therapeutics, 1968-1998. *Isis*, 91(3), 504-541.

Notes

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Contributor(s)

Karin Ellison

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