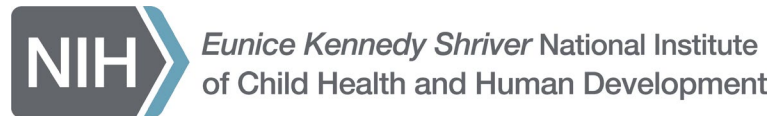


NICHD Director's Report ***NACHHD Meeting***

Diana W. Bianchi, M.D.

September 4, 2024



Talk Outline

- FY25 Appropriations Bills and Transition
- Women's Health Research
 - Women's Health Research Initiative, Endometriosis, IMPROVE Initiative
- Pediatric Research
 - Injury Prevention, Mood Disorders and Driving, Adversity and Development, Reducing Unnecessary CT Scans
- Rehabilitation Research
- Training
- Kudos!
- Hiring and Resources



FY25 Appropriations Bills and Transition

FY25 House Appropriations Bill

- **House Appropriations Bill**

- NIH - \$48.6B (increase over FY24 enacted level of \$47.1B)
- Proposed reorganization of NIH from 27 to 15 institutes
 - NICHD and NIDCD would merge to become the National Institute for Disability Related Research
 - Proposed \$2.3B budget (approximate combined FY24 total for NICHD and NIDCD)
 - Opportunity for public comment on Energy & Commerce report closed Aug. 16



FY25 Senate Appropriations Bill

- **Senate Appropriations Bill**

- \$50.3B (increase over FY24 enacted level)
- \$20M additional funding for IMPROVE Initiative (NICHD base)
- \$76M in additional funding for Office of Research on Women's Health at NIH
- Term limits for IC Directors (10 years)

- **Sen. Cassidy White Paper**

- NIH in the 21st Century: Ensuring Transparency and American Biomedical Leadership
- <https://www.help.senate.gov/nih-modernization-5924pdf>



2024 Election and Presidential Transition

- The NIH Director is a political appointment requiring Senate confirmation.
- During a Presidential transition, all political appointees customarily submit a letter of resignation, which will then be accepted or rejected by the incoming President.
- NIH works with HHS to prepare Presidential transition informational briefing documents across NIH research priorities.
 - For NICHD, examples include intellectual and developmental disabilities, reproductive health, maternal health, rehabilitation research



Women's Health “Below the Belt”



Gynecologic Health and Disease

Contraception Research

Fertility and Infertility

Pregnancy and Perinatology

Maternal and Pediatric Infectious Disease

Obstetric and Pediatric Pharmacology and Therapeutics

Intellectual and Developmental Disabilities

Population Dynamics

White House Women's Health Research Initiative (WHRI)

- [Executive Order on Advancing Women's Health Research and Innovation](#)
 - Cross-government initiative to promote collaborative, interdisciplinary research
- NIH actions related to the Executive Order
 - Notice of Special Interest on Women's Health Research:
<https://grants.nih.gov/grants/guide/notice-files/not-od-24-079.html>
 - Review of women's health research at NIH submitted for publication
 - NIH Women's Health Roundtable Series
 - Future of Menopause Research (May 16, 2024)
 - **Endometriosis (Aug. 19, 2024)**
 - Maternal Mental Health Research (Sept. 16, 2024)
 - Further implementation of the EO is under discussion at NIH
- Funds for the WHRI have not yet been appropriated



RADx® Tech ACT ENDO Challenge Launched!

Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays (ACT ENDO)



- Endometriosis diagnosis can be delayed an average of 10 years
- NICHD, partnering with NIBIB, is leveraging Rapid Acceleration of Diagnostics Technology (RADx® Tech) "innovation funnel" program
- **Challenge Goal:** Accelerate the time to diagnosis, eliminate invasiveness of current techniques, and/or improve accessibility, safety, convenience, and cost of diagnosis
- \$3M in prizes
- Submissions to Phase I due October 11, 2024
- Final winners expected to be announced in March 2026



