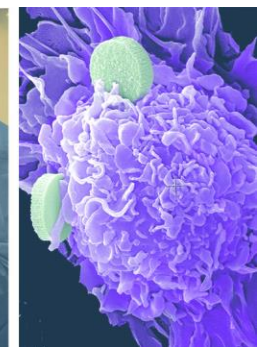
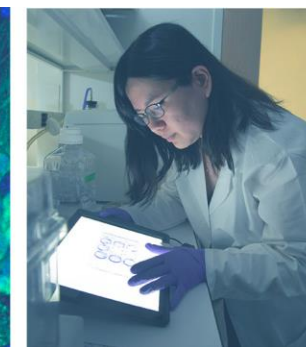
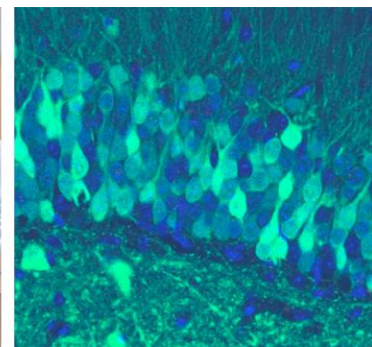
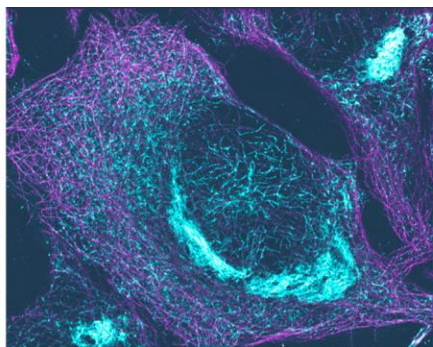
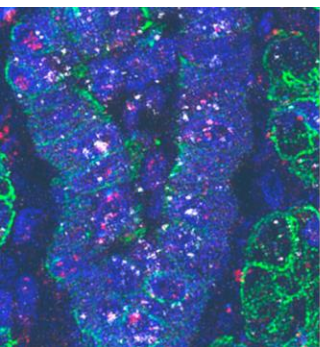


# Toward Evidence-Based Health Care for Women and for All

60<sup>th</sup> Meeting of the NIH Advisory Committee on Research on Women's Health  
April 9, 2024



**Monica M. Bertagnoli, MD**  
Director, National Institutes of Health



# Today's Discussion

- Introducing myself
- My vision for NIH
  - Trends in the health of the U.S. population
  - Guiding principles
  - What should NIH do?
- Support for women's health research
  - White House Women's Health Initiative
  - Mid-life health and menopause
  - NIH efforts





