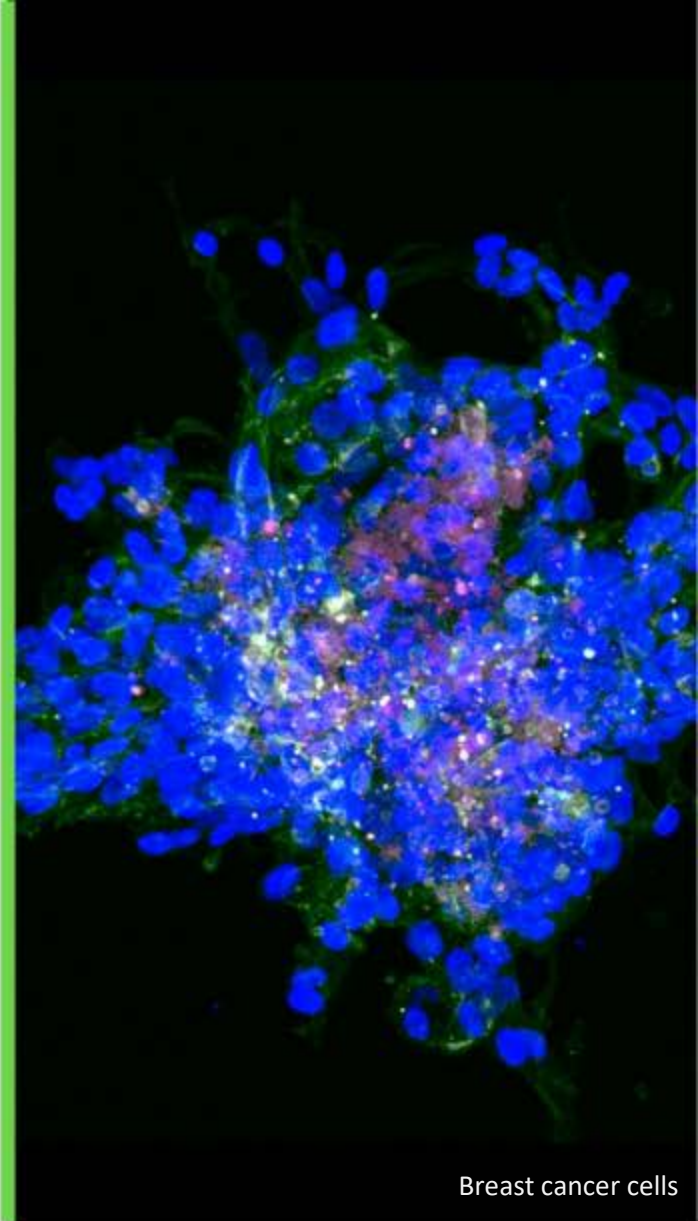




30 YEARS OF ADVANCING WOMEN'S HEALTH AT NIH



Breast cancer cells

2020 has been a momentous year for women's health. ORWH is celebrating its 30th anniversary as well as NIH's many contributions to improving the health of women. We also saw gains in women's entry and advancement in biomedical careers and their participation in NIH-funded clinical studies. Advances in these areas have been especially significant under the leadership of NIH Director Francis S. Collins, MD, PhD.

These gains are important, but more work needs to be done. The coronavirus pandemic also poses tremendous risks to women and girls and is exacerbating health disparities among women of color and other underserved and vulnerable populations. In addition, its impact on women scientists' careers has been significant.

For ORWH the path forward holds great promise; we believe that the more we study sex and gender, the better the science. And the better the science, the better the health of all.

Janine Austin Clayton, MD
Director, NIH Office of Research on Women's Health



CELEBRATION & RECOMMITMENT

Since 1990, ORWH has advanced biomedical research that has improved the health of women.



OFFICE OF RESEARCH
ON WOMEN'S HEALTH

*Advancing the Health of
Women Through Science*

1960s - 1970s

The civil rights and women's movements gave rise to the women's health movement, which drew attention to inequities in research and health care. The book *Our Bodies, Ourselves* and the National Black Women's Health Project* also raised awareness of women's health.

* Now the Black Women's Health Imperative

1980s

The scientific community responded, led by Edward Brandt, Ruth Kirschstein, Bernadine Healy, and Vivian Pinn. The Public Health Service Task Force on Women's Health Issues advocated greater inclusion of women in NIH-funded clinical trials and more research of conditions and diseases affecting women.

In response to calls from scientific and advocacy organizations, the Congressional Caucus for Women's Issues—led by Reps. Barbara Mikulski, Connie Morella, Olympia Snowe, and Pat Schroeder—pushed for the inclusion of more women in clinical studies.

1990s

In a study of NIH grant applications, most relating to conditions affecting both men and women, GAO found that ~20% of them provided no information on the sex of the study population. Over a third indicated that both sexes would be included but did not specify in what proportions.

Sen. Mikulski and Reps. Morella, Schroeder, and Snowe expressed concerns about the lack of inclusion of women in clinical studies. That same day in 1990, NIH established ORWH, naming Dr. Kirschstein Acting Director. A year later, Dr. Vivian Pinn became the first full-time Director of ORWH, a position she held until she retired in 2011.