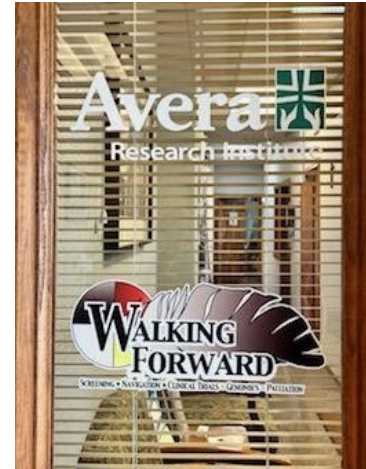
IMPROVE Initiative

Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone

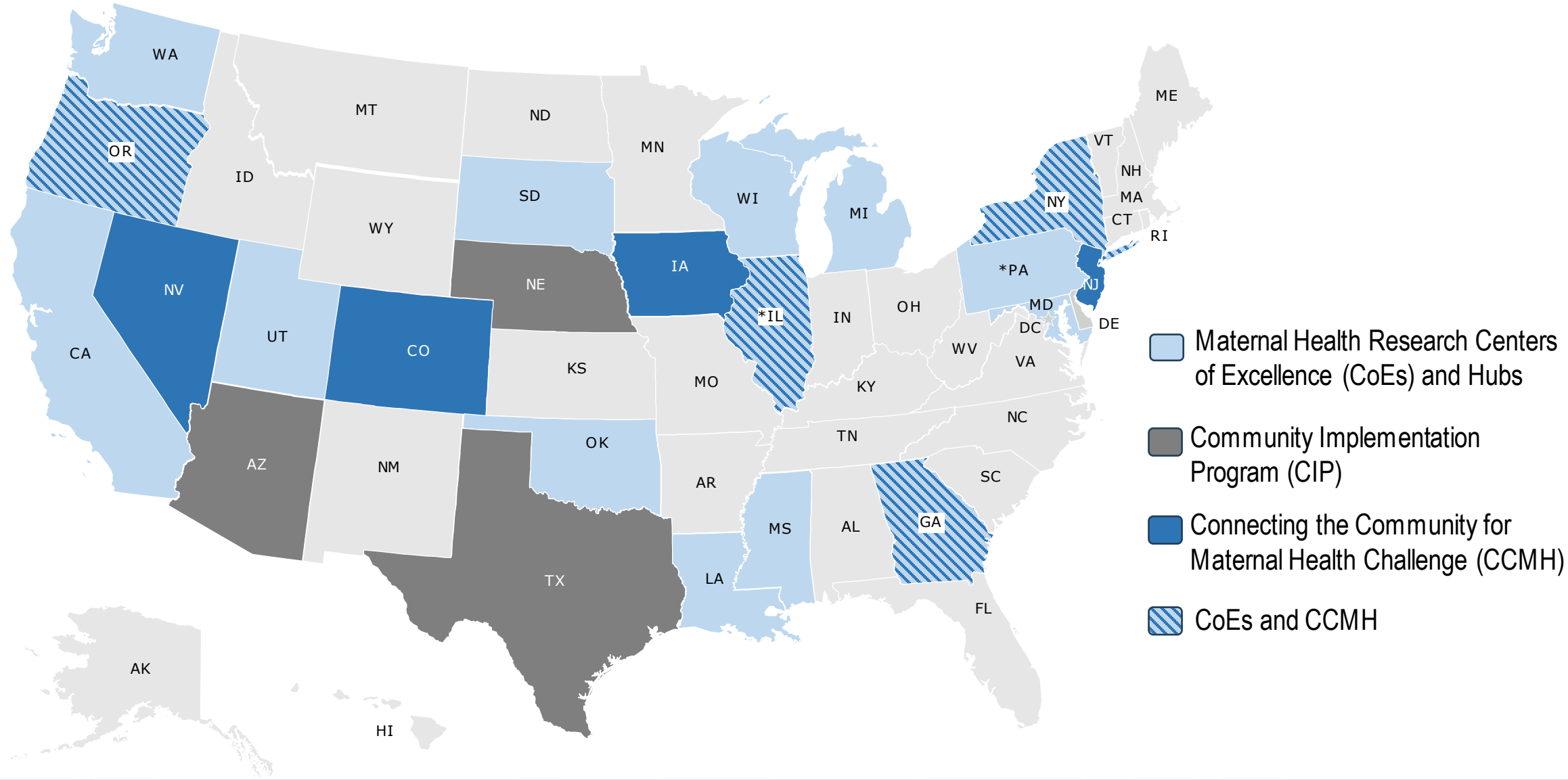
- **2 new Maternal Health Research Centers of Excellence** (12 total)
 - University of Illinois Chicago
 - University of Pittsburgh
- **Connecting the Community for Maternal Health Challenge** to build research infrastructure in communities
 - Final winners announced **September 5, 2024**
- **RADx Tech for Maternal Health challenge** for postpartum diagnostics and monitoring
 - Final winners anticipated in October 2024
- **IMPROVE 5th Anniversary Meeting**, October 15-16, 2024



NICHD recent site visits to CoEs



Geographic Distribution of IMPROVE Programs



*There are two CCMH participants and one CoE located in Illinois; There is one CoE site and one CoE Hub in Pennsylvania.