# About Me

# Career timeline



Wyoming ranch



 PRINCETON UNIVERSITY



University of Utah School of Medicine



Brigham and Women's Hospital



*Began work on Familial adenomatous polyposis (FAP)*



**NewYork-Presbyterian**  
The University Hospital of Columbia and Cornell





*Elected to  
National  
Academy of  
Medicine*

*Chair,  
Alliance for  
Clinical Trials  
in Oncology*

**Director,  
National  
Cancer  
Institute**

**Director,  
National  
Institutes of  
Health**



**Harvard  
Medical  
School**



**Dana-Farber  
Cancer Institute**

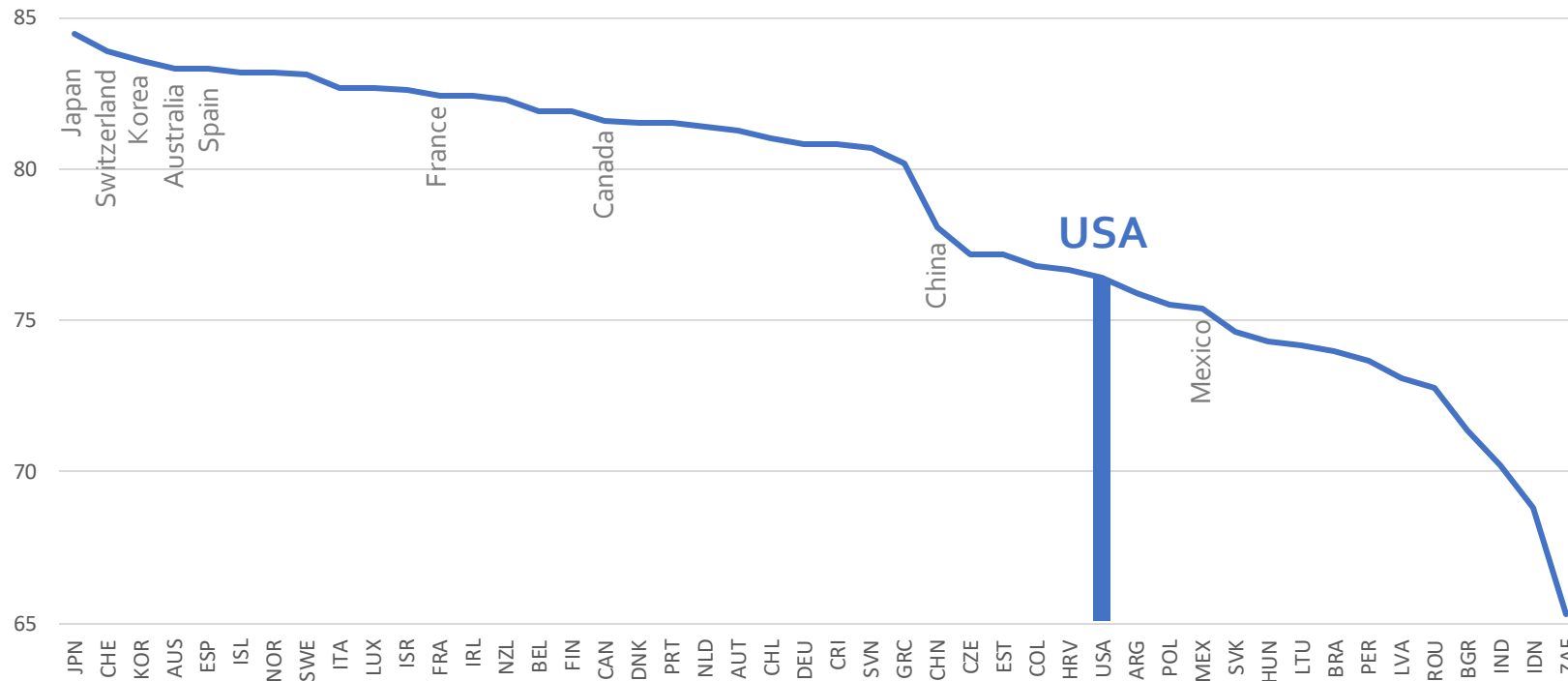




# Disturbing trends in the health of the U.S. population

# U.S. life expectancy ranks low among peers

2021 Life Expectancy Throughout World<sup>3</sup>



## Concerning U.S. life expectancy trends:

- Declined 2014-2017<sup>1</sup>
- Dropped significantly—2.4 years—between 2019 and 2021<sup>2</sup>
- Increased in 2022 by 1.1 years; gain does not make up for pandemic losses.<sup>2</sup>

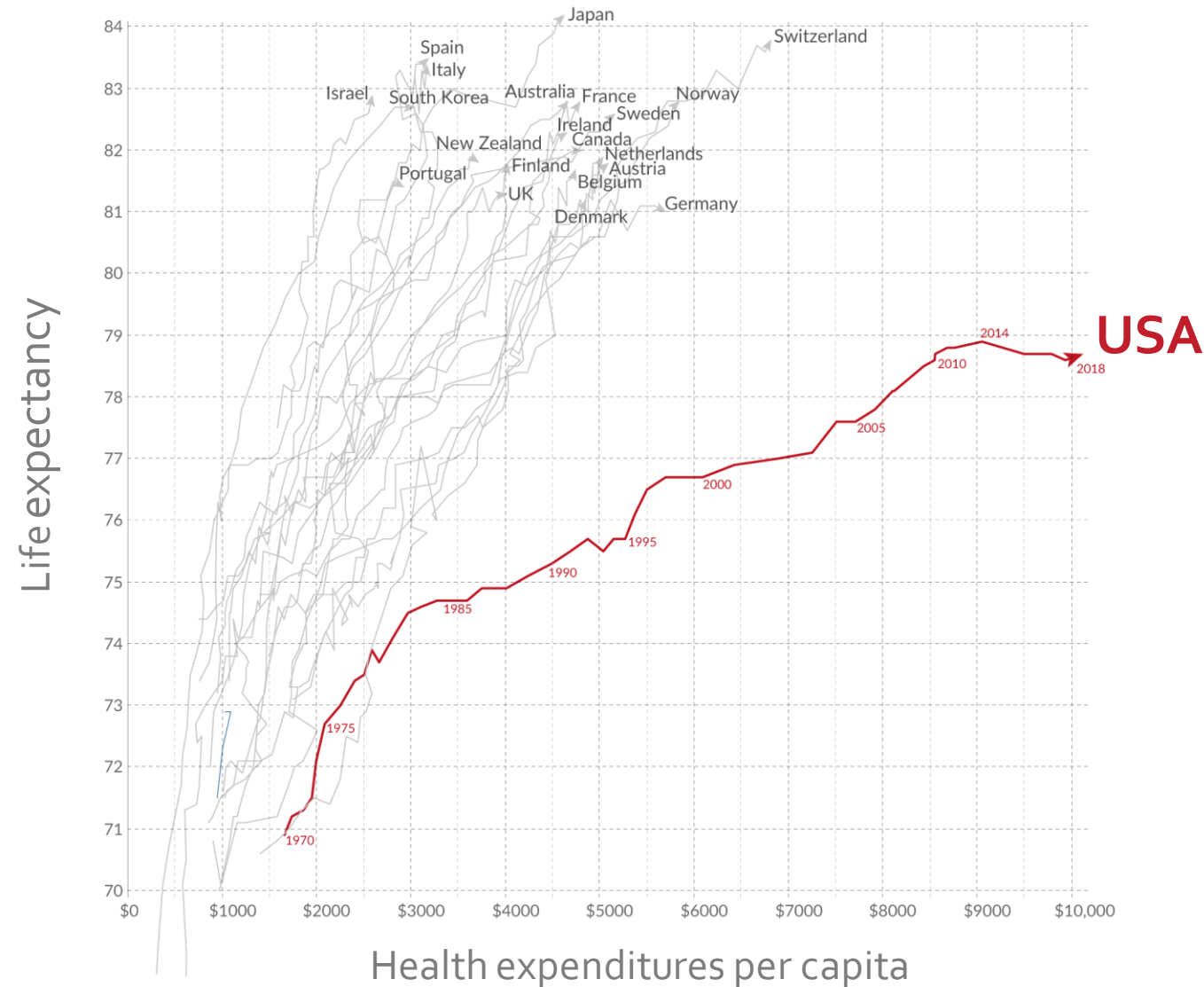
(1) National Academies of Sciences, Engineering, and Medicine. 2021. *High and Rising Mortality Rates Among Working-Age Adults*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25976>.

(2) Arias E, Kochanek KD, Xu JQ, Tejada-Vera B. Provisional life expectancy estimates for 2022. Vital Statistics Rapid Release; no 31. Hyattsville, MD: National Center for Health Statistics. November 2023. <https://dx.doi.org/10.15620/cdc:133703>.

