

# Expanding the ePCT Ecosystem to Better Serve Minoritized Communities

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**NIH PRAGMATIC TRIALS  
COLLABORATORY**

Rethinking Clinical Trials®

# Panelists

- Eliseo Pérez-Stable, MD
  - Director, NIH National Institute on Minority Health and Health Disparities
- Stephanie Fitzpatrick, PhD
  - Maternal Outcomes Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity
- Sebastian Tong, MD
  - Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain

# Session Goals

- Discuss the increasing burden on minoritized communities and health systems serving them
- Review the makeup of NIH Collaboratory Trial sites (academic medical centers, community hospitals, etc.) and explore how to expand the types





# Expanding the ePCT Ecosystem to Better Serve Minoritized Communities

May 10, 2024

*NIH Pragmatic Trials Collaboratory Steering Committee*

**Bethesda, Maryland**

Eliseo J. Pérez-Stable, M.D.  
Director, National Institute on  
Minority Health and Health Disparities  
[eliseo.perez-stable@nih.gov](mailto:eliseo.perez-stable@nih.gov)



# What Can Science Do to Reduce Inequities?

- Be an engine for **promoting diversity** of the scientific and clinical workforce
- Cultivate **community engagement** and build trust for sustainable relationships
- **Standardized measurement** of social and demographic factors that affect health
- Facilitate **discovery science** with big data
- **Implement** what we know can work to promote health equity



# Designated Populations with Health Disparities

- **Racial and ethnic minorities –Census**
- **Less privileged socio-economic status**
- **Underserved rural residents**
- **Sexual and gender minorities (LGBTQ+)**
- **Persons with disabilities**
- **Social disadvantage results in part from being subject to discrimination or racism, and from being underserved in health care**



# Health Disparities Research

- **Race and ethnicity and SES are the fundamental drivers of health disparities science**
- **Intersectionality of race and ethnicity and SES with rural populations, SGM persons, and people with disabilities**
- **Apply intersectionality to all demographic factors and clinical conditions**
- **Establish aspirational goals for populations based on national metrics and not assume Whites have best outcomes**



# The Economic Burden of Racial, Ethnic, and Educational Health Inequities in the U.S., 2018

*Dollar estimates are based on excess medical care expenditures, lost labor market productivity, and premature death using national data (NCHS, BRFSS, MEPS) compared to a health equity goal*

## By Racial and Ethnic Minority Groups

**\$451B**

Burden by Racial & Ethnic Minority Groups

|  |        |     |
|--|--------|-----|
| Black/African American ○               | \$310B | 69% |
| Hispanic/Latino □                      | \$94B  | 21% |
| American Indian/<br>Alaska Native ☼    | \$26B  | 6%  |
| Native Hawaiian/<br>Pacific Islander ◇ | \$12B  | 3%  |
| Asian △                                | \$8B   | 2%  |

## By Educational Levels

**\$978B**

Burden by Educational Levels

|                         |        |     |
|-------------------------|--------|-----|
| Less than High School ○ | \$256B | 26% |
| High School/GED □       | \$593B | 61% |
| Some College ◇          | \$128B | 13% |





# Assessment of Demographic Factors and Social Determinants of Health

- **OMB-Census categories for race and ethnicity**
- **Educational attainment — college degree**
- **Sexual orientation, gender identity**
- **Disability status based on function**
- **Community measure – where do patients live**
- **Access to food, jobs, transportation, housing, green space, safety**
- **Impute data from census tracts using address**



# PhenX Toolkit SDOH Measures Collection



Affordability accessing dental care and prescriptions, health care communications, internet access, water quality access, neighborhood walking environment, housing instability, minimum wage, residential concentrations of income

- Core Collection-16 protocols
- Individual SDOH-22 protocols
- Structural SDOH-15 protocols

Adoption of Common Data Elements (CDEs) and standard measures will promote and facilitate data harmonization and cross-study analysis

<https://www.phenxtoolkit.org/collections/view/6>



# Perceived Unfair Treatment Due to Race or Ethnicity

*In health care visits over the past 3 years, have you ever felt that a doctor, health care provider, or other staff treated you unfairly or with disrespect because of your race or ethnic background?*

|                                  |     |
|----------------------------------|-----|
| American Indian or Alaska Native | 12% |
| African American                 | 18% |
| Asian                            | 10% |
| Latino/a                         | 11% |
| White                            | 3%  |

*Kaiser Family Foundation Survey on Racism, Discrimination, and Health, December 2023*