ORWH'S FOUNDING



Expansion of Federal offices on women's health

Following ORWH's founding, the focus on women's health expanded

- 1991 | U.S. Department of Health and Human Services Office on Women's Health
- 1992 | Substance Abuse and Mental Health Services Administration Associate Administrator for Women's Services
- 1994 | Food and Drug Administration Office of Women's Health
- 1994 | Centers for Disease Control and Prevention Office of Women's Health
- 1999 | Agency for Healthcare Research and Quality Office of Women's Health and Gender Research
- 2000 | Health Resources and Services Administration Office of Women's Health

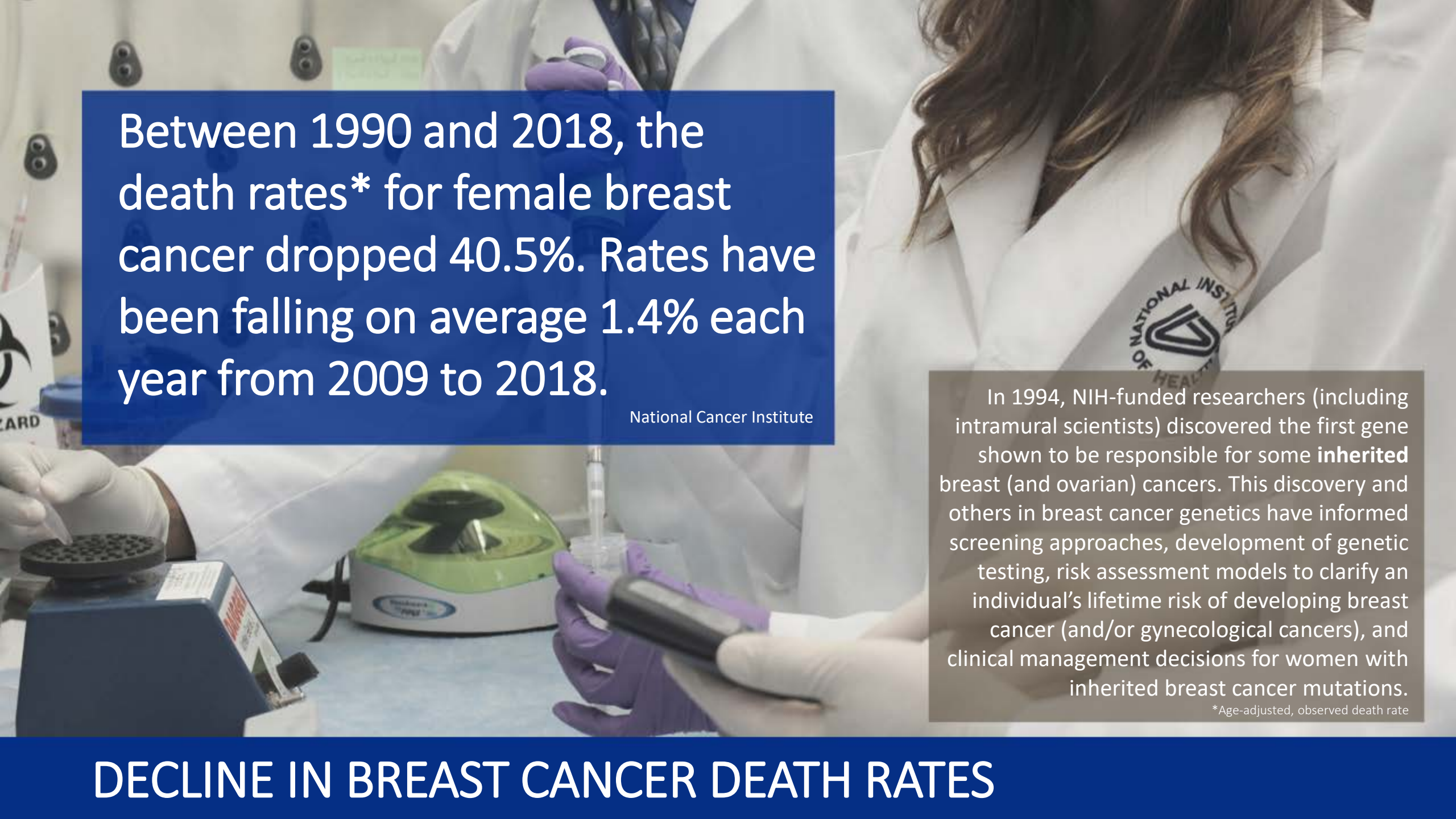


*As we celebrate our 30th Anniversary,
we mark the contributions NIH has
made to improving women's health.*



WOMEN'S HEALTH GAINS AND MILESTONES





Between 1990 and 2018, the death rates* for female breast cancer dropped 40.5%. Rates have been falling on average 1.4% each year from 2009 to 2018.

National Cancer Institute

In 1994, NIH-funded researchers (including intramural scientists) discovered the first gene shown to be responsible for some **inherited** breast (and ovarian) cancers. This discovery and others in breast cancer genetics have informed screening approaches, development of genetic testing, risk assessment models to clarify an individual's lifetime risk of developing breast cancer (and/or gynecological cancers), and clinical management decisions for women with inherited breast cancer mutations.