(3) Chart data: OECD (2024), Life expectancy at birth (indicator). DOI: 10.1787/27e0fc9d-en (Accessed on 10 January 2024)

# Life expectancy vs. health expenditures

1970-2018



Source: Max Roser (2020) - "Why is life expectancy in the US lower than in other rich countries?" Published online at OurWorldInData.org. Retrieved from: 'https://ourworldindata.org/us-life-expectancy-low' Data source for table: Organisation for Economic Co-operation and Development (OECD)



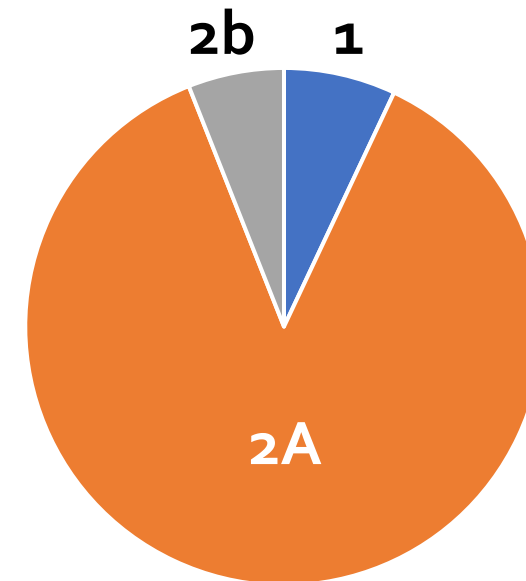
## Category of evidence and consensus underlying National Comprehensive Cancer Network guidelines: Is there evidence of progress?

Aakash P Desai <sup>1</sup>, Ronald S Go <sup>2</sup>, Thejaswi K Poonacha <sup>3</sup>

### NCCN Levels of Evidence

- 7%** **Category 1:** High level evidence such as randomized controlled trials with uniform consensus
- 87%** **Category 2A:** Lower level of evidence with uniform consensus
- 6%** **Category 2B:** Lower level of evidence without a uniform consensus but with no major disagreement
- 0%** **Category 3:** Any level of evidence but with major disagreement

Distribution in 2019



# Guiding Principles







Our work is not finished when we deliver scientific discoveries, our work is finished when all people are living long and healthy lives.







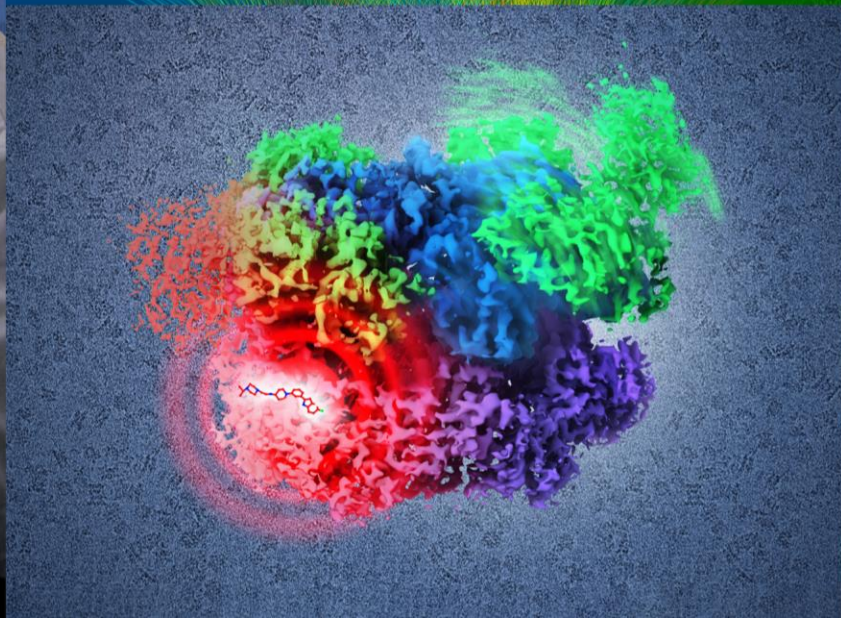
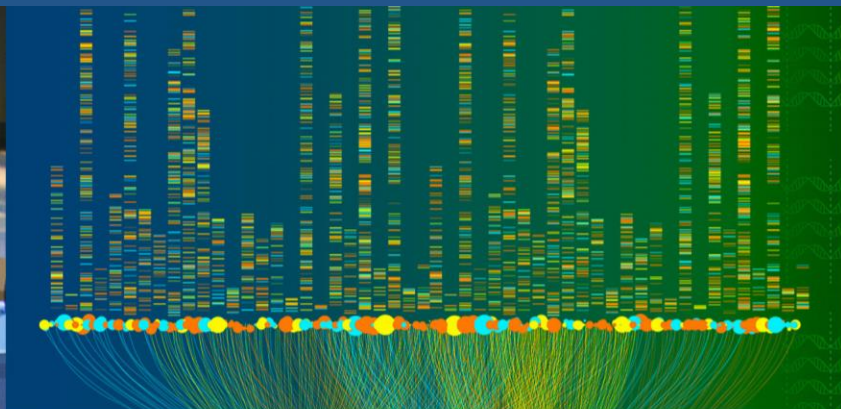
NIH research encompasses the laboratory, the clinic, and the community.







Progress is accelerated when advanced scientific methods, such as new data analytics, are applied to data that includes everyone, and when new discoveries are rapidly and equitably adopted in clinical care.







# What Should NIH Do?



# Connect research to primary care to optimize outcomes for patients



Meet people where they already **receive care** to better engage underrepresented communities in research.



Use **EHR** to respectfully engage people in research with their permission.



Increase research capabilities and efficiency with **innovative study designs** that address common health issues, prevention and implementation relevant to individual communities.