National Institute  
on Minority Health  
and Health Disparities



# Need a Population Health Approach

- **Define the catchment area**
- **Understand the population and community**
- **Consider physical space and environment**
- **Apply metrics that are sensitive**
- **Evaluate outcomes by race and/or ethnicity, SES, and other demographic factors**
- **Address inequities based on regional data**



## Challenge of Multiple Chronic Conditions

- **Prevalence of  $\geq 2$  chronic conditions: 33% of adults 45-64 y and 64% of those  $\geq 65$  y**
- **Adults  $\geq 40$  years: 69% take a prescription drug and 22.4% use at least five Rx**
- **Research almost always focuses on one condition at a time**
- **Added complexity of preventive measures**
- **Lack of integration of health care services, under-value of primary care and behavioral**



# NIMHD Activities Related to Pragmatic Trials

- **Workshop on Inclusive Participation in Clinical Research – March 30-31, 2023**
- **Community Engagement Alliance (CEAL) Network for Community-Engaged Research – Morehouse/HCN and Ochin**
- **RCMI Clinical Research Network: Howard, N Carolina Central, San Diego State, U Hawaii**
- **Value placed on communication skills and sustaining a trusting relationship**



# NIMHD Funding Opportunities with Pragmatic Clinical Trials Option

[PAR-24-077](#) Addressing Health and Health Care Disparities among Sexual and Gender Minority Populations (R01)

[PAR-24-053](#) Multi-sectoral Preventive Interventions That Address Social Determinants of Health in Populations That Experience Health Disparities (UG3/UH3)

[PAR-24-059](#) Understanding the Impact of Healthcare System and Clinician Factors on Disparities in Maternal Morbidity and Mortality (R01)

[RFA-MD-24-003](#) Interventions to Address HIV-Related Comorbidities among Highly Affected Populations Experiencing Health Disparities (R01)



# Equity Recommendations to Consider

- **Emphasis on Patient-Clinician communication**
- **Engage community members and resources from the start on a partnership model**
- **Recognize and manage structural and interpersonal discrimination at all levels**
- **Leverage health IT and EHR to address equity**
- **Performance measurement: Risk, need Equity Quality Measure to reward systems**





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**Feinstein Institutes  
for Medical Research**  
Northwell Health®

# MOMS CHAT & CARE STUDY

NINR R01NR021134

NIH Pragmatic Trials Collaboratory  
FTF Meeting  
May 9-10, 2024

# HEALTH EQUITY

## CDC Definition

State in which everyone has a fair and just opportunity to attain their highest level of health.

## WHO Definition

Absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality.

## Stephanie's Remix Definition

Approach(es) that ensures everyone has a fair opportunity to achieve their full health potential.

