



Institute for Women's Health Research *Putting Women's Health First*

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Dear Friends and Colleagues,

An enormous scientific knowledge gap regarding the sex- and gender-based differences in the human experience of health, as well as disease, continues to exist. This edition of the Institute for Women's Health Research's monthly e-newsletter will reflect on just a few of the barriers that have slowed progress in women's health and why we need to continue advocating for more sex-based research. For additional information about specific programs that the Institute has developed to address these gaps and barriers, please check our [web site](#).

Sincerely,

The Institute Staff



INSTITUTE FOR
WOMEN'S HEALTH
RESEARCH™
AT NORTHWESTERN UNIVERSITY

Addressing the Barriers to Advancing Women's Health Research

Numerous reports now indicate that males and females display different symptoms of similar illnesses and have discordant incidence of disease prevalence, onset, severity and susceptibility. Some of the factors that have delayed progress in women's health across all disciplines are discussed below.

Sex and gender are often used interchangeably.

Imprecise use of the terms "sex" and "gender" has serious implications for future biomedical research, clinical practice, and treatment. Without a clear distinction between sex and gender, the nature of related health outcomes and differences in health status will continue to be inadequately understood and addressed.

Sex refers to the physical and biological characteristics that identify a person as male or female. Gender, however, is largely a social construct that associates certain behaviors, roles, expectations, and values with being male or female. The chromosomal sex of an individual plays a pivotal role in the origin, onset, and progression of illness, whereas gender is more likely to influence risk profiles, symptom recognition, the severity of disease, the way a healthcare professional treats a man or women, or access to quality healthcare services.

When doing research on non-human animals, the term 'sex' rather than 'gender' applies.

Most women's health research has focused on reproductive health.

Often times, women's health concerns are focused primarily on reproductive health, yet women live nearly two-thirds of their lives outside their childbearing years. New advances in molecular biology reveal that sex as a modifier on cellular and molecular function can affect an individual's health far beyond the reproductive system. While hormone cycles have a tremendous impact on sexual dimorphisms, our genetic, environmental and experiential differences can also contribute. Sex differences are being discovered at the system, organ, tissue and sub-cellular level. However, our knowledge in this area is underrepresented in the NIH research portfolio and in clinical trial literature. The 2000-2003 average of grant awards for the study of sex/gender differences across the NIH was 3% (1).

Most research has been done in males.

The fact is that most basic science research is conducted in male animal models and this carries forward to an environment where the majority of clinical based investigation is conducted in men. Until the 1990's males were believed to be a representative model of human biology, and any differences found in females were considered "atypical" or "anomalous" (1). Due to the earlier exclusion of women from clinical research and the lack of sufficient numbers of women enrolling in studies that looked at diseases that occur in both sexes, researchers have often erroneously applied results from studies conducted in men to both sexes. The debatable rationale why researchers have preferred male subjects have been:



- a general belief among clinical researchers that men and women do not differ significantly in response to treatment
- a sense of having to protect vulnerable women and/or a potential fetus
- the complications of the menstrual cycle
- a perceived complexity of recruiting women and the cost of managing two study groups.

In other words, it is cheaper, easier, and less risky to study men only.

However, failure to remedy this practice can result in unnecessary expense and can have dire consequences when new treatments, inadequately studied in females, are applied to both men and women.

Lack of studies that value sex as a significant variable.

Since the early 1990's women have been participating in clinical trials in increasing numbers, but most of this increase is largely due to female-only trials (breast, ovarian, cervical, uterine cancers and menopause). Because of the perceived burden of inclusion (discussed above), women are still underrepresented in studies of diseases or conditions that can affect both men and women across the lifespan. Examples of invisibility of women in clinical research continue to be published in high-impact medical journals. In cardiovascular studies that include both men and women, sex as a variable is examined in a remarkably few number of cases (2), and women are under-enrolled in studies of heart failure (3).

Inadequate policies that mandate inclusion of women in studies.

While federally funded clinical trials are under the mandate for inclusion of women, set by the NIH Revitalization Act of 1993, the literature is plagued with instances of non-compliance. Moreover, the majority of drug trials (around 80%) are sponsored by pharmaceutical companies (4). The FDA ultimately regulates these trials, but unlike the NIH, the FDA does not have a federal mandate for inclusion of women in clinical trials.