Rapidly **disseminate evidence** to guide patient and provider decisions.

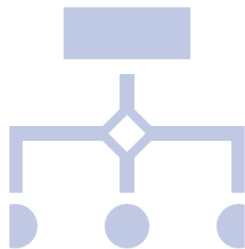
# Expand biomedical research data use to inform new research and improve health outcomes



**Integrate** data from basic and social science research, public health, and clinical care.



Increase capacity for data hosting,  
Enable low-cost **access** to data using open-industry data standards,  
Support broad access to advanced analytics and computational power.



Employ a **federated architecture** for data sharing and use.



Provide **education** and workforce development.



# Federal support for women's health









President Biden's  
Executive Order To  
**Advance Research  
on Women's Health**  
As part of the  
White House Initiative  
on Women's  
Health Research

Integrate women's health across the federal research portfolio

Help unlock innovation and open new doors to breakthroughs in women's health

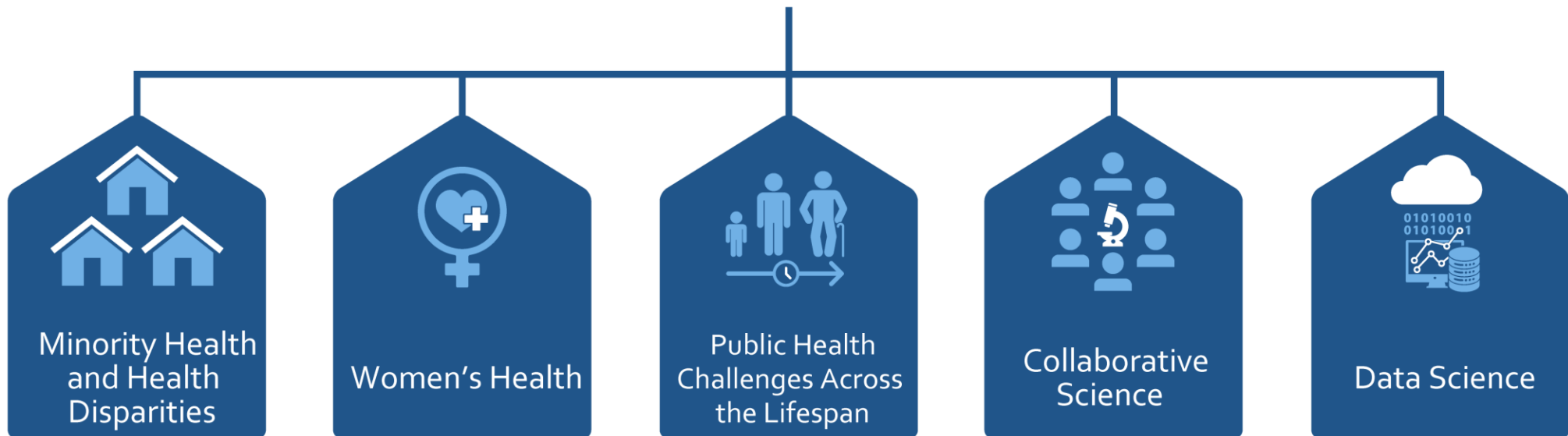
Galvanize research on diseases and conditions associated with women's midlife health

Assess gaps in funding for women's health research

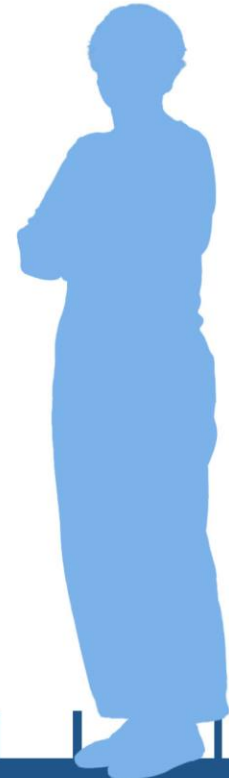
# Women's Health: A cross-cutting theme in the NIH-Wide Strategic Plan

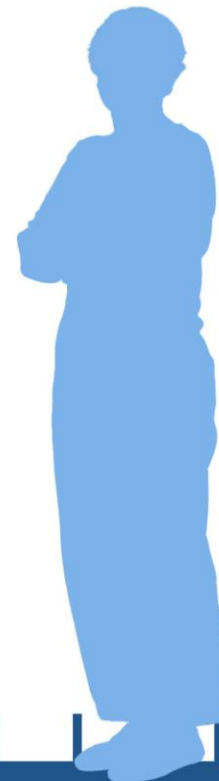
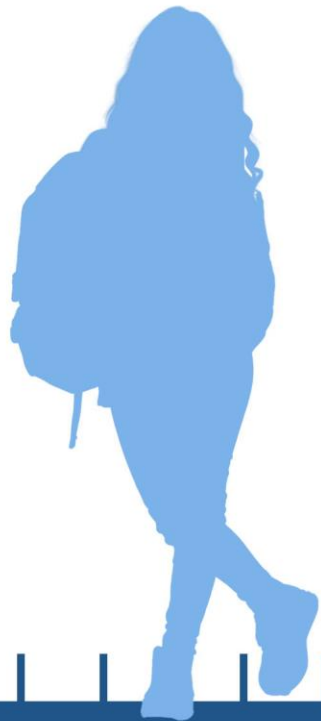
## NIH-Wide Strategic Plan Framework

