

# Lessons and Challenges Engaging Rural Populations

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**NIH PRAGMATIC TRIALS  
COLLABORATORY**

Rethinking Clinical Trials®

# Panelists

- Julie Fritz, PhD, PT
  - Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics (BeatPain Utah)
- Richard Skolasky, MD
  - Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth (ARBOR-Telehealth)
- Sebastian Tong, MD
  - Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain (AIM-CP)
- Katie Hadlandsmyth, MD
  - Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention (RAMP)

# Session Goals

- Share progress on ePCTs for the prevention and management of chronic pain in rural populations, describing challenges and lessons learned
- Begin communication that may lead to joint publications on methods and strategies, and/or future collaborations



BEATPAIN Utah: Nonpharmacologic Pain Management in Federally  
Qualified Health Center Primary Care Clinics

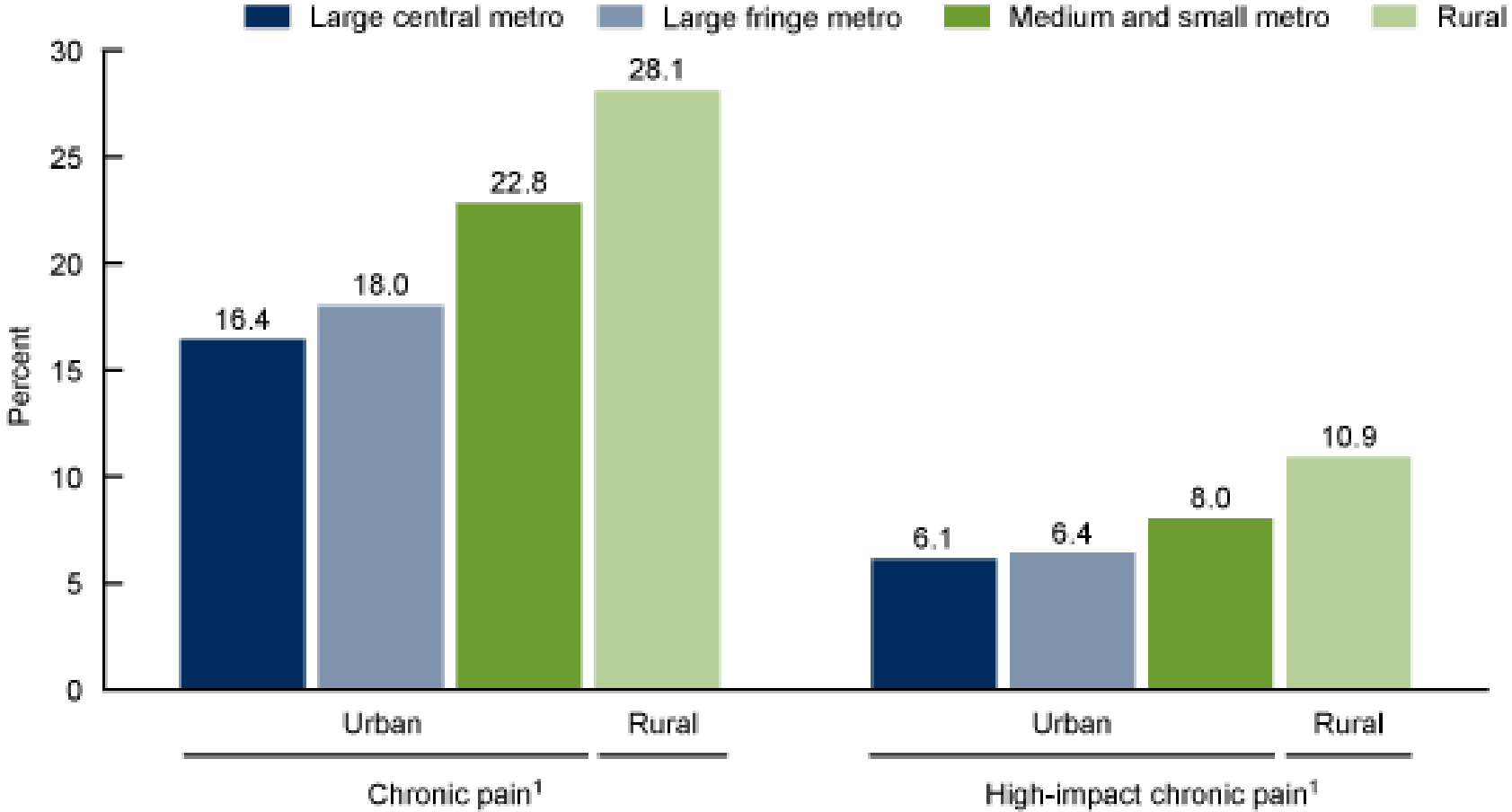
# Lessons and Challenges Engaging Rural Populations