Pediatric Research



Developmental Biology and Congenital Anomalies

Child Development and Behavior

Intellectual and Developmental Disabilities

Pediatric Growth and Nutrition

Pediatric Trauma and Critical Illness

Maternal and Pediatric Infectious Disease

Obstetric and Pediatric Pharmacology and Therapeutics

Pregnancy and Perinatology

Population Dynamics

Drowning Prevention Research

- Foremost cause of injury death in children aged 1-4; leading cause for ages 5-19
- Stark racial and socioeconomic disparities in drowning death rates
- Recent study identified disparities in adolescents' access to drowning prevention strategies such as swimming lessons and life jacket use in same demographic groups who experience higher drowning rates (*Morgan, ER et al. J Adolescent Health 2022.*)
- NICHD researchers investigating:
 - Virtual reality lifeguard surveillance environment to identify points of failure and inform training (*PI: Cathleen Moore*)
 - Effects of swim instruction on autistic children's swimming and water safety skills (*PI: Lisa Lawson*)
 - Effectiveness of public policy interventions in reducing racial disparities in drowning (*PI: Samuel Myers*)



Youth Driving and Mood Disorders

- **Youth with mood disorders less likely to get driver's license**
 - Driving requires multiple neurocognitive skills (e.g., executive functioning, sensory perception, attention); these skills are often impaired in individuals with mood disorders
 - Obtaining a license has been associated with higher self-reports of health and educational attainment in young adults; lack of license could be associated with adverse psychosocial outcomes
 - **Youth with mood disorders** who obtained licenses also had **a higher overall risk of crashing** than other youth
 - *Gaw, CE, et al. 2024. doi:10.1001/jamanetworkopen.2024.5543*



Developmental Effects of Childhood Adversity

- **Early childhood adversity may affect neurological and cognitive development**
 - Combinations of exposure to parental divorce/separation, family loss and instability (e.g., foster care), crowded housing, particularly in households below the federal poverty threshold
 - Exposed children had lower scores on tests of visual-motor and sensory-motor functioning; and on intelligence and achievement tests
 - Long-term implications for educational success, social and emotional wellbeing, and physical health in adulthood
 - NICHD intramural research (DiPHR; Dr. Stephen Gilman)
 - Yu, J, et al. *JAMA Pediatrics*. 2024.



Reducing Inappropriate CT Scans for Children and Youth

- Pediatric Emergency Care Applied Research Network (PECARN)
- Developed prediction rules for emergency departments to distinguish children with high vs. low risk (CT scan vs. no CT scan) for serious abdominal or brain injuries
- Prediction rules were 100% accurate for severe abdominal injuries; 100% accurate for head trauma in children <2 yrs; 98.8% accurate in children >2 yrs
- Prediction rules are validated and can be considered safe for minimizing inappropriate CT scans in children
- *Holmes, JF et al. The Lancet, Child and Adolescent Health. 2024.*

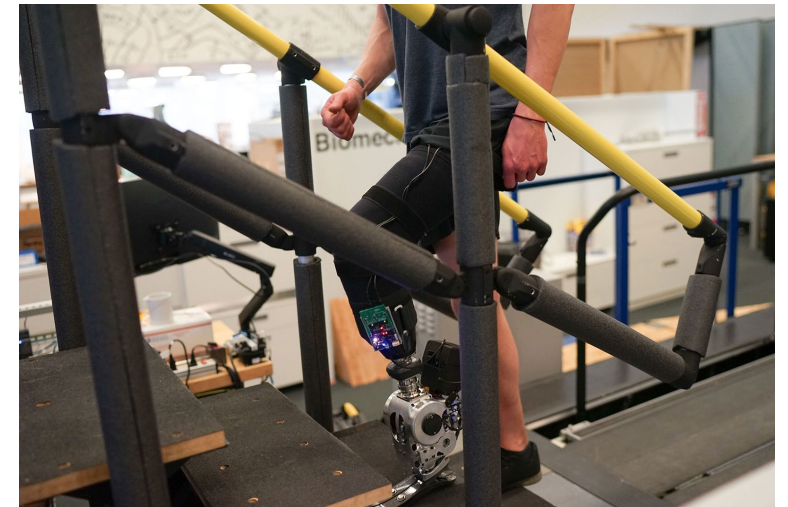




Rehabilitation Research

Recent Rehabilitation Research Highlights

- **Aerobic exercise may improve sleep for adolescent concussion patients**
 - Many concussion patients experience sleep problems, which can worsen concussion symptoms
 - Adolescent concussion patients who performed more than 150 minutes of aerobic exercise per week scored better on a sleep quality questionnaire than a group who exercised less
 - *Howell, DR, et al. 2024. DOI: 10.1097/HTR.0000000000000918*
- **New surgical procedure enables below-knee amputees to achieve more natural gait**
 - Procedure allows continuous neural control via sensors in neuroprosthetic interface; improves maneuverability of robotic limb
 - Patients walked faster with their prostheses and were better at climbing stairs and avoiding obstacles after the procedure
 - *Song, H, et al. 2024. <https://doi.org/10.1038/s41591-024-02994-9>*