*Age-adjusted, observed death rate

DECLINE IN BREAST CANCER DEATH RATES

In response to WHI research in 2002 that post-menopausal women taking combination hormone therapy for menopause symptoms had an increased risk for breast cancer, many women stopped taking hormone therapy, producing a sharp decline in breast cancer.

76,000
fewer cases of cardiovascular disease

126,000

fewer breast cancer cases


143 Times

**multiple of economic benefits over
original cost**

National Heart, Lung, and
Blood Institute

Between 2003 and 2012

WOMEN'S HEALTH INITIATIVE




Most maternal deaths are preventable.

California cut its maternal death rate by more than half in seven years, giving it the lowest in the nation.

National Institute for Child Health
and Human Development


MATERNAL MORBIDITY AND MORTALITY

A pregnant woman is shown in silhouette, standing in a field of tall grass or brush. She is looking down at her belly. The background is a bright sunset or sunrise, with the sun low on the horizon, creating a warm, golden glow. The sky transitions from orange near the horizon to a darker blue at the top. The overall mood is serene and hopeful.

**Because of NIH-funded
research, we know how to
prevent transmission of
HIV from mother to child.**

National Institute of Allergy and
Infectious Diseases

HIV PREVENTION



With FDA approval of brexanolone in 2019, women who suffer from postpartum depression for the first time ever had effective and immediate relief.

National Institute of Mental Health

Many years of NIH-funded research led to the development of this breakthrough drug.

Photo by Alex Boyd on Unsplash

POSTPARTUM DEPRESSION

A person is lying on a bed with white sheets, appearing to be in pain or discomfort. The person is wearing a white long-sleeved shirt and dark shorts. Their legs are bent and they are holding their back. The background is dark, suggesting a bedroom or hospital room.


What NIH research says

Women have higher pain sensitivity than men, in general, and studies show that chronic pain is more common in women than men.

Males and females have different physiological responses to coping with opioid withdrawal.

National Institute of Neurological Disorders and Stroke

SEX AND GENDER DIFFERENCES IN PAIN



NIH's HEAL InitiativeSM is investing \$1 billion to find scientific solutions to the opioid crisis.

National Institute on Drug Abuse

Fueled by the opioid crisis, rates of drug overdose death skyrocketed among U.S. women aged 30–64 from 1999 to 2017. The Helping to End Addiction Long-term InitiativeSM is an NIH-wide effort to improve prevention and treatment strategies for opioid misuse and addiction and to enhance pain management.

OPIOID CRISIS


Did you know that women who drink have a higher risk of certain alcohol-related problems than men?

- Women who regularly misuse alcohol are more likely to develop alcoholic hepatitis and alcohol-related heart disease than men
- Alcohol misuse produces brain damage more quickly in women than men
- Women who have ~1 drink/day also have a 5–9% higher chance of developing breast cancer than women who don't drink

National Institute on Alcohol Abuse and Alcoholism emphasizes SABV in a large proportion of its funding opportunities



NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM



"An Estimated 92% of Cancers Caused by HPV Could be Prevented by vaccine."

CDC

NIH scientists developed the technology underlying the vaccine


Human papillomavirus (HPV) vaccination with booster shots offers durable protection against the types of HPV that cause almost all cases of cervical cancer. In addition, more than 1/3 of HPV-associated cancers are diagnosed in males (e.g., oropharyngeal) – more than half of oropharynx cancers are type 16.

National Cancer Institute

An NIH-funded clinical trial, with support from ORWH, is testing the efficacy of a single-dose HPV vaccine against cervical cancers. "A single dose of bivalent HPV vaccine may induce sufficiently durable protection that obviates the need for more doses."

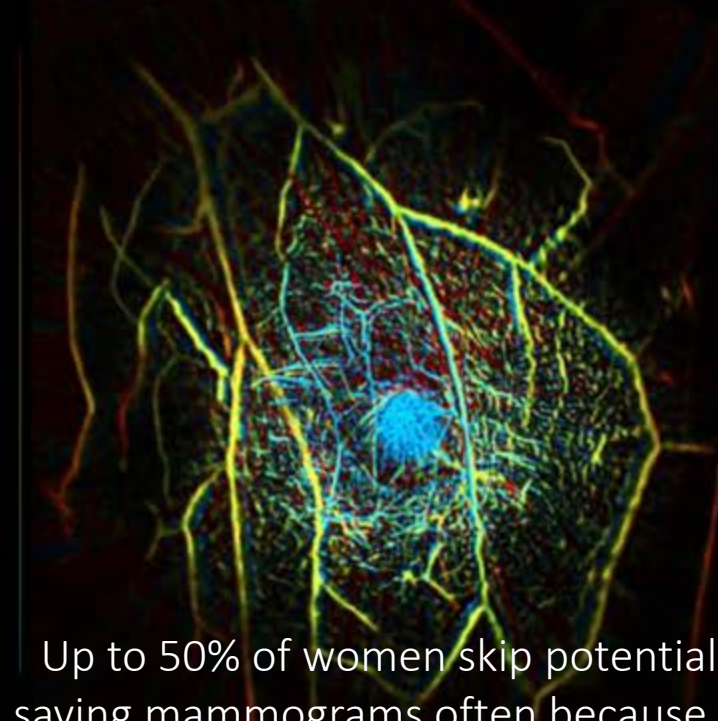
J Natl Cancer Inst. 2020. doi: 10.1093/jnci/djaa011

HPV VACCINE



A new painless, fast,
light-based, non-
radioactive procedure
could revolutionize
breast cancer screening
and save lives.