Failure to report and analyze findings based on sex.

Even though there are guidelines addressing inclusion of women and minorities, the guidelines do not really address the requirement of sex specific analysis and reporting of sex-specific results from federally funded protocols. Carnes et al. recently summarized findings from randomized, controlled trials published in nine influential medical journals in 2004 that showed women were generally underrepresented, comprising on average 37% of the sample and only 24% of participants in drug trials (5). Further, 87% of the studies did not report any outcomes by sex or include sex as a

covariate in design, illustrating inadequate compliance with the current NIH guidelines (6).

What about men?

Overcoming the knowledge gap that exists regarding the sex and gender differences in health and disease by increasing our knowledge about women will ultimately create a system that highly values sex as an important research variable. This type of scientific inquiry is as much about women's health as it is about men's health. It's time to level the playing field so that both sexes may benefit from future scientific research.

References

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2. Blauwet, LA, et al., Low rate of sex-specific result reporting in cardiovascular trials. Mayo Clin Proc, 2007. 82 (2):p 166-70
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5. Carnes, M, Morrissey C, and Geller SE, Women's health and women's leadership in academic medicine: hitting the same glass ceiling? J Womens Health (Larchmt), 2008.17(9): p. 1453-62
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Upcoming Events

[Stand-up for Women's Health](#)

May 12, 2010

Location: Chicago Center for Performing Arts, 777 N Green St, Chicago, IL

Celebrate National Women's Health Week and help raise funds for the Institute for Women's Health Research at Northwestern University.

Please join us for an evening filled with laughter, good cheer, and Chicago's funniest comedienne!

May 18, 2010 Noon-1 pm

IWHR Monthly Research Educational Forum

[What We Do \(and Don't\) Know About the Role of Gender in Influencing Patient-Provider Communication](#)

Location: Prentice Women's Hospital, 250 E Superior St, 3rd Floor Conference Center

[Spotlight on Women's Health](#)

Join Northwestern Memorial Hospital experts as we discuss a variety of issues important to women's health!

Tuesday, May 18, 2010

5:30 - 6:30 PM

Fibroids: Cutting Edge Options for Treatment

Michelle Luthringshausen, MD & Susan Tsai, MD

These programs are free of charge. Contact Health Resources at 312-926-8400 to register.

Innovation and Your Success at Northwestern

May 21, 2010

Location: Pritzker Auditorium in the Feinberg Pavilion, Chicago

Faculty members Teresa Woodruff, Institute for Women's Health Research, Richard Wunderink, Dept of Medicine will present new ideas in clinical research followed by a panel who will discuss career development. May 21, 2010 from 8am to noon. Event is free but space is limited. Register by emailing nu-ori@northwestern.edu

Health Tip:

Yoga for Women's Health

Camel Pose, Urdhva Dhanurasana

Camel Pose - Ustrasana

Many women turn to yoga when they are feeling stressed, or are just in need of a good body adjustment. This particular pose opens the chest, stretching the intestines and stomach and is thought to be beneficial for digestion and reproductive health. The camel pose may be an advanced pose if you have not tried yoga before, so please use caution when attempting this pose.

To assume the camel pose:

1. Sit on your knees with feet flat on the floor.
2. Reach backwards slowly, grabbing the left ankle with the left hand and right ankle with right hand.
3. Inhale and lift the hips, arching the back and pushing the abdominals forward.
4. Tilt your head back and open the chest.
5. Hold this posture for 10-20 seconds.
6. To come out, slowly place the hands on the lower back.
7. Rest in Child's pose (Face down on the floor with knees tucked under you and arms outstretched in front).



Please join the [Illinois Women's Health Registry](#). To date, more than 4,300 female Illinois residents are participating, and 1,028 have been contacted for possible study participation.

Why should you join?

To gain **access** to groundbreaking research studies and clinical trials.

To help improve **prevention** and **treatment** of certain diseases and health conditions.

To **improve** women's healthcare by making you more aware of your own health issues.

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