Training

NICHD Extramural Training and Career Development Working Group Recommendations



- Reinvigorate Institutional Training & Career Development Programs



- Rethink How We Talk About Outcomes
- Create Community Amongst Trainees
- Use Training and Career Development Programs to Diversify NICHD's Reach



- Reinvigorate the Loan Repayment Programs (LRPs)



- Use Training Programs to Support Strategic Research Priorities



Implementation Updates: NICHD Extramural Training and Career Development Working Group

- Funding for NICHD's Loan Repayment Program **increased substantially** in FY24 (~28%) compared to FY23
- Expanding outreach for training opportunities
 - Opened OPTTB workshop for Clinical Pharmacology Training Network (8/28/24) to all NICHD-funded trainees
 - NICHD Office of Health Equity (OHE) created new materials for extramural and intramural training opportunities to distribute at scientific conferences
 - Submitted abstracts for presentation at major national meetings (e.g., SACNAS, APHA, ABRCMS)
 - Scheduled trainee webinars about specific funding opportunities (F99, K99, diversity supplements), led by OHE in collaboration with DER and DEA



Implementation Updates: NICHD Extramural Training and Career Development Working Group (continued)

- New (Type 1) and Renewal (Type 2) T32 applications will be clustered separately for peer review
- Competing T32 applications will require PO input on Diversity Recruitment and Retention Plans during funding plan development; NICHD has drafted language to encompass individual *and* institutional diversity for our T32s and K12s
- Adding a cross-cutting theme in training to NICHD's 2025 Strategic Plan





Kudos!

Deb Henken, Ph.D.

Congratulations!

- Program officer in Developmental Biology and Congenital Anomalies Branch
- Recognized recently by the *13th International Conference on Neural Tube Defects* for her “unfailing enthusiasm, mentorship, guidance, and championing of research into the causes and prevention of structural birth defects.”



Retirement: James Coulombe, Ph.D.

Best wishes!

- Chief, Developmental Biology and Congenital Anomalies Branch (DBCAB), since 2018
- Joined NICHD in 2006
- Gabriella Miller Kids First Research Program (since 2017)
- Mahua Mukhopadhyay, Ph.D., Acting DBCAB Branch Chief
 - *Thank you!*



Henry Levin, Ph.D.

NICHD Deputy Scientific Director

- Senior investigator and the head of the Section of Eukaryotic Transposable Elements
- Chair of DIR's Tenure & Promotions Committee
- Program director for Early Career Awards and the Career Awards for Staff Scientists/Staff Clinicians
- Received NIH Outstanding Mentor Award





Hiring and Resources

We're Hiring!

- Extramural Branch Chiefs, Program Officers, Extramural Policy Officers
 - National search for Branch Chief for **Developmental Biology and Congenital Anomalies** and **Fertility and Infertility** Branches (contact Rohan.Hazra@nih.gov if interested or with suggestions)
- Intramural Labs (postdocs, fellows, trainees)
<https://www.nichd.nih.gov/about/jobs>



Check Out Our New Women's Health Research Fact Sheets!

- Assisted Reproductive Technology
- Femtech Small Businesses
- Uterine Fibroids
- Endometriosis
- Infertility
- Polycystic Ovary Syndrome
- Pelvic Floor Disorders
- Covid-19



Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Uterine Fibroids and Women's Health

Advancing Diagnostics & Treatments to Improve Patient Care

What are uterine fibroids?

Uterine fibroids, or leiomyomas, are benign tumors that grow in or on the wall of the uterus. Typically made of muscle and connective tissue cells, uterine fibroids are the most common non-cancerous tumors in women of childbearing age. Some women experience debilitating pain, heavy menstrual bleeding, and problems with fertility from fibroids, while other women have minor or no symptoms. Research suggests that fibroids occur disproportionately among Black and African American women, who also tend to develop fibroids at younger ages and have more severe symptoms than other groups. Removing the uterus (hysterectomy) is currently the only "cure" for fibroids, although symptom management can also include medication and minimally invasive surgeries.