National Institute of Biomedical Imaging
and Bioengineering



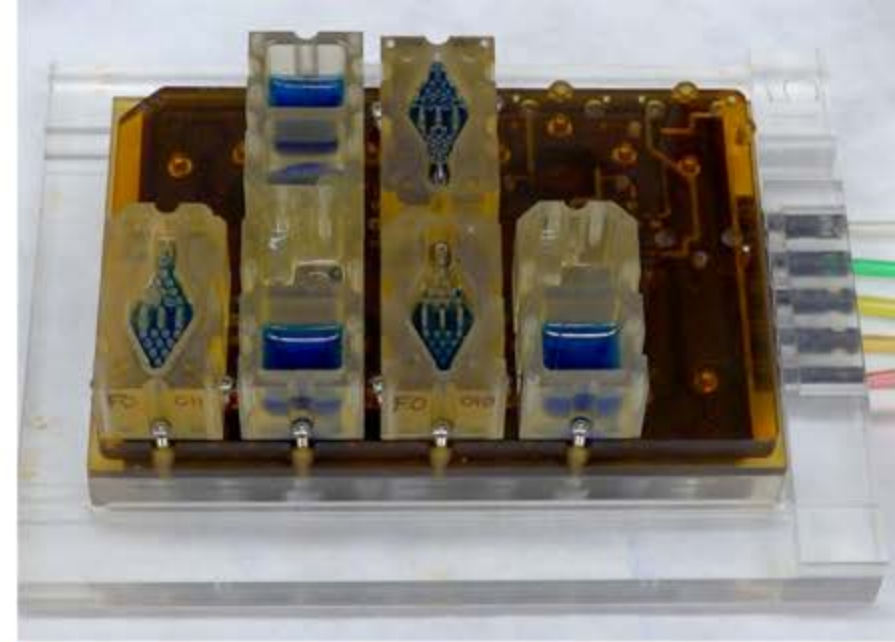
Up to 50% of women skip potentially life-saving mammograms often because of the extreme discomfort and pain. In a small study, photoacoustic-computed tomography correctly detected 8 of 9 breast tumors present in the 8 women.

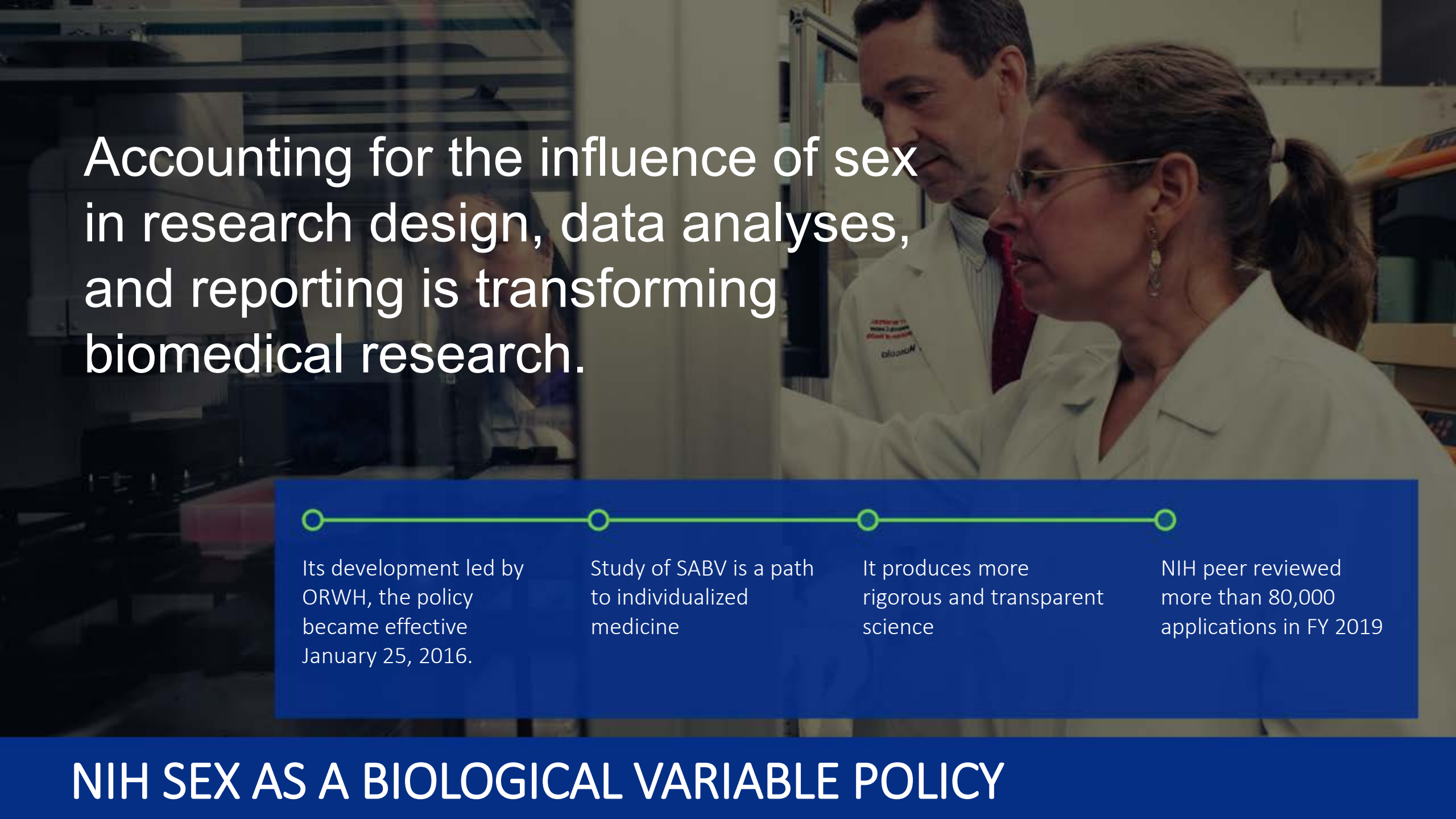
<https://www.nibib.nih.gov/news-events/newsroom/light-based-15-second-scan-aims-replace-painful-mammograms>

