

## Institute for Women's Health Research

*Putting Women's Health First*

January 2012

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Dear Friends,

Happy New Year!

The Institute for Women's Health Research at Northwestern University monitors, reports on and advocates for sex-based research from the bench to the bedside. We believe that the first step towards personalized medicine is a better understanding of the role sex and gender play in health and disease. This edition of our e-newsletter highlights what we believe are some of the key women's health stories of 2011.

There have been exciting breakthroughs that are 'game changers' because they alter the direction of research or clinical care. There have also been disappointments when long awaited results of some clinical trials reported that a promising therapy is no better (and may be worse) than standard treatments. The good news is that scientists are becoming increasingly aware that sex differences matter in their study designs. We are also learning that beyond sex differences, one size does not fit all, and as we dig deeper into the cause and effect of disease, an individualized approach will become increasingly important.

Sincerely,

The Institute staff



INSTITUTE FOR  
**WOMEN'S HEALTH**  
RESEARCH™

AT NORTHWESTERN UNIVERSITY

**MAJOR WOMEN'S HEALTH STORIES OF 2011**

## **Hormone Therapy and Heart Disease: Critical Window Hypothesis**

For years, it was believed replacing hormones lost during menopause could prevent heart disease. But that belief was questioned when the results of the large [Women's Health Initiative study](#) indicated that hormone therapy (HT) increased risk of heart disease and stroke in some women and physicians were instructed NOT to use HT for prevention. Other studies disputed these findings suggesting that the women in WHI were older and as many as 10 years past the start of menopause suggesting that their heart health had already started deteriorating before they started HT and that perhaps age was a major modifying factor. A prospective cohort study by Stam and colleagues noted that menopausal women should not be regarded as a single group, and a women's age must be considered when decisions about HT are made (Menopause. 2011 Mar). Younger women with less or no atherosclerosis still seem to have a positive cardiovascular effect of HT when started at the onset of menopause. On the other hand, it may be detrimental to older women who have already built up unhealthy plaque. Game changer: HT decisions related to heart disease risk need to be tailored to a woman's specific age and heart health profile.



## **Heart Disease: Sometimes Size Matters**

Heart disease affects women in different ways: symptoms are often more insidious and heart attacks more deadly. When reviewing the medical literature, Dr. Noel Bairey Merz and colleagues from the Women's Heart Center in Los Angeles found that women's hearts were less likely than men's to lose their ability to pump blood after a heart attack, and that female heart patients were less likely to present with obstructive coronary heart disease. Instead, the oxygen deprivation and subsequent damage to the heart is more likely to occur when small blood vessels, not major arteries become dysfunctional. This may be one reason women are often misdiagnosed. Game changer: Scientists now have cause and the tools to look at small blood vessels objectively rather than focusing on larger anatomy.

## **Mammography: Benefits and Harms Revisited**

Mammography remains the best means of detecting breast cancer in its earliest form yet new evidence about long-term risks continues to question current guidelines. Early studies from the 1980s reported that mammography would reduce the death rate from breast cancer by almost a third, with few harms and at low cost. Since then, a number of negative side effects associated with screening have been acknowledged, particularly, false positives and over diagnoses of cancers that would unlikely cause problems. A [study](#) from the United Kingdom looked at 8 studies that included 100,000 women and found that when false positive diagnoses and unnecessary surgeries were taken into account, the quality adjusted life years (QALYs) gained were significantly reduced. Game changer: These findings may lead to changes in screening frequency based on risk profile in the future; research will continue on alternatives to mammography.

## **Breast Cancer in the News**

In November, the Food and Drug Administration (FDA) revoked their approval of the drug, bupropion (Wellbutrin), for the



the drug bevacizumab (Avastin) for the treatment of metastatic breast cancer. The additional studies requested from the manufacturer showed that bevacizumab delayed tumor growth slightly but did not improve survival or patients' quality of life. In light of the drug's potentially severe side effects, including heart attack or heart failure, severe high blood pressure, and bleeding or hemorrhage, "...there is no proof of a benefit in breast cancer patients that would justify those risk," said FDA commissioner Dr. Margaret Hamburg. The drug has shown promise for other types of cancer including late stage ovarian cancer. Game changer: Women who are currently taking the drug for metastatic breast cancer have been encouraged to discuss benefits and risks of continuing this drug off-label; researchers will search for subgroups of women who may benefit.