### CROSSCUTTING THEMES

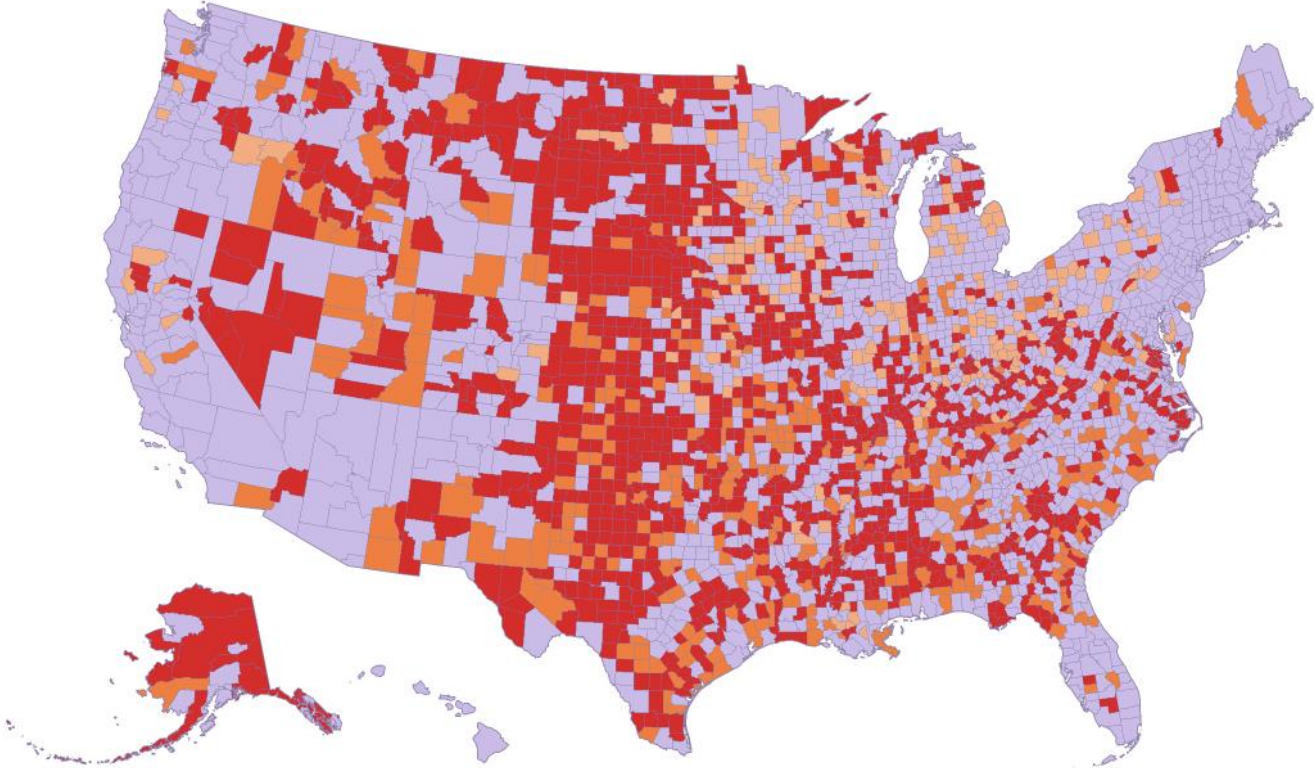








# Nearly 7 million women have no or limited access to maternity care



- Maternity Care Deserts
- Low Access to Maternity Care
- Moderate Access to Maternity Care
- Full Access to Maternity Care

Maternity Care Deserts, 2020  
Source: U.S. Health Resources and Services Administration (HRSA), Area Health Resources Files, 2021



# Improving Maternal Health with Community-Engaged Research Interventions



## Initiative Purpose

*Supports research to reduce preventable causes of maternal deaths and improve health for women before, during, and after pregnancy.*

## Select Initiative Functions

- Focusing on racial/ethnic minorities, very young women, older mothers, and women with disabilities
- Reducing maternal morbidity and mortality and health disparities through community-engaged partnerships
- Addressing cerebrovascular disease and hypertension
- Partnering across NIH



# Harnessing the Power of Implementation Science for Maternal Health Equity

IMPROVE-Community Implementation Program (IMPROVE-CIP)

## Promoting health equity

- **Community-engaged research** before, during, and after pregnancy
- Building **trust and strong partnerships** that encourage maternal health
- Developing and testing **implementation strategies** to increase use of **evidence-based interventions**

IMPROVE-CIP University of Nebraska Research Coalition

Multi-level intervention to increase kinship involvement and improve maternal health outcomes, including mental health, in the **Winnebago Tribe**



# Addressing Maternal Health Inequity in the Primary Care Setting

## CEAL Primary Care Research Network (CEAL-CAREnet)

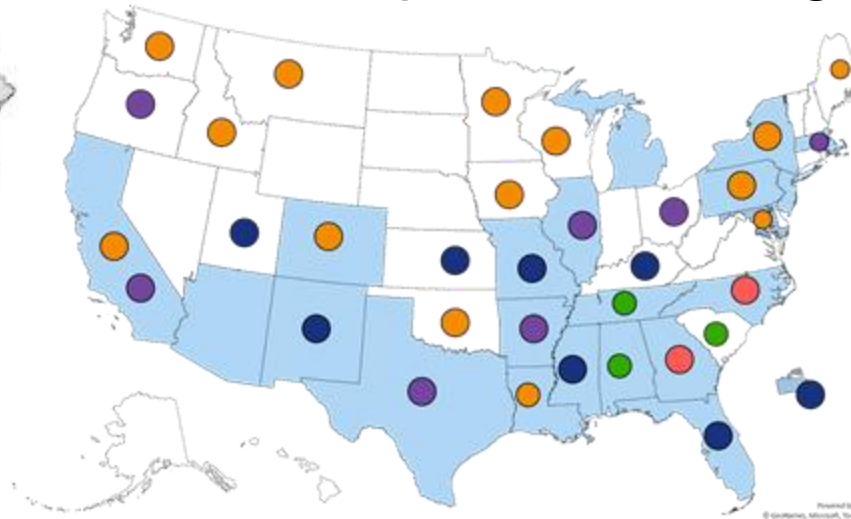
Maternal Mortality/Morbidity across the U.S...



Maternal Mortality Rate

10.2-20.2	20.5-25.2	28.2-40.4	N/A
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... can be addressed through CEAL's Network of Primary Care Research Programs



○ OCHIN members    ● OCHIN & SERCN members    ● HCN members  
● CEAL    ● OCHIN & HCN members    ● OCHIN & SERCN & HCN members

### CEAL-CAREnet Footprint

Includes 40 states/territories, leveraging:

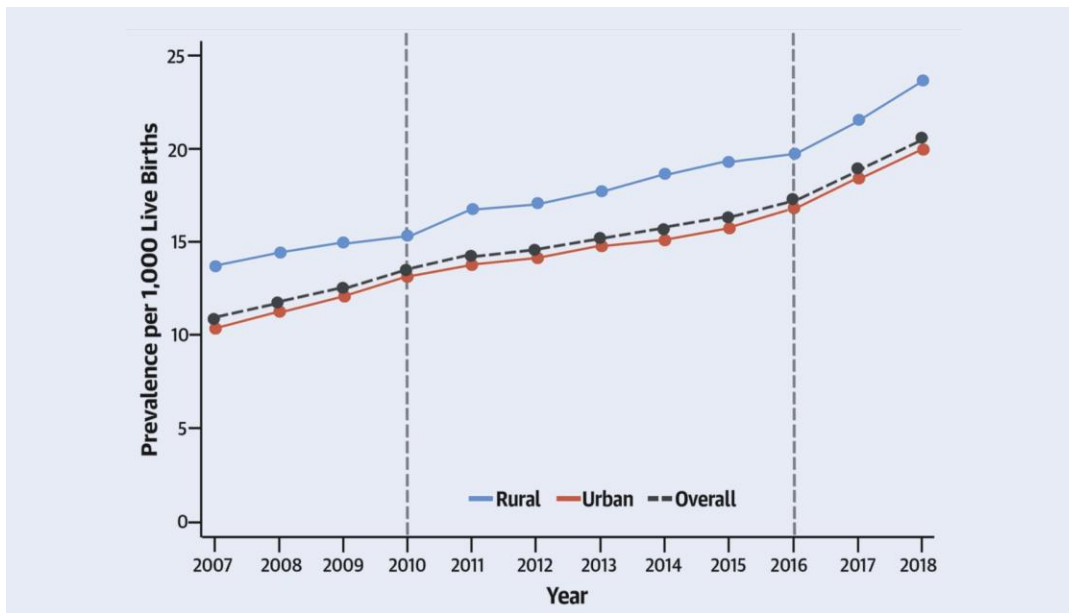
- CEAL Regional Teams
- FQHCs, including community health centers, within
  - OCHIN Network
  - SERCN Network
  - HCN Network



# Expanding Knowledge of Effective Interventions and Putting Them Into Practice

## Chronic Hypertension (CHTN) in Pregnancy

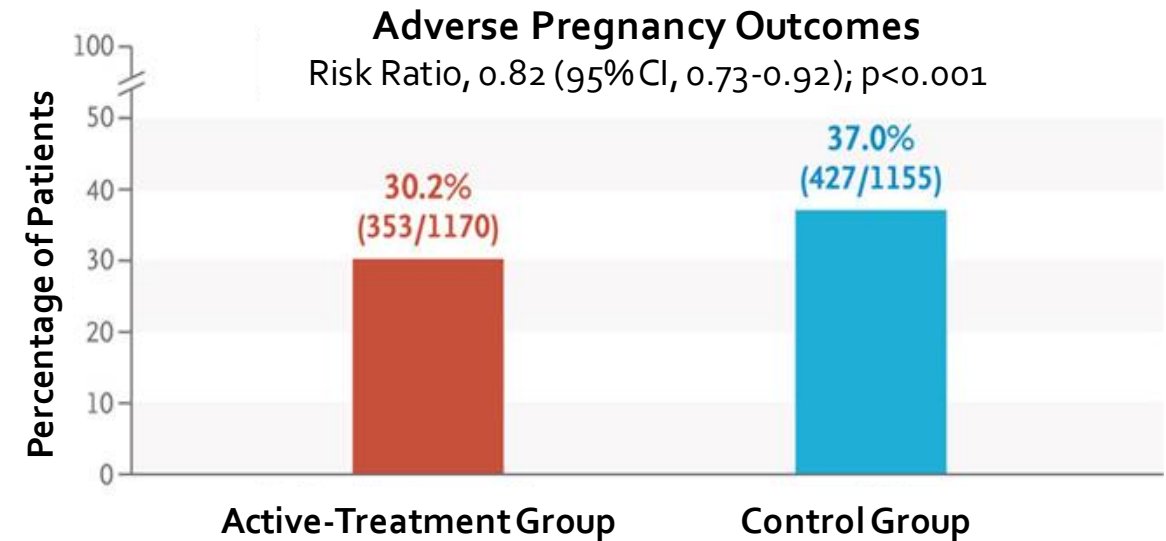
Disturbing trend in pre-pregnancy hypertension, with significant urban-rural disparities



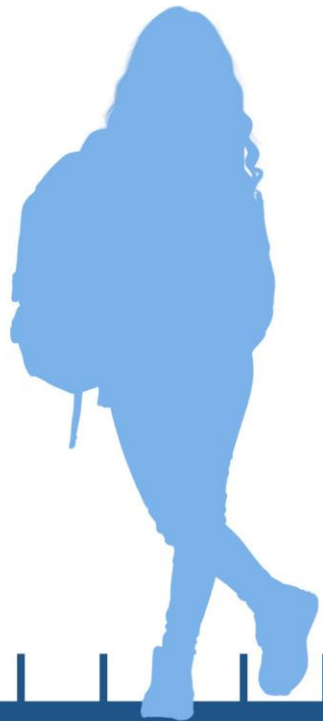
Cameron et al. *J Am Coll Cardiol.* 2020.

## CHAP Chronic Hypertension and Pregnancy Trial

Treatment of mild chronic hypertension during pregnancy reduced adverse pregnancy outcomes, changing clinical guidance



Tita et al. *NEJM.* 2022



# Preventing Chronic Disease in Older Women: The Women's Health Initiative

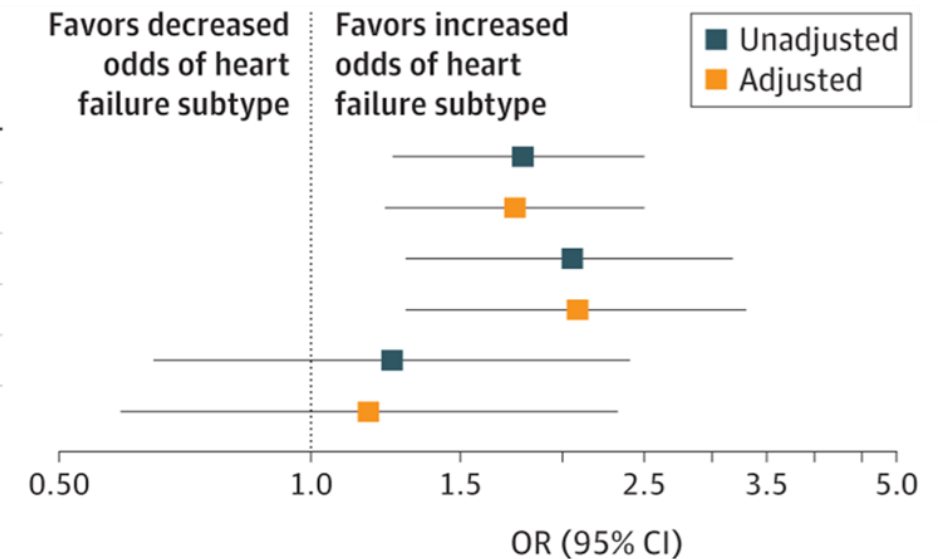


## Women's Health Initiative (WHI)

- Est. 1991
- 161,808 postmenopausal women, aged 50-79
  - 3 clinical trials
  - 1 observational Study
- Public Health Impact of Hormone Trials
  - 76,000 fewer CVD cases
  - 126,000 fewer breast cancer cases

## WHI: Hypertensive Disorders of Pregnancy Associated with Incident Heart Failure in Postmenopausal Women

	OR (95% CI)
Total HF	1.77 (1.25-2.50)
	1.75 (1.22-2.50)
HFpEF	2.04 (1.30-3.19)
	2.06 (1.29-3.27)
HFrEF	1.24 (0.64-2.39)
	1.17 (0.59-2.30)