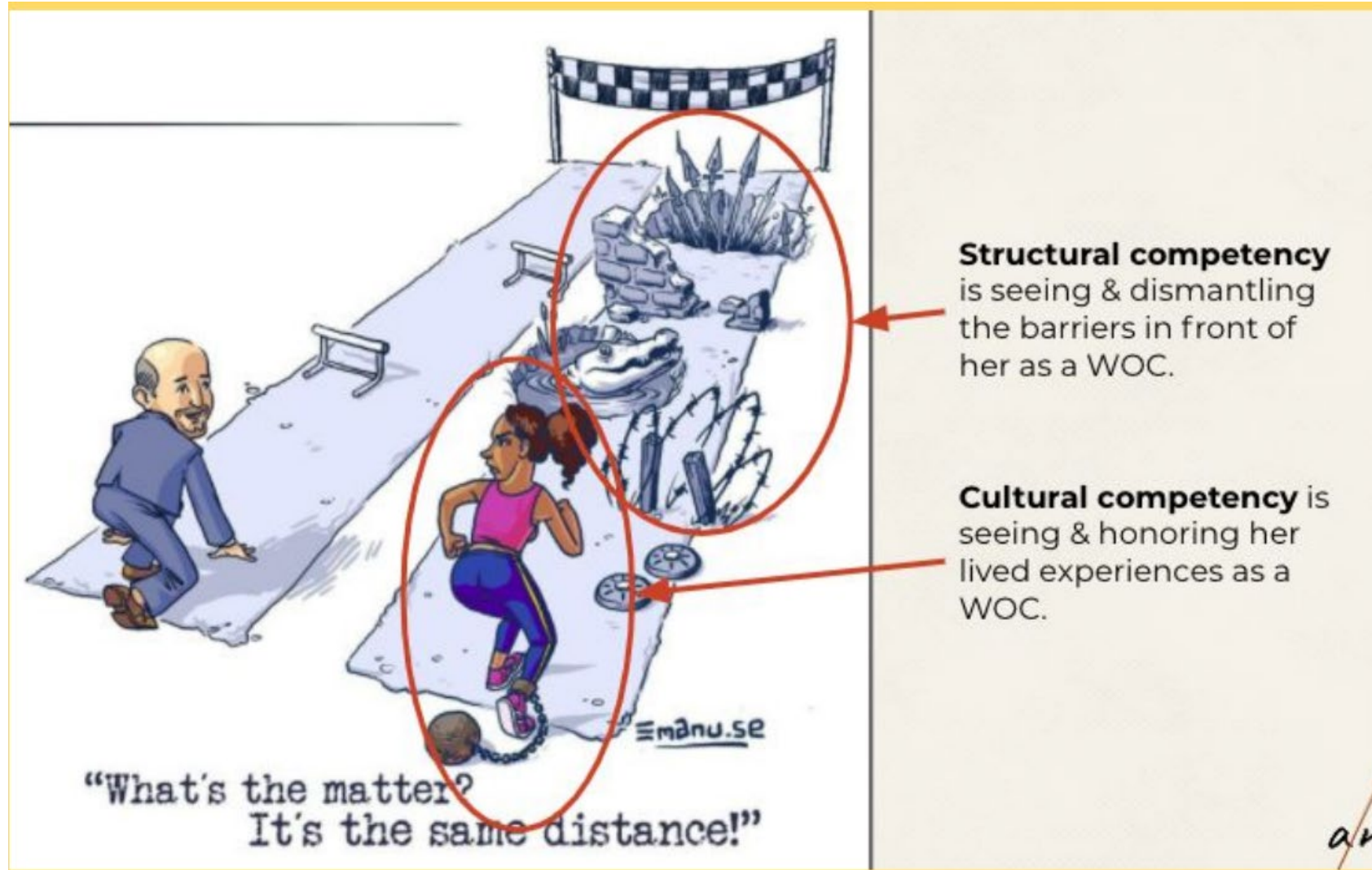
# BACKGROUND

- Severe maternal morbidity (SMM) – “unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a birthing person’s health.” (CDC)
- SMM increases the risk for re-hospitalization post-delivery, disability, and maternal mortality. [Black et al. *J Womens Health*. 2021;30(12); Admon et al. *Obstet Gynecol*. 2018;132(5)]
  - BUT, most cases are avoidable if timely, appropriate care is provided.
- Black birthing people have the highest rate of SMM throughout the birthing continuum; [Liese et al. *J Racial Ethn Health Disparities*. 2019;6(4); Brown et al. *Obstet Gynecol*. 2020;136(5)]
  - 2 times more likely to experience SMM than non-Hispanic White birthing people, even with similar economic backgrounds and medical coverage [Howell et al. *Obstet Gynecol*. 2020;135(2); Howland et al. *Matern Child Health J*. 2019;23(3)]