\* \* \*

A Northwestern study reported that 36% of breast cancer patients quit the drugs that have been prescribed to prevent their disease from recurring due to severe side effects. "Clinicians consistently underestimate the side effects associated with treatment," said lead investigator Lynne Wagner. The most likely symptom to make women quit is joint pain due to aromatase inhibitors. Other symptoms that cause women to quit therapy are hot flashes, mood swings, low libido, bloating and nausea-- effects which are more severe and widespread than previously known, especially by doctors. Game changer: This study encourages doctors to consider quality of life issues when treating their patients; efforts to identify women at greatest risk for compliance should be made so appropriate counseling can be provided.

### **Women's Health Policy Becomes Political**

Historical new guidelines recommended by the independent Institute of Medicine to ensure women receive preventive health services at no additional costs were announced by the U.S. Department of Health and Human Services in 2011. Starting in August 2012, new health insurance plans will be required to cover such services as well-women visits, domestic violence screening, HIV testing and counseling, breast feeding support and contraception without a co-payment, co-insurance or a deductible. Controversy continues over this new legislation due to a provision that allows religious institutions that offer insurance to their employees the choice of whether or not to cover contraceptive services. Game changer: This debate, centering on separation-of-church-and-state, will continue through enactment and may impact universal access to other services.



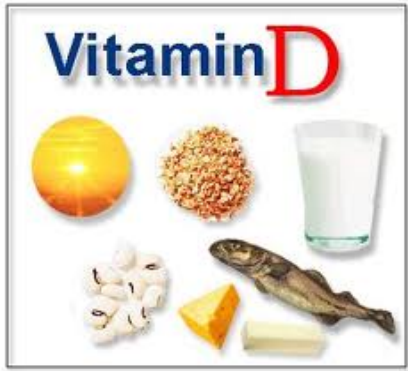
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U.S. Dept. of Health and Human Services Secretary Kathleen Sebelius overruled federal drug regulators to block wider access to the emergency contraceptive known as Plan B. A panel of scientists at the FDA determined that Plan B should be made



Plan B. A panel of scientists at the FDA determined that Plan B should be made available without a prescription to women of all ages, but Sebelius intervened. This action raises concerns among advocates that scientific experts charged with making access determinations about this drug have been stripped of their authority due to political pressure from conservative politicians. On the other hand, balancing the innocence of youth with political, moral and parental fear regarding sex is not easily answered in our society. Game changer: Women's health issues are likely to emerge during the 2012 presidential election.

### **The Big 'D': Vitamin "du jour"**



While some [studies](#) are reporting that vitamins and mineral supplements may be overused and causing harm, one exception may be Vitamin D. Well-known for its role in bone health, recent evidence suggests that vitamin D insufficiency may adversely affect heart health, neuromuscular function, and breast cancer. What is not clearly known is the actual recommended daily allowance of vitamin D and the serum 25-OH level needed to attain desirable levels. Game changer: More doctors will be ordering Vitamin D serum levels on their patients and will likely offer supplements to women who may appear deficient as researchers continue to

explore optimal dosages to optimize potential benefits while minimizing any risks.

### **Reproductive Health**

Teen pregnancies are down, abortions are down, yet half of all pregnancies are unintended. According to the American College of OB/GYN, 62% of childbearing age women are using contraceptives, especially the 'pill'. So what else can we do to prevent unintended pregnancies? A recent [study](#) assessed the compliance and satisfaction with use of other long-acting, reversible contraception options including intrauterine devices (IUDs), subdermal implants, and depot medroxyprogesterone acetate (DMPA or the "shot") that many believe are underutilized. The researchers found that certain subgroups of women (older, heavier, higher parity, and who experienced an unintended pregnancy) had much better continuation rates with long-term contraception than with the 'pill'. Game changer: The results of this study should encourage health providers to use more long-acting contraceptives for more patients.



\* \* \*

In vitro fertilization (IVF) has been practiced with much success over the last 30 years resulting in an estimated 4 million babies. When IVF was first introduced we did not know what the long-term health risks might be. Now, a recent [study](#) found that IVF stimulation may increase the risk for ovarian malignancies, especially borderline tumors (that have a more favorable outcome than invasive cancers). Despite these new findings, IVF is still considered a safe and effective treatment for infertility. The ongoing study of infertility is also likely to open up new doors to understanding how hormones impact women's health even beyond fertility issues. Game changer: Women who undergo these procedures need long-term gynecological followup and screening for ovarian cancer; researchers may explore more non-hormonal treatments for infertility;

researchers will gain additional knowledge about hormones.