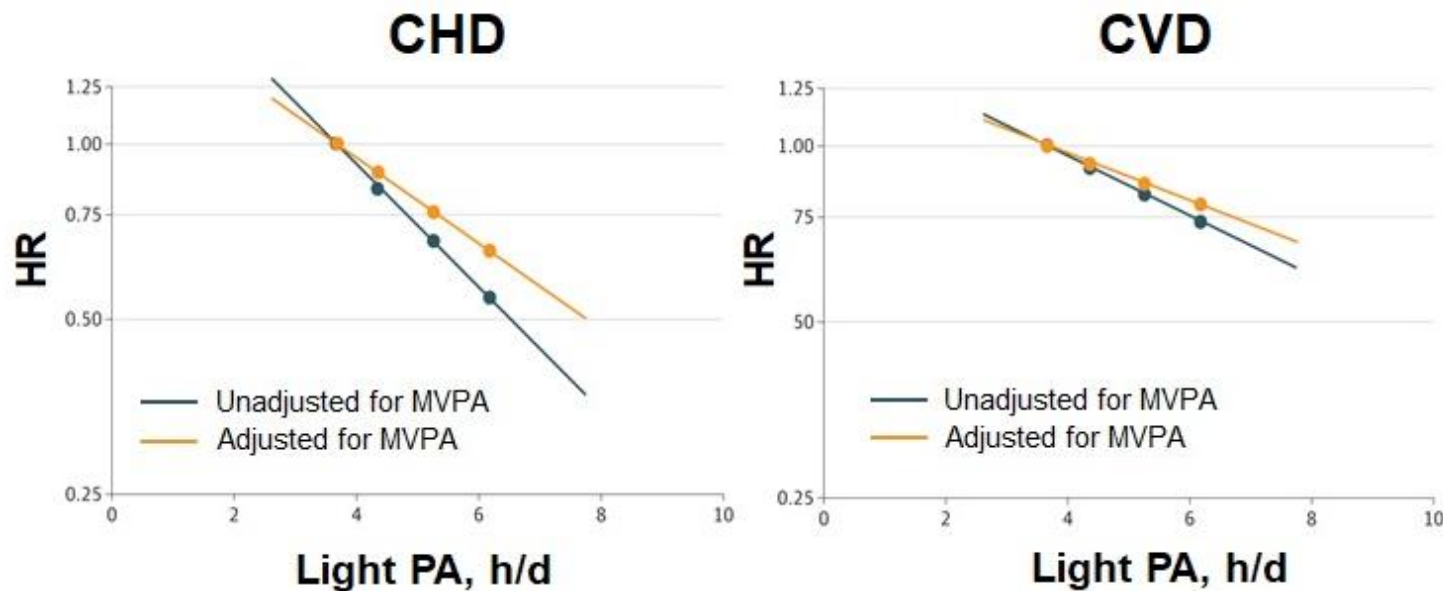


# Physical Activity and Health for Older Women

## Observational

### The WHI Objective PA and Cardiovascular Health Study (OPACH)

Light physical activity associated with reduced risk of CHD or CVD



## Interventional

### WHI Strong and Healthy Study (WHISH)

Ongoing PA intervention trial for CVD prevention in ~50,000 older women



# Promising research on endometriosis pain

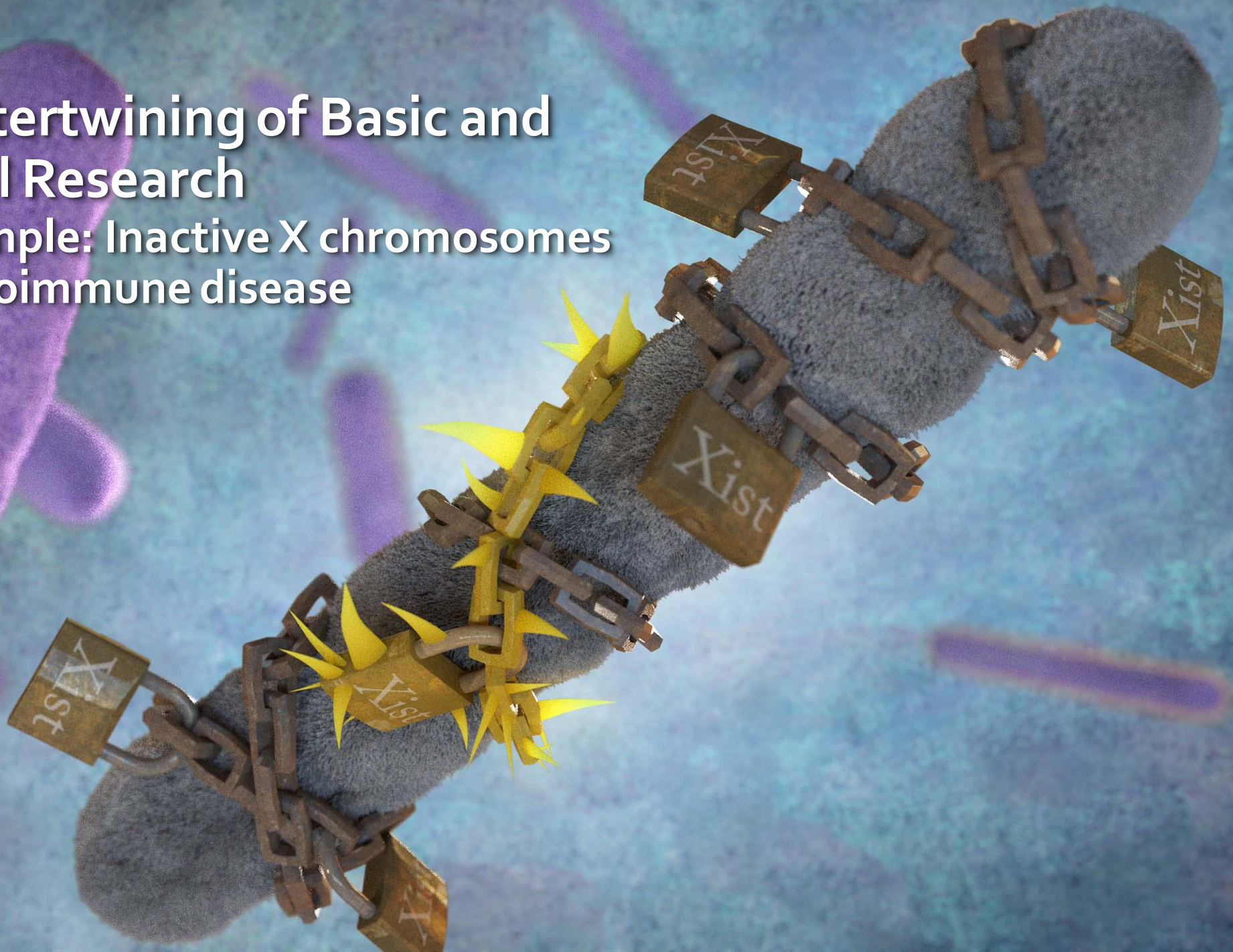
- A repurposed drug—the NSAID fenoprofen—alleviated pain and inflammation in a rodent model of endometriosis



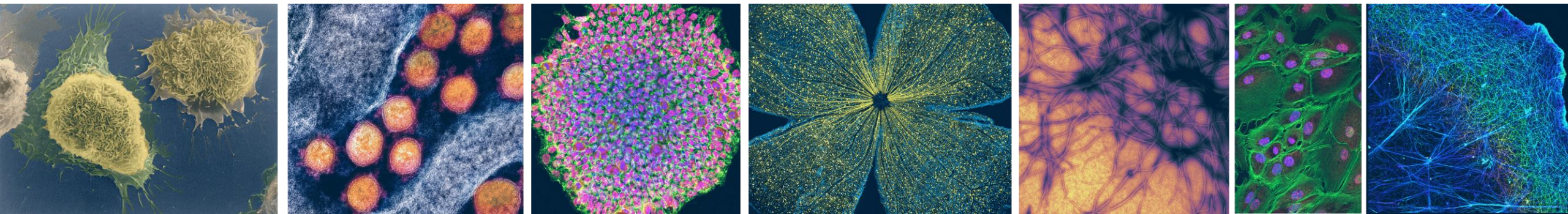


# The Intertwining of Basic and Clinical Research

An example: Inactive X chromosomes and autoimmune disease







# NIH

*Turning Discovery Into Health*