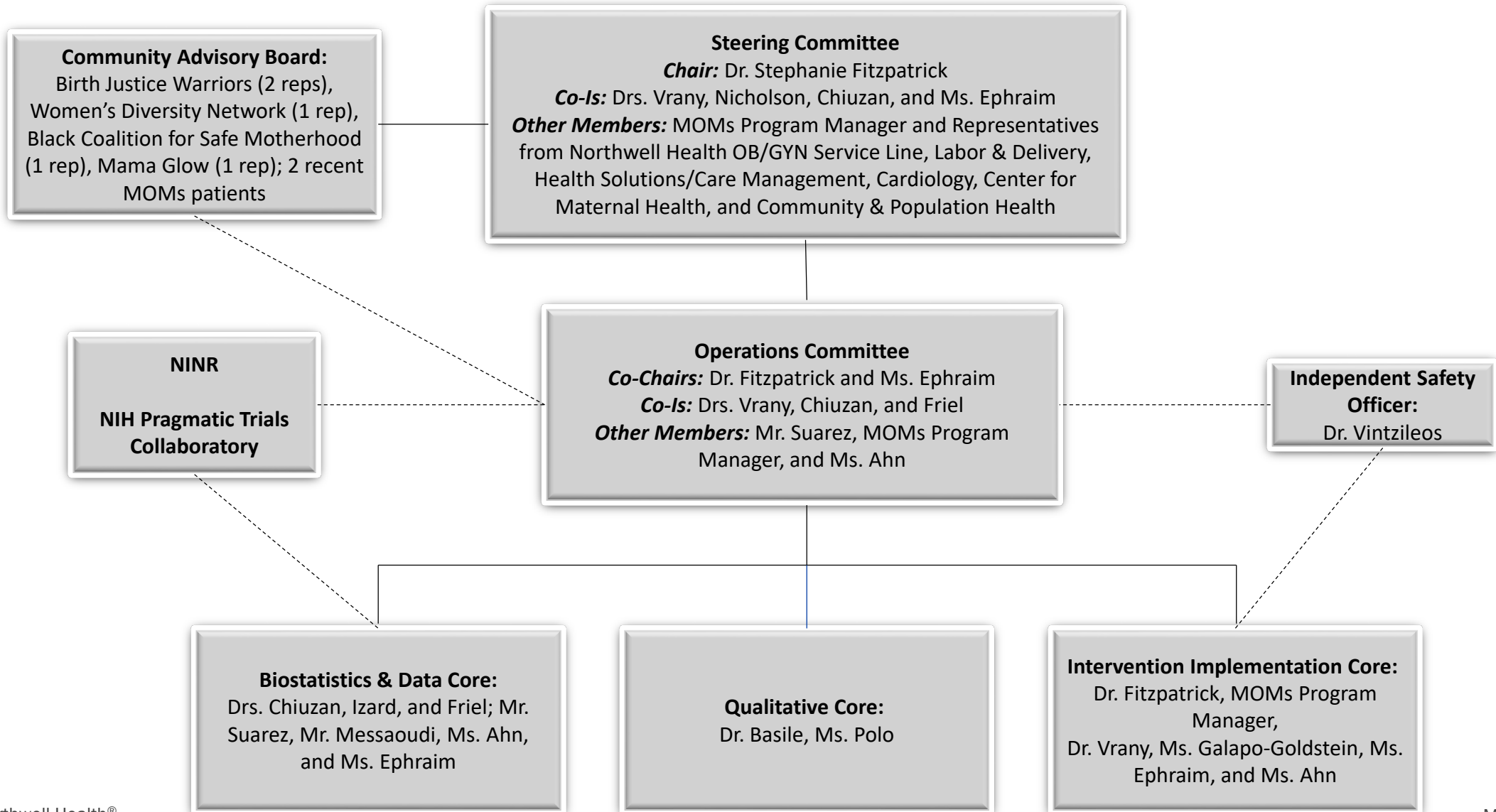
# BACKGROUND – MATERNAL HEALTH INEQUITIES

- Hypertensive disorders in pregnancy (e.g., preeclampsia) are the leading cause of SMM
  - Black birthing people are 3 times more likely to experience preeclampsia than non-Hispanic White birthing people
- Birthing people who experience SMM have smaller support networks and lower satisfaction with perceived support compared to birthing people who don't experience SMM
- Lack of medical coverage and transportation can delay and/or interrupt timely prenatal care and attendance at postpartum visits
- Food insecurity increases risk for pregnancy complications via increased stress and anxiety and poor health outcomes for the birthing person and the baby
- Poor access to affordable housing increases risk for SMM, especially among birthing people with low levels of education

# TRAINING OF RESEARCH AND CLINICAL TEAMS



# STUDY TEAM





# RECRUITMENT MATERIALS (SENT VIA EMAIL OR MAIL)

Greetings,

We are inviting you to join the **MOMs Chat & Care Study**. This is a research study conducted by Northwell Health. The goal of this study is to understand how best to support Black women to ensure a healthy pregnancy, healthy birth, and healthy outcomes post-delivery. We are sending you this letter because you were identified as a person who is pregnant and receiving care at one of our Northwell Health Obstetrics clinical practice sites.



If you say yes to join this study, you will receive:

- Access to the Northwell Health Pregnancy Chats, an interactive digital resource that offers weekly insights and 24/7 access to support your needs throughout your pregnancy journey and beyond.
- Brief support from a post-partum care coordinator (virtually or by phone) after you deliver your baby who will make sure you receive the care you need when you need it after your baby arrives.
- A FitBit to wear and track your physical activity.

You may also receive:

- 12 one-to-one virtual health self-management and empowerment sessions with a trained MOMs care manager during your pregnancy to promote healthy birth outcomes.
- A home blood pressure cuff and monitor to track your blood pressure during your pregnancy and after delivery.

We will ask you to complete questionnaires about your level of social support, engagement in physical activity, and health by phone 2 times during pregnancy and 1 time after delivery. If you choose to join this study, we will pay you up to \$75 for your time answering questionnaires.

**If you want to join this study:** A study team member will call you to tell you more about the study and see if you want to participate. You can also call us at XXX-XXX-XXXX or email us at [momschatcare@northwell.edu](mailto:momschatcare@northwell.edu) to find out more about the study.

Thank you for thinking about joining this study. We hope that you will join us in helping to improve the care and birthing experience for Black women everywhere.



Best Regards,

Stephanie Fitzpatrick, PhD



|   |   |  |
|---|---|--|
| <p><b>WHAT PEOPLE ARE SAYING ABOUT THE MOMS PROGRAM...</b></p> <p>“You feel more human, you don't feel like a number or a quota. I felt like the people that I was interacting with were all moms in a sense because they got it. They understood it.”</p> <p>“So, it wasn't just questions about the baby, they asked me how I'm doing, how I'm feeling. So, it's like reminding me I have to take care of myself as well.”</p>          | <p><b>DR. STEPHANIE FITZPATRICK</b><br/>Institute of Health System Science<br/>Feinstein Institutes for Medical Research<br/>Northwell Health</p> |  |
| <p><b>WANT MORE INFORMATION?</b></p> <p>If you are interested in learning more about this research study, please contact us:</p> <p><a href="mailto:momschatcare@northwell.edu">momschatcare@northwell.edu</a><br/>(516) XXX-XXXX</p> <p><small>This study is sponsored by the National Institute of Nursing Research (R01NR023136). This study is approved by the Northwell Health Institutional Review Board (No. XXXXXXX).</small></p> | <p><b>MATERNAL OUTCOMES (MOMs) CHAT &amp; CARE STUDY</b></p>  | <p><b>MATERNAL OUTCOMES (MOMs) CHAT &amp; CARE STUDY</b></p> |



# STUDY WEBSITE

<https://www.momschatandcare.com/>

# SOCIAL RISK SCREENINGS AND ADDRESSING HEALTH-RELATED SOCIAL NEEDS


- Social Risk Screener Administered via Chatbot, MOMs Team, Nurse/Social Worker on Admission
- Domains:
  - Food
  - Transportation
  - Housing
  - Safety
  - Financial hardships
  - Support
- Frequency: 14- and 28-weeks gestation; labor and delivery; 3-days postpartum; 5- and 12-weeks postpartum; 5, 7, 9, and 11 months postpartum

The image shows a screenshot of a medical form with a sidebar on the left and a main content area on the right. The sidebar lists various sections: Physical Exam, Counseling, Assessment, Plan, and End of Visit. The 'Counseling' section is expanded, showing 'MoMs - Referrals to Reso...' which is highlighted in blue. The main content area shows a form with several sections: 'Other Referrals, if applicable:' with checkboxes for Endocrinology, Healthy Living Program, Lactation Consultant, and Breast Pump; 'Community Resources:' with radio buttons for 'Not applicable (not eligible)', 'Assessed and confirmed connected to service', and 'Assessed and made referral'; 'WIC:' with similar radio buttons; 'WIC Office:' with a text box; and 'SNAP:' with radio buttons for 'Not applicable (not eligible)', 'Assessed and confirmed connected to service', and 'Assessed and gave instructions for pa...'. A red box highlights the 'Community Resources', 'WIC', and 'SNAP' sections.

Referrals: Community Resources – in the text box indicate the **specific adverse individual-level social determinants of health (e.g., food insecurity, housing instability, lack of transportation, lack of medical coverage/access, intimate partner violence, other financial hardships) AND which community-based organization or social service referred to**

# THANK YOU

A d a p t i n g a n d i m p l e m e n t i n g a N u r s e C a r e M a n a g e m e n t M o d e l t o C a r e f o r R u r a l P a t i e n t s w i t h C h r o n i c P a i n (AIM-CP):  
*Expanding the ePCT Ecosystem to Better Serve Minoritized  
Communities*



Co-PIs: Sebastian Tong, MD, MPH; Kushang Patel, PhD, MPH

NIH Collaboratory Steering Committee Annual Meeting

May 10, 2024

# DISCLAIMER

- None

# Our team

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## Investigative Team

- Kushang Patel, PhD, co-PI (gerontologist, epidemiologist, exercise expert)
- Dennis Ang, MD (rheumatologist, North Carolina site PI)
- Laura-Mae Baldwin, MD (practice-based research)
- Basia Belza, PhD, RN (nurse co-investigator, community engagement)
- Andrew Humbert, PhD (biostatistics)
- Tom Ludden, PhD (informatics)
- Stacy Shaw, PhD (clinical psychologist)
- Kari Stephens, PhD (clinical psychologist)
- Mark Sullivan, MD, PhD (pain specialist)
- Hazel Tapp, PhD (practice-based research)

## Partners

- Atrium Wake Forest Health
- Clearwater St. Mary's: Kelly McGrath, MD
- Healthwest: John Holmes, PharmD
- Providence Northeast: Caleb Holtzer, MD
- Rural Resources: Cheri Peterson