### **Researchers Overreach: the Chronic Fatigue Syndrome (CFS) Dilemma**

CFS refers to a severe, continued tiredness that is not relieved by rest and is not directly caused by other medical conditions or identified by any specific diagnostic test. It is more common in women and, because no exact cause is known, women have often been dismissed by their doctors and told "it is all in your head". In 2009, a publication by well known researchers was released that gave hope to CFS sufferers that claimed an association between CFS and a mouse leukemia retrovirus known as XMRV. A second study backed up the findings. However, in December 2011, both studies were retracted by the prestigious publications when the findings could not be replicated in other labs and antibodies to this virus could not be found in patient blood samples. Despite these retractions, the NIH is continuing a large scale study that will be the final word if mouse leukemia virus is the cause. Meanwhile, patients with this condition range from being hopeful to greatly disappointed. Game changer: This controversy has brought needed attention to this debilitating condition more common in women.

### **Disasters in the Environment**

Environmental disasters have been happening for centuries with the poorest countries hit hardest. Women and children in the third world countries are particularly vulnerable.



This year's catastrophes have struck richer areas, including Australia (earthquakes and floods), Japan (earthquakes, tsunamis and nuclear meltdowns) and the United States (Midwest tornados) where media coverage brought them front and center. These disasters immensely impact public health not just when they first hit but continue today. One of the most troubling to women is the radioactive meltdown that occurred at the Fukushima nuclear plant in Japan. While most of the immediate radioactive cloud went out to sea there are still concerns about lasting effects on reproductive health and newborns whose mothers may have been exposed.

Game change: More research on global warming, waste management for infectious disease control, alternatives to nuclear energy, and capacity building for disaster relief.

### **Women's Health Heroes (Two out of many are cited below!)**

Out of the eight best physicians of the year cited by Medscape Today one was a woman. University of Pittsburgh Medical Center psychiatrist Katherine L. Wisner, MD, MS, a pioneer in the study of postpartum depression, received the 2011 Women in Science Award from the American Medical Women's Association. She did her early training in England because it was far ahead of the US in the study of prenatal psychiatric disorders. Dr. Wisner recalled that when she first went into medicine, "we were pondering as a society why all the data were based on men. We didn't want to include women with messy menstrual cycles and pregnancy---so I was able to carve out women's mental health as an area of research. We must get data on things that aren't being studied, and pregnant women have been neglected for so long." Dr. Wisner met with Institute staff in 2011, encouraging our efforts on behalf of women.

\* \* \*

Teresa Woodruff, the Thomas J. Watkins Professor of Obstetrics and Gynecology at Northwestern University Feinberg School of Medicine and director of the Institute for Women's Health Research, received the





prestigious Presidential Award for Excellence in Science, Mathematics and Engineering Mentoring at the White House from President Barack Obama in December. The award was for an Institute run program called the [Women's Health Science Program for High School Girls and Beyond](#) created by Dr. Woodruff. The program mentors urban minority high-school girls for college and careers in science and health. "Meeting President Obama in the Oval Office was a true honor and

humbling event," said Woodruff. "This award is for the hundreds of faculty, staff and students throughout Northwestern University and Northwestern Memorial Hospital who donate their time to mentorship," Woodruff added. "Our program focuses on the next generation of female leaders. Our goal is to ensure that the future is filled with a diverse group of problem solvers ready to meet the world's challenges."

## UPCOMING EVENTS

January 17, 2011, 12:00pm

[IWHR Monthly Research Forum--Estrogen and the Menopausal Years](#)

Prentice Women's Hospital, Chicago, Illinois

February 3, 2012, 8:00am-12:00pm

[Heart Health: What Smart Women Need to Know](#)

Prentice Women's Hospital, Chicago, Illinois

February 3, 2012, All Day

[Fifth Annual Women's Cardiovascular Health Symposium](#)

Prentice Women's Hospital, Chicago, Illinois

## HEALTH TIP

Most professional health associations suggest an annual "women's health" visit with a medical provider that includes a review of your medical history and a physical exam. Sexual behaviors, nutrition, fitness and risk factors should be assessed for all age groups and screening tests based on age should be scheduled.

Current guidelines for recommended screenings by age can be assessed by clicking [HERE](#).

Starting August 2012, the Affordable Care Act will require new insurance plans to cover most screening tests without charging a co-payment, co-insurance or deductible making preventive health care more available to more women.



[Illinois Women's Health Registry News](#)

Don't forget to join the [Illinois Women's Health Registry](#). If you are already a member, be sure to update your profile when you get your renewal reminder! Your participation helps us advance women's health by linking women to ongoing clinical trials taking place across Illinois.

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