BIOENGINEERING ADVANCES

The EVATAR™ miniaturized 3-D models of reproductive organs and liver are helping predict the safety and efficacy of new drugs.

- In 2012, the National Center for Advancing Translational Sciences (NCATS) launched a collaboration with the Defense Advanced Research Projects Agency and FDA to develop 3-D chips with living cells and tissues to more accurately model human organs.
- A main goal is to address the high rate of failure of candidate medications due to their toxicity or lack of efficacy when they reach human trials.
- EVATAR™ is being used to model PCOS (polycystic ovary syndrome) and test candidate therapeutics. It could pave the way toward improved reproductive health testing for conditions like infertility, endometriosis, uterine fibroids, and female cancers.





Accounting for the influence of sex in research design, data analyses, and reporting is transforming biomedical research.



Its development led by ORWH, the policy became effective January 25, 2016.



Study of SABV is a path to individualized medicine

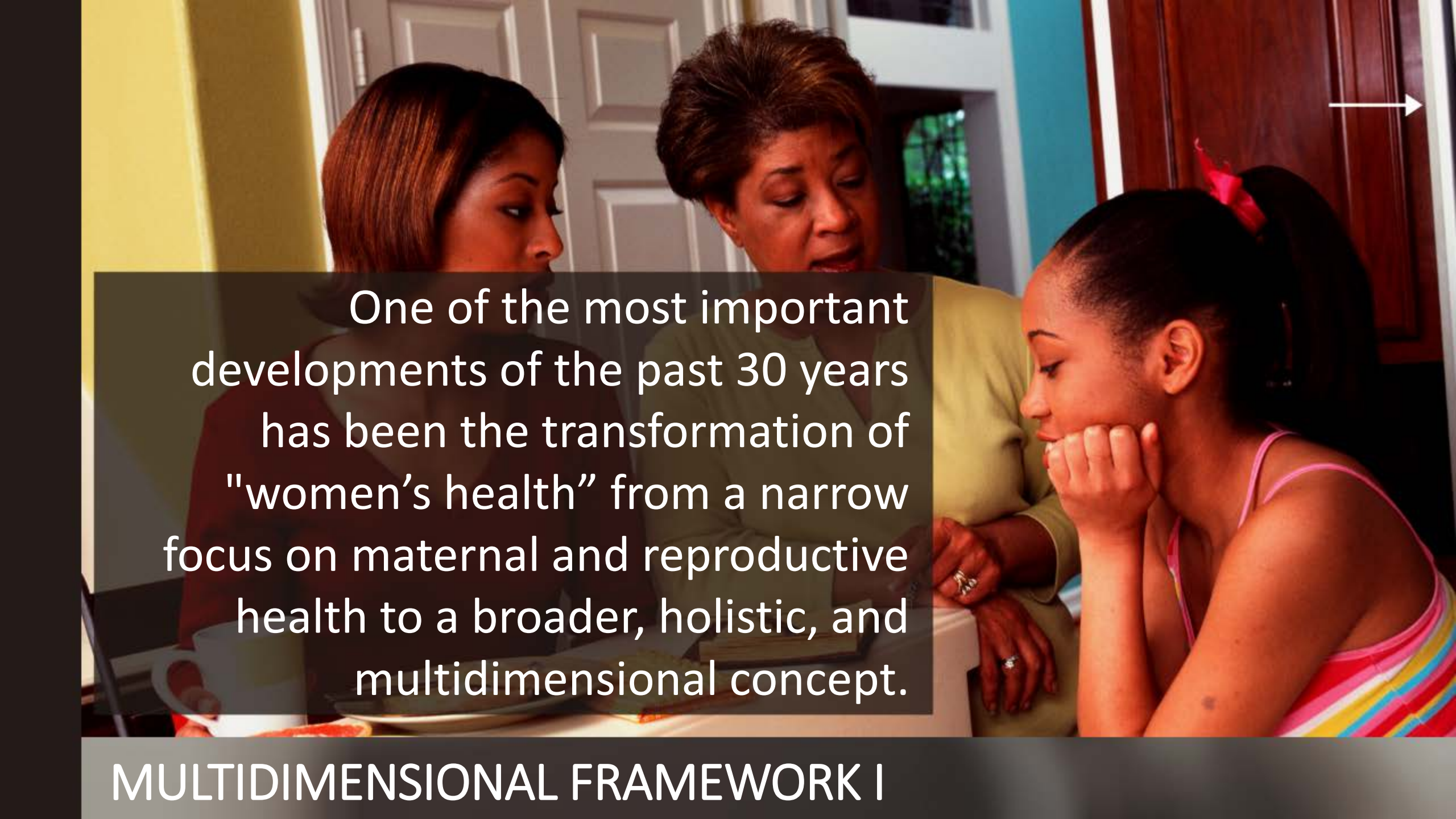


It produces more rigorous and transparent science



NIH peer reviewed more than 80,000 applications in FY 2019

NIH SEX AS A BIOLOGICAL VARIABLE POLICY



One of the most important developments of the past 30 years has been the transformation of "women's health" from a narrow focus on maternal and reproductive health to a broader, holistic, and multidimensional concept.

MULTIDIMENSIONAL FRAMEWORK I

Women are incredibly diverse; many internal and external factors affect a woman's health – from **head to toe** and across her **life course**.

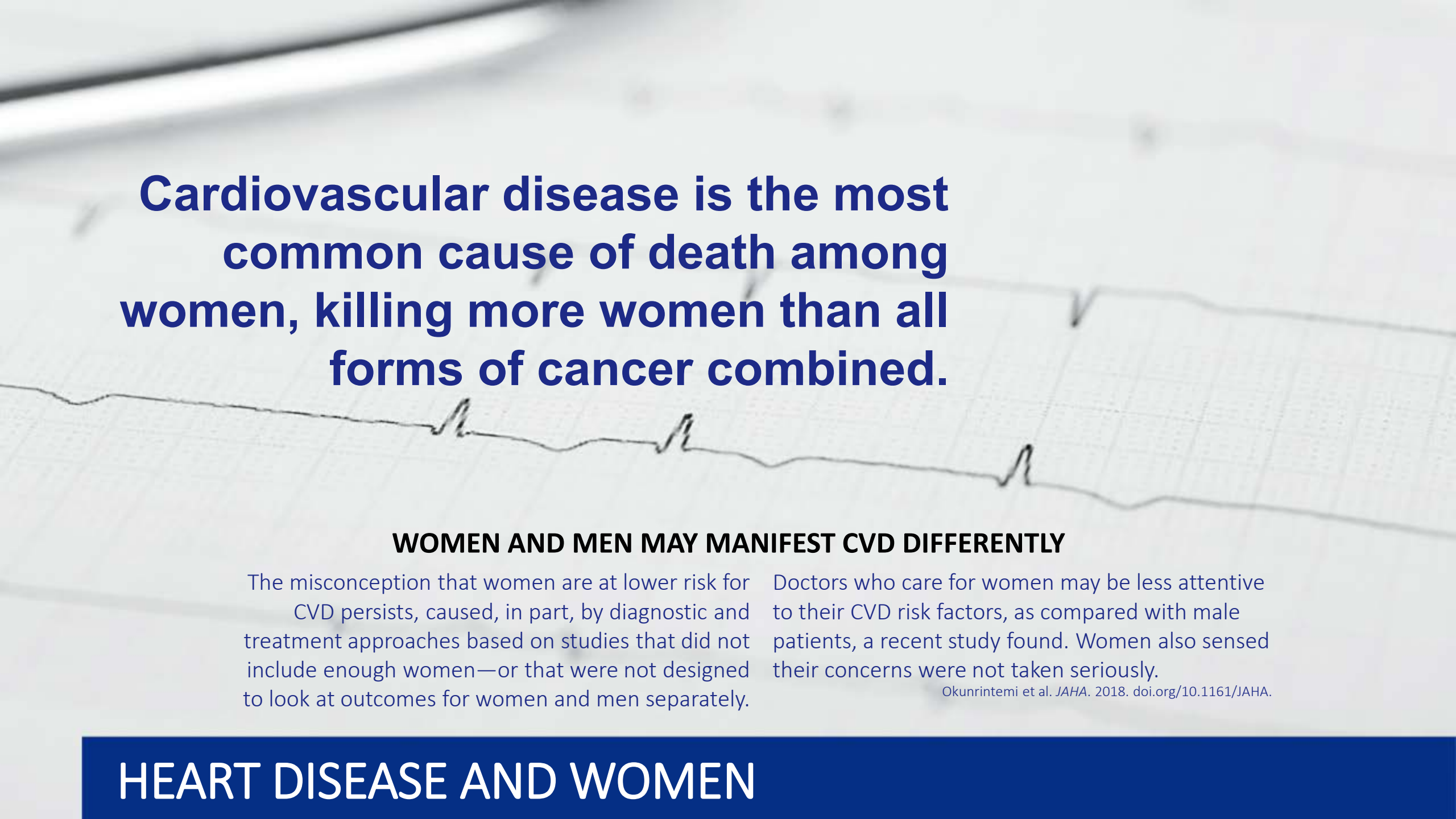


INTERNAL

Factors include sex influences at genetic, molecular, cellular, and physiological levels