## Research Team

- Karina Cortez, BS
- Elise Hoffman, MPH
- Brennan Keiser, MSW
- Ajla Pleho, MPH

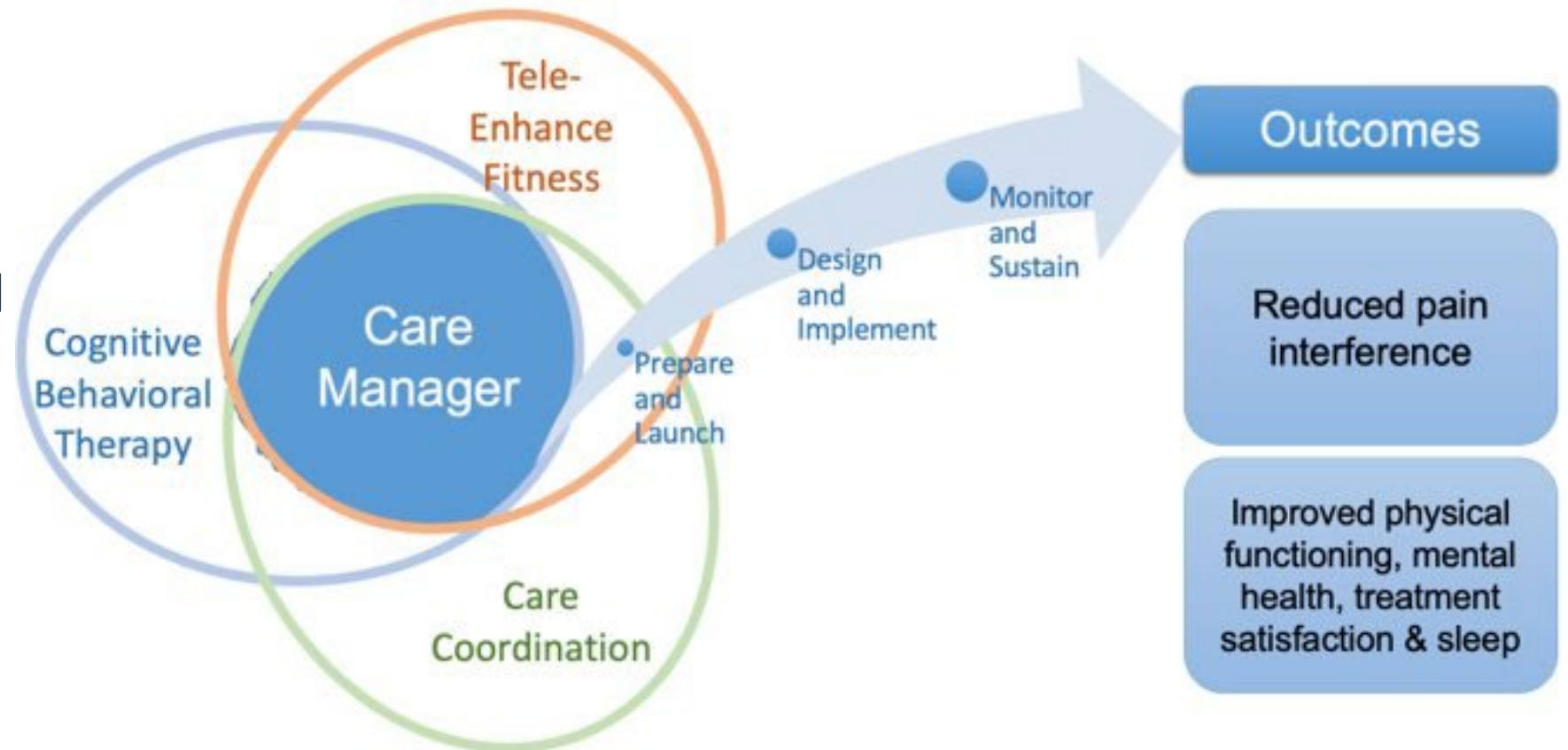
# Overall Objective

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- To adapt and test a nurse care management model to provide comprehensive care for patients with chronic pain in rural communities
- Long-term: reduce geographic disparities in pain-related outcomes through dissemination of this comprehensive approach to chronic pain management

# Care Management Model

1. Care Coordination
2. Cognitive Behavioral Therapy
3. Remotely delivered *Enhance Fitness* exercise program

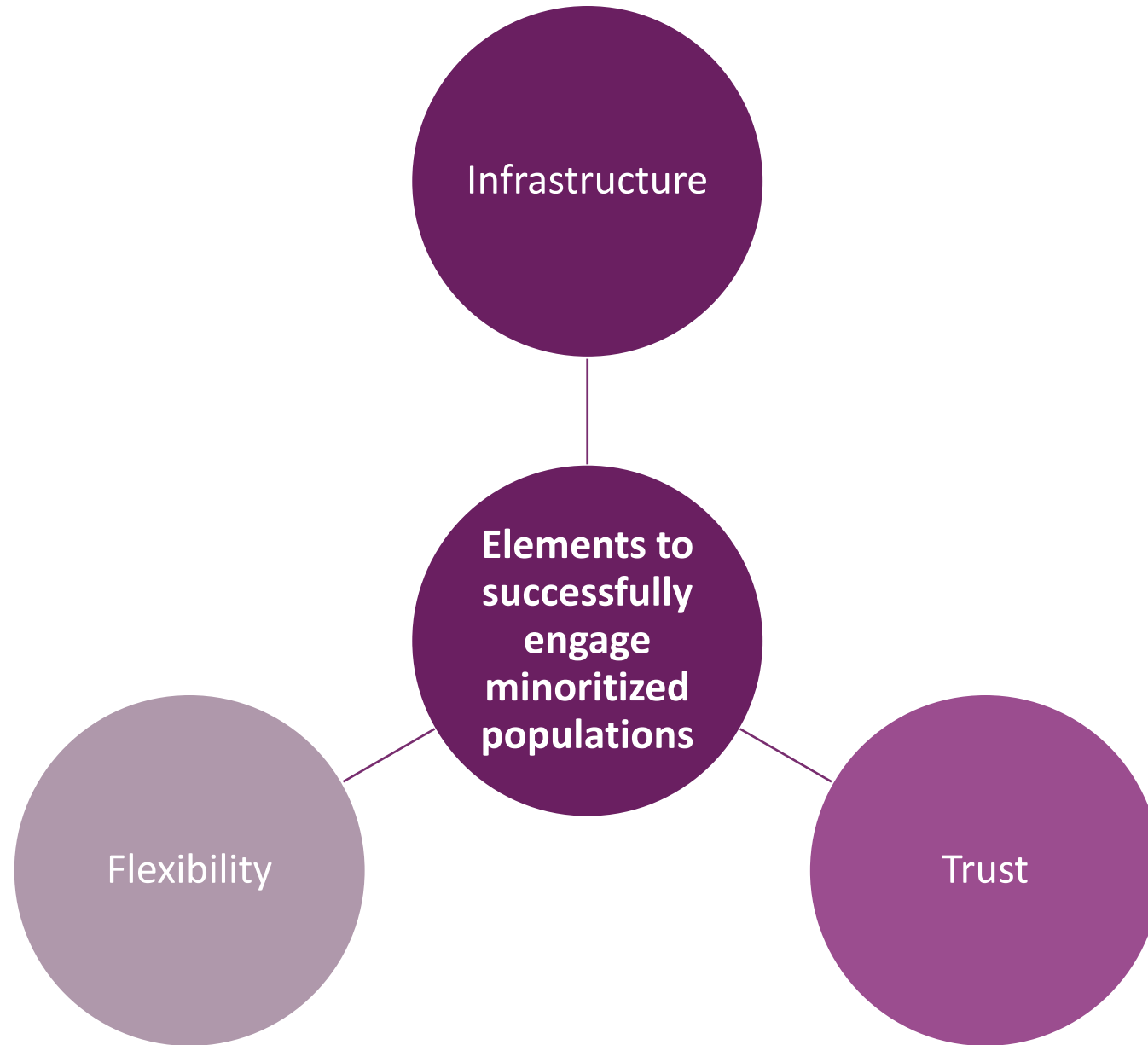




# Intervention components

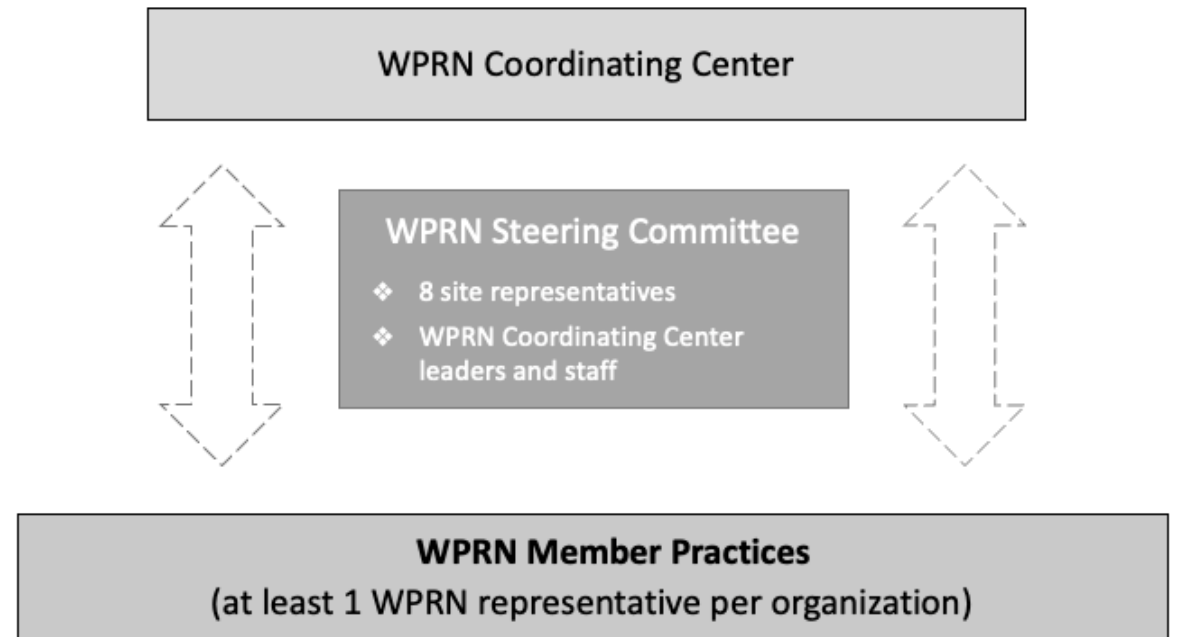
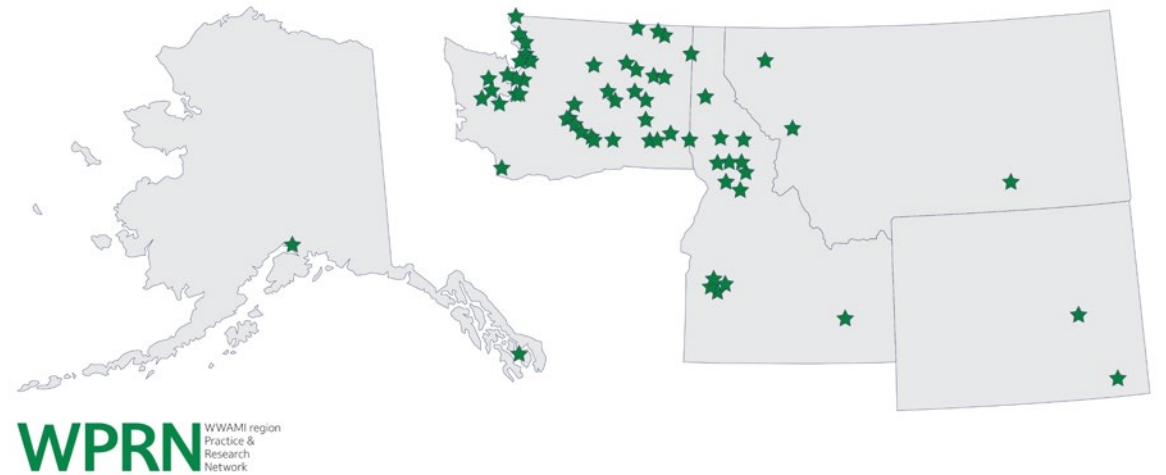
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| Individual component         | Description   |
|------------------------------|---|
| Care Coordination            | <ul style="list-style-type: none"><li>• Assessing patients for social service, behavioral health and specialty care needs</li><li>• Linking patients with community resources</li><li>• Tracking and supporting patients when care received outside health system</li><li>• Coordinating behavioral health and specialty care</li><li>• Using PainTracker to develop goals of care, track progress and refine treatment plans</li></ul> |
| Cognitive Behavioral Therapy | <ul style="list-style-type: none"><li>• 6-10 weekly to every other week sessions with care manager to develop strategies to change maladaptive cognition and behaviors around pain</li></ul>  |
| Tele-Enhance Fitness         | <ul style="list-style-type: none"><li>• Instructor-led, group exercise program for 1-hour, 2-3 times weekly remotely delivered program</li></ul>  |



# Infrastructure

- 5-state practice-based research network
- Supported by NIH CTSA and CTN grants
- Practice input from concept formulation stage through conduct to dissemination



# Trust

- Intentionality in research team members
- Longitudinal relationships
- Ex. Sustainable funding for model from previous project on chronic opioid prescribing



# Flexibility

- Planned Community Consultation Studio
- Collaborating with community organization partners
- Deciding on core elements of intervention and being adaptable for other elements

# THANK YOU!

- National Institute of Nursing Research (UG3NR020930)
  - Karen Kehl, PhD, RN, FPCN
  - Alexis Bakos, PhD, MPH, RN

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# Let's Discuss....