Pragmatic and Implementation  
Studies for the Management  
of Pain (PRISM)

NIH  
**HEAL**  
INITIATIVE

The percentage of adults with chronic pain in the past 3 months, and those fitting the definition of high impact chronic pain, increases as place of residence became more rural.

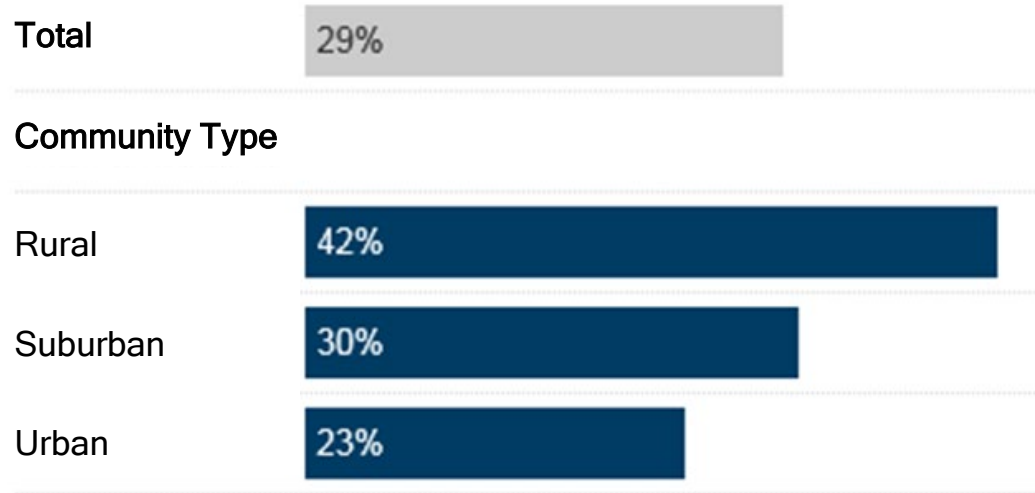
SOURCE: NCHS Data Brief No. 390, November 2020



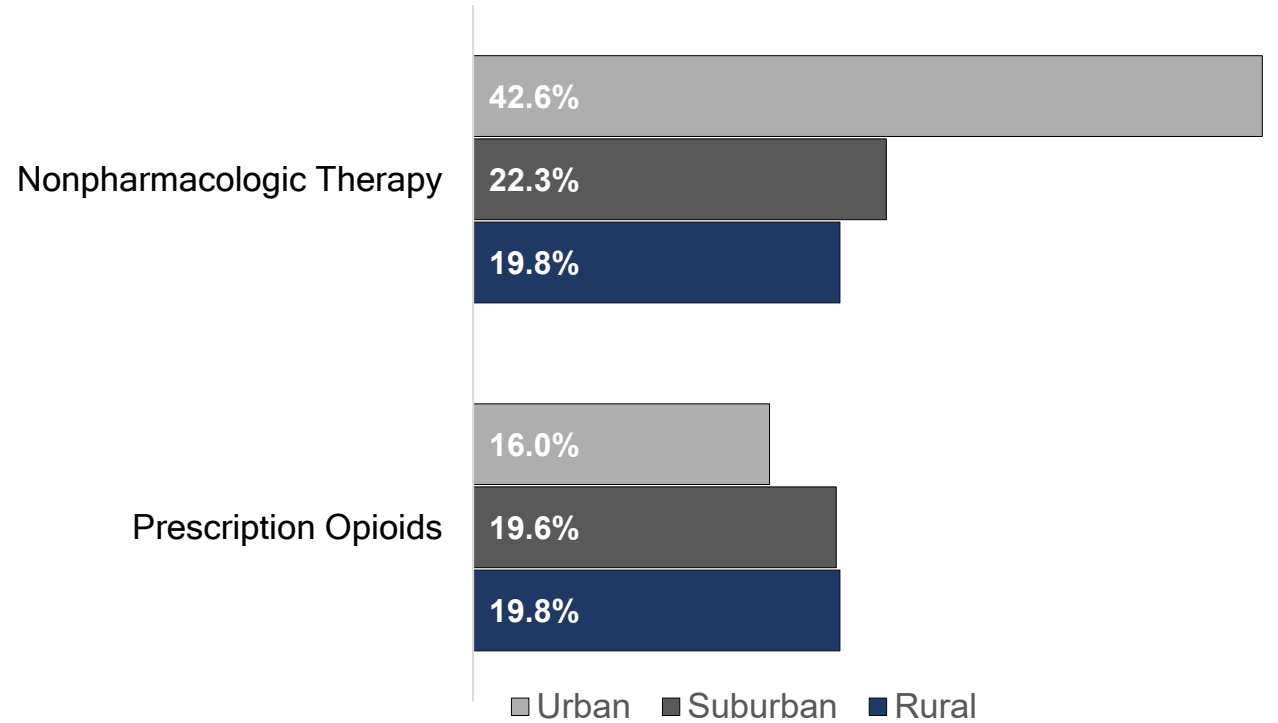
Chronic pain is based on responses of “most days” or “every day” to the survey question, “In the past 3 months, how often did you have pain? Would you say never, some days, most days, or every day?” High-impact chronic pain is defined as adults who have chronic pain and who responded “most days” or “every day” to the survey question, “Over the past 3 months, how often did your pain limit your life or work activities? Would you say never, some days, most days, or every day?”