EXTERNAL

Factors include gender, social determinants of health, behaviors, environment, and policies

The background of the slide is a blurred ECG (heart rate) tracing on a grid. The text is overlaid on this background.

Cardiovascular disease is the most common cause of death among women, killing more women than all forms of cancer combined.

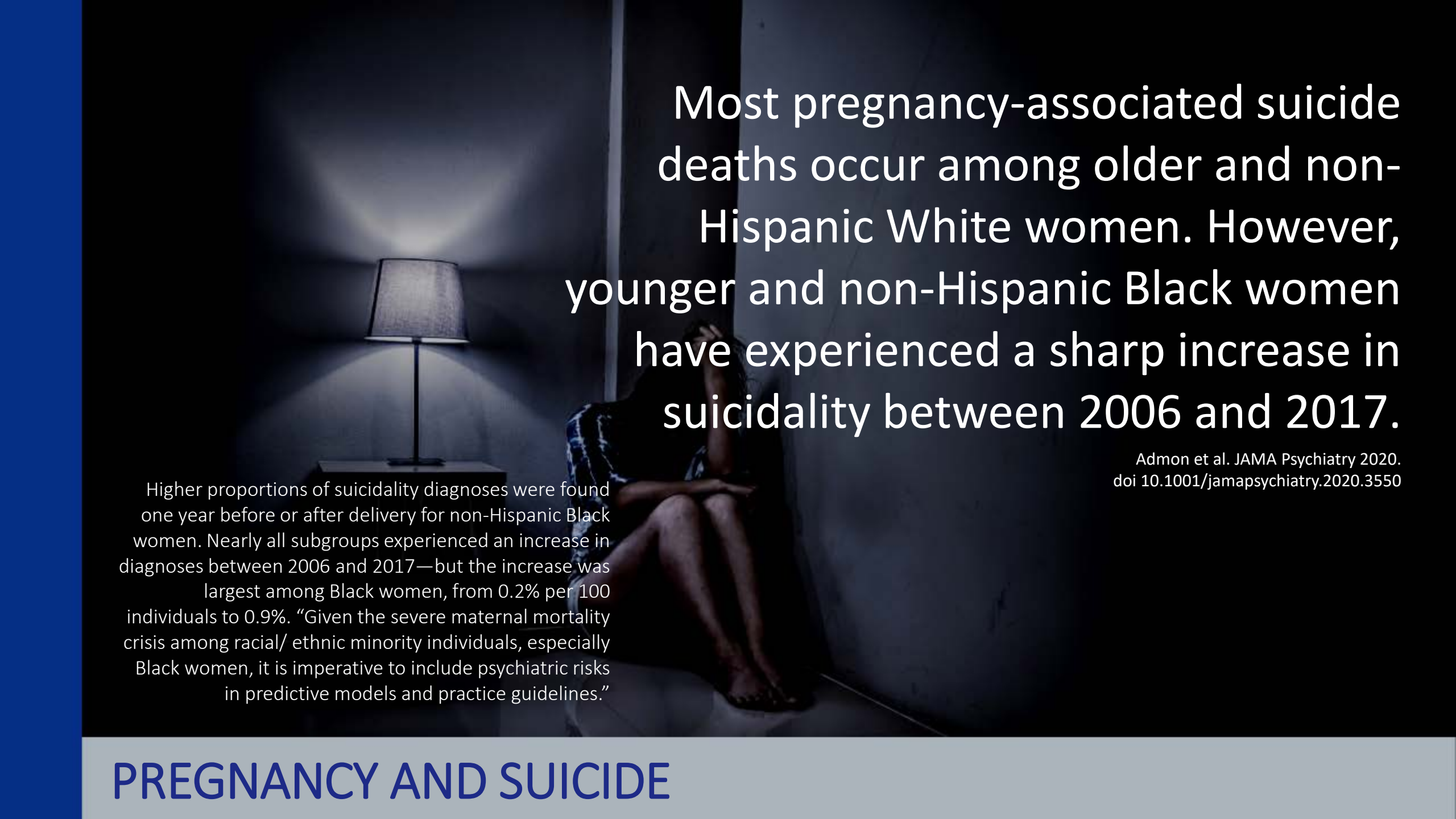
WOMEN AND MEN MAY MANIFEST CVD DIFFERENTLY

The misconception that women are at lower risk for CVD persists, caused, in part, by diagnostic and treatment approaches based on studies that did not include enough women—or that were not designed to look at outcomes for women and men separately.