How does NICHD support research on uterine fibroids?

NICHD funds research to understand the causes and risk factors of fibroids and to identify better ways of diagnosing and treating them. In 2020, the U.S. Food and Drug Administration approved the drug Oriahnn® for treating heavy menstrual bleeding from uterine fibroids. The drug contains elagolix, which was initially developed through an NICHD small business grant. In 2024, NICHD launched the Specialized Centers for Research on Health Disparities in Uterine Leiomyoma to learn more about fibroids and explore the disparities related to fibroid risk occurrence, and symptom severity among Black and African American women. The overall goal is to improve gynecological health for all women.

Success Snapshots

Developing a Prototype to Predict Risk

Knowing who is at risk for developing uterine fibroids could facilitate earlier treatment and prevention. With NICHD support, researchers developed a gene-based score to help predict aspects of fibroid disease. Created by analyzing genome-wide scans and electronic health records, these polygenic risk scores estimate the likelihood that a person will have a particular pattern of fibroid disease characteristics, as well as their severity of symptoms. Additional evaluation of the prototype is underway.

Identifying New Uses for Existing Drugs

The oral medication tranilast decreases production of collagen (a building block of muscle, skin, and connective tissues) and inflammation-causing elements. In other countries, it is approved for treating asthma, and issues linked to collagen in an inflammatory substance overproduction. Testing in a uterine fibroid mouse model, NICHD-funded researchers found that treatment with the drug for 8 weeks led to notably smaller tumors compared to untreated mice. This work suggests new uses of existing drugs for treating fibroids.

Selected NICHD-Funded Projects on Uterine Fibroids

Fibroid Origins & Health Disparities

Understanding the Role of Genes

To explore fibroid origins, a NICHD-funded study examined gene expression or activity in uterine muscle tissue. The team noted higher expression of the von Willebrand factor gene (*VWF*) in uterine muscle samples from Black women, compared to White women. *VWF* includes instructions for a protein that regulates blood vessel formation, a key aspect of fibroid growth.

Another NICHD-supported team used new genetic sequencing technology to identify 21 genes that are expressed differently in fibroid tissue samples from Black and Hispanic women, compared to samples from White women. Understanding how genetics may contribute to racial disparities can help inform care.

Linking Ancestry to Fibroid Characteristics

NICHD-funded researchers linked fibroid risk and features among U.S. Black and White women to their ancestry. For Black women: West African ancestry correlated with risk for a single fibroid, East African ancestry correlated with risk for multiple fibroids, and Northern European ancestry protected against multiple fibroids. For White women: Northern European ancestry protected against fibroids; and West African ancestry was linked to risk for larger fibroids. These insights may help quantify risk and define treatments.

Identifying the Effects of Stress on Fibroids

Exposure to stress affects health in many ways. NICHD-supported researchers found that women with fibroids who scored high on questionnaires about stress had high levels of microRNAs linked with tumor growth in their uterine muscle. The researchers suggest that stress from structural racism and other situations may explain some disparities in fibroid rates.



Fibroid Factors, Effects, & Treatments

Identifying Environmental Effects on Risk

Exposure to phthalates, chemicals in personal care products, cosmetics, and medical items, has wide-ranging health effects. One NICHD-funded study found that phthalate exposure may trigger the growth of fibroid cells and delay the rate at which they die. This finding explains higher fibroid rates in phthalate-exposed women and suggests that reducing such exposures may prevent fibroids.

Other NICHD-funded research discovered that the green-tea compound epigallocatechin gallate (EGCG) reduced levels of substances that promote cell division and proteins that cause the tumors' fibrous contents. This team now leads an NICHD-funded clinical trial to test if EGCG reduces fibroid symptoms, including improving fertility.

Evaluating Fibroids' Role in Fetal Growth

NICHD researchers found that uterine fibroids do not seem to restrict fetal growth in pregnancy. Earlier studies suggested that fibroids could cause smaller full-term infants. The study also confirmed a higher risk of preterm birth for pregnant women with fibroids. These findings can help optimize outcomes for those with fibroids.

Developing Non-Surgical Treatments

Current non-invasive fibroid treatments reduce symptoms, but do not affect tumor size or growth. NICHD-funded researchers created a new method that shrinks fibroids non-invasively in mice by encasing a tumor-killing drug in nano-sized spheres, and using the bloodstream to deliver the spheres directly to the fibroid. They are now exploring whether the technique is safe and effective for treating fibroids in humans.

Learn More About NICHD Uterine Fibroid Projects



NICHD's Fibroids Website:
<https://go.nih.gov/9vCkUes>





Thank You!
Questions?