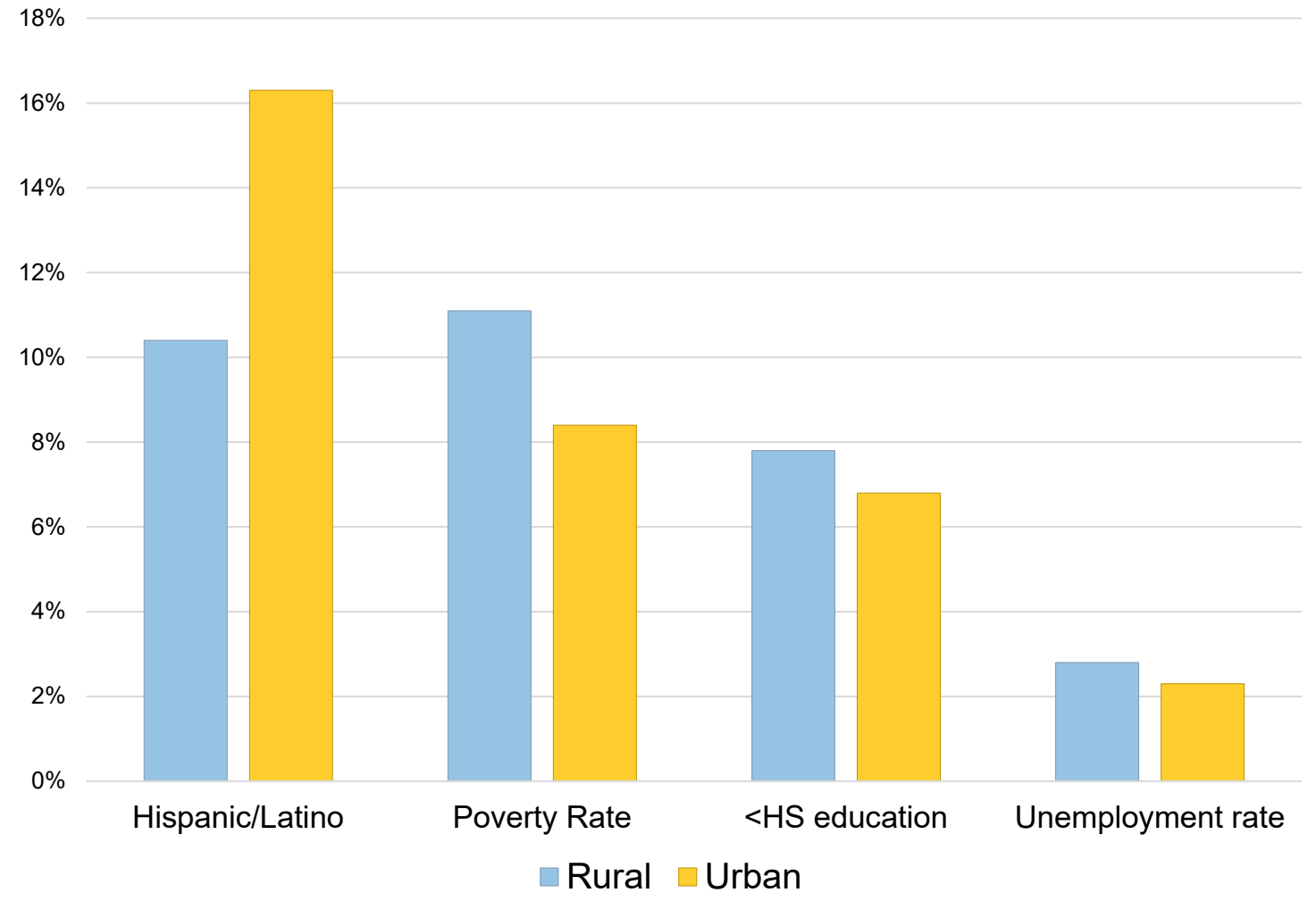
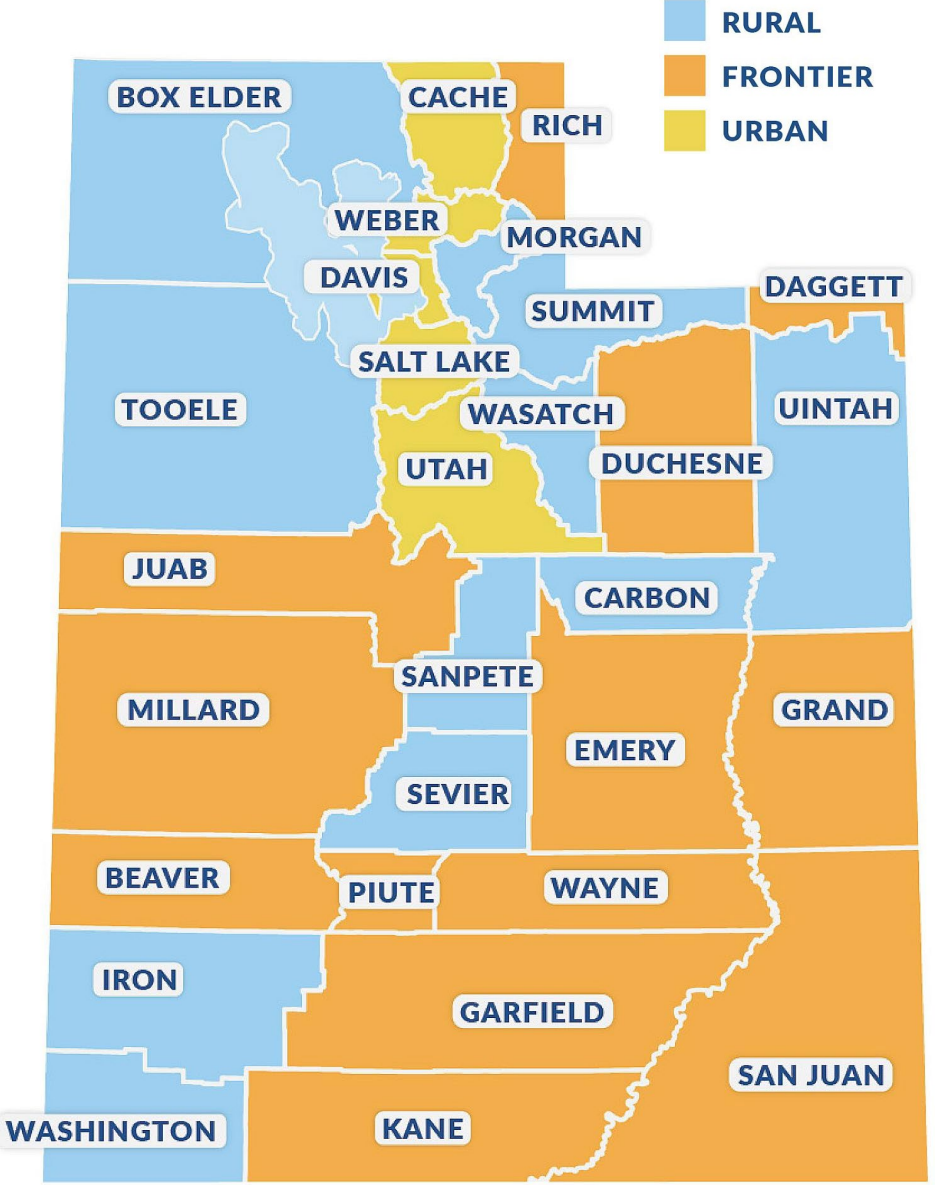
# Pain Disparities in Rural Communities

## Three in Ten Adults Say They Or Someone in Their Family Have Ever Been Addicted to Opioids



## Prevalence of Coping Mechanism Use for Chronic Pain





# Patient Profile



**90%** at or below 200% federal poverty level



**56%** identify as racial or ethnic minority



**39%** uninsured



**33,742** rural Utahns



**7,651** agricultural workers

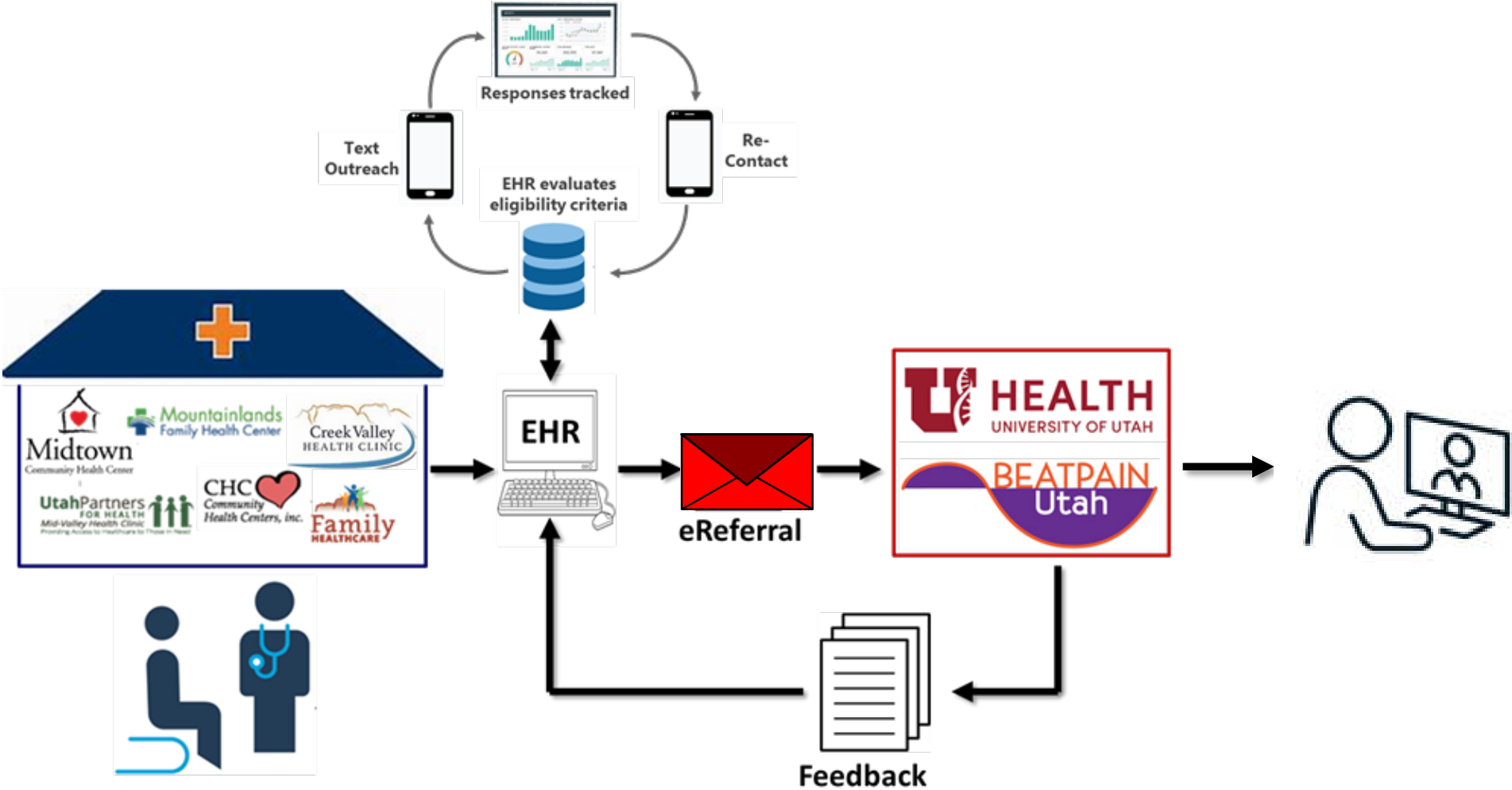


**8,355** persons experiencing homelessness





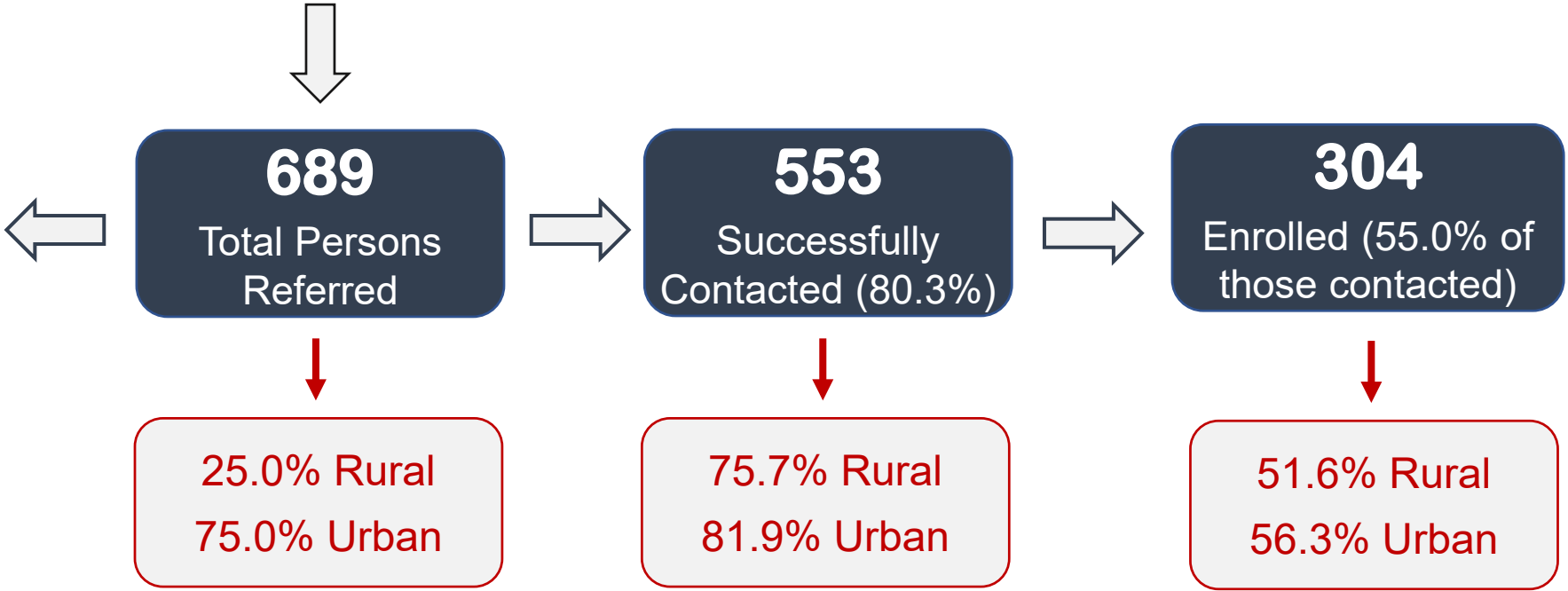
*Providing a nonpharmacologic option for persons with chronic back pain using telehealth*



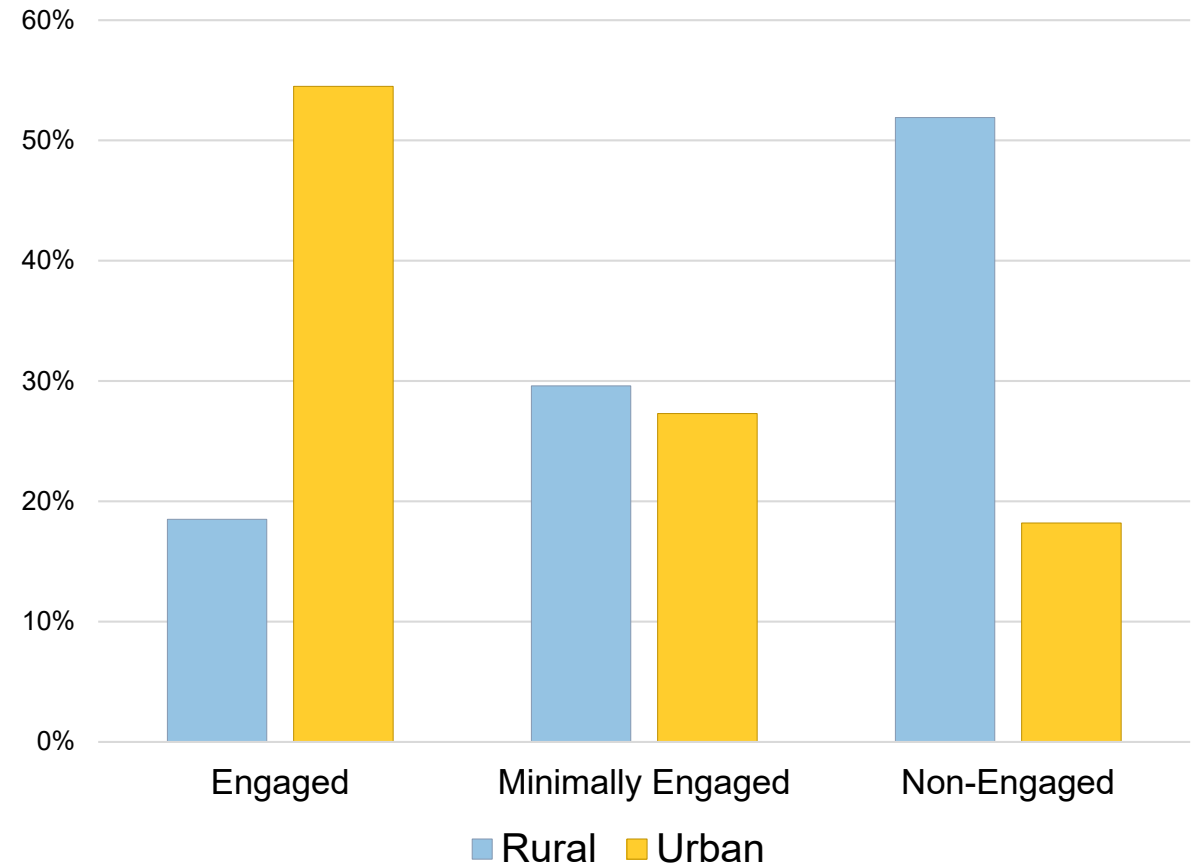
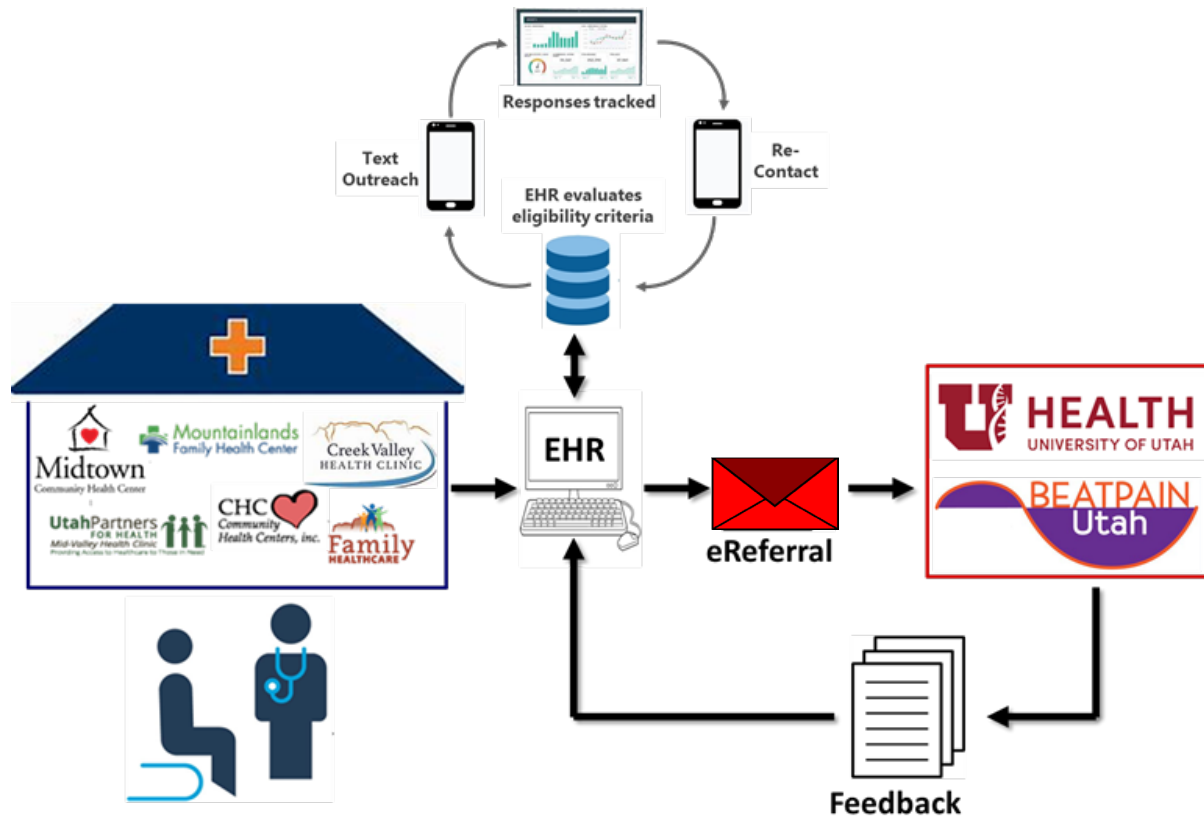
*Providing a nonpharmacologic option for persons with chronic back pain using telehealth*



	Rural	Urban
Age	52.0 (13.8)	51.5 (12.4)
Female	63.6%	63.6%
Hispanic/Latino	22.2%	63.0%
SDoH (ADI>8)	66.7%	43.4%



# Providing a nonpharmacologic option for persons with chronic back pain using telehealth



# Some Lessons Learned

- ✓ Engaging rural clinics has proven more challenging than engaging rural participants
  - Resource and staffing issues disproportionately impact rural settings
  - Communication is more fragmented
  
- ✓ Unique perspectives on health care and telehealth among rural clinicians and patients
  - Importance of familiarity in patient-provider relationships
  - Concerns with privacy and confidentiality
  - Resourcefulness, frugality, partiality for self-reliance



## University of Utah

- Tom Greene
- Jincheng Shen
- Nora Fino
- **Biostatistics**
- Kelly Lundberg
- **Psychiatry**
- Guilherme Del Fiol
- Bryan Gibson
- Leticia Stevens
- **Biomedical Informatics**
- Julie Fritz
- Anne Thackeray
- **Physical Therapy**



## AUCH

- Alan Pruhs
- Courtney Dinkins
- **Leadership**
- Tracey Siaperas
- **Care Coordination**
- Shlisa Hughes
- **Quality Improvement**



## Center for HOPE

- David Wetter
- **Director**
- Melissa Hall Yack
- **Community Engagement**
- Jennyfer Morales
- **Program Management**



## BeatPain Team

- Adrianna Romero
- Juliemar Medina
- Dania Iniguez
- **Research Staff**
- Isaac Ford
- Laura Vinci de Vanegas
- Kate Addis
- Cynthia DeFrancesco
- Juan Paz Delgado
- Whitney Rokui
- **Physical Therapists**



## Duke University

- Adam Goode
- **Physical Therapy**

# Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth (ARBOR-Telehealth)



MPIs: Richard L. Skolasky, ScD; Kevin McLaughlin, DPT

Funded by National Institute of Arthritis and Musculoskeletal and Skin  
Diseases (UG3AR083838)

# Overview

## Low Back Pain (LBP)

- Most common cause of disability in the US
- Largest driver of US healthcare spending growth
- Number one reason for opioid prescriptions

## Physical Therapy (PT)

- First line treatment
- Cost-effective in reducing disability and pain
- Decreased risk of opioid use
- 7-13% of patients attend PT
  - Barriers surrounding travel, missed work time, etc.

# Overview

## Rural Communities

- 40% fewer therapists per capita
  - Longer distance to travel
- Fewer patients attend PT within 30 days of onset
- Higher rates of opioid use