Doctors who care for women may be less attentive to their CVD risk factors, as compared with male patients, a recent study found. Women also sensed their concerns were not taken seriously.

Okunrintemi et al. *JAMA*. 2018. doi.org/10.1161/JAHA.

HEART DISEASE AND WOMEN

A woman is sitting on a chair in a dimly lit room. To her left is a small table with a lamp that has a textured shade. The room is dark, with light coming from the lamp and possibly a window or doorway in the background. The woman is wearing a dark, patterned dress and has her hands clasped in her lap. The overall mood is somber and contemplative.

Most pregnancy-associated suicide deaths occur among older and non-Hispanic White women. However, younger and non-Hispanic Black women have experienced a sharp increase in suicidality between 2006 and 2017.

Admon et al. JAMA Psychiatry 2020.
doi 10.1001/jamapsychiatry.2020.3550

Higher proportions of suicidality diagnoses were found one year before or after delivery for non-Hispanic Black women. Nearly all subgroups experienced an increase in diagnoses between 2006 and 2017—but the increase was largest among Black women, from 0.2% per 100 individuals to 0.9%. “Given the severe maternal mortality crisis among racial/ ethnic minority individuals, especially Black women, it is imperative to include psychiatric risks in predictive models and practice guidelines.”

PREGNANCY AND SUICIDE


NIH research may bring relief to the 4-8 million women who suffer from a chronic, debilitating condition whose physical and physiological impact greatly decreases their quality of life.



Interstitial cystitis (IC), or bladder pain syndrome (BPS), also affects 1–4 million men in the U.S. The Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network was established by the National Institute of Diabetes and Digestive and Kidney Diseases with support from ORWH.

Network studies have yielded new insights into associated brain changes, whole-body pain patterns symptom flares, and the relationship between IC/BPS and other chronic pain disorders.

INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME



**NIH-funded researchers
are targeting 3
conditions that have
long impacted women's
health and quality of life.**

ALZHEIMER'S DISEASE

Women are two-thirds of the people diagnosed with Alzheimer's disease. The 2011 National Alzheimer's Project Act called for a coordinated national plan to accelerate research and provide better care for people living with dementia. Milestone 2.D focuses on understanding sex differences in brain aging trajectories, categories of risk, and responsiveness to treatment.

National Institute on Aging

RHEUMATOID ARTHRITIS


With rheumatoid arthritis, an autoimmune disease that affects women more often than men, the immune system attacks the body, resulting in tissue damage and dysfunction. NIH-supported research that began in the 1990s led to the development of tofacitinib, which was approved by the FDA in 2012.

National Institute of Arthritis and
Musculoskeletal and Skin Diseases

MATERNAL HEALTH

Pregnant women in rural and medically underserved communities experience challenges in their access to prenatal, obstetric, and postnatal care. The National Institute of General Medical Sciences and ORWH recently announced supplemental funding for Institutional Development Award program grant awards to address maternal and infant morbidity and mortality.

PROMISE OF BIOMEDICAL RESEARCH



By seeking to explain why COVID-19 affects women and underserved and vulnerable populations differently, NIH research could save millions of lives.

APPLYING A SEX-AND-GENDER LENS

To bring a sex-and-gender lens to COVID-19 studies, ORWH has signed onto 15 FOAs; updated its Signature programs, U3, R01, and Sex and Gender NOSIs; and co-funded 2 Administrative Supplements.

SEEKING ANSWERS ON:

- Risk factors associated with disease prevalence among health disparity populations, women living in underserved rural or urban settings, pregnant and lactating women, and women frontline healthcare workers, among others
- Immediate and downstream impacts of containment and mitigation on economic, social, and personal well-being
- Effectiveness of community interventions in slowing spread
- Strategies to increase access to and quality of digital health interventions and diagnostics for health disparate populations
- Sex and gender influences in access to care
- Risk of adverse maternal and perinatal health outcomes among pregnant women with opioid use disorder

ON WOMEN SCIENTISTS & RESEARCH

Pandemic-related household and caregiving responsibilities are interrupting research and impeding publishing, which can impede advancement. Impact on early-career investigators is especially devastating. Women's departure and slowed advance will affect the direction of research for many years.

We've made so many more scientific advances to improve the health of women over the past 30 years.

These are just a few of NIH's many initiatives and advances in women's health research. Visit [ORWH's 30th anniversary](#) webpage to learn about other NIH breakthroughs in women's health research.

RECORD OF ACHIEVEMENT



**“WE’RE CHARTING OUR
COURSE. STAY CONNECTED
WITH US AND JOIN US ON OUR
JOURNEY FORWARD!”**

We strive for continued progress in women’s health research – in pursuit of the NIH vision in which sex and gender influences are integrated into the biomedical research enterprise and every woman receives evidence-based disease prevention and treatment tailored to her own needs, circumstances, and goals.

 /NIHORWH

 @NIH_ORWH

 nih.gov/women

#ResearchForWomen #ORWHturns30



**OFFICE OF RESEARCH
ON WOMEN’S HEALTH**

*Advancing the Health of
Women Through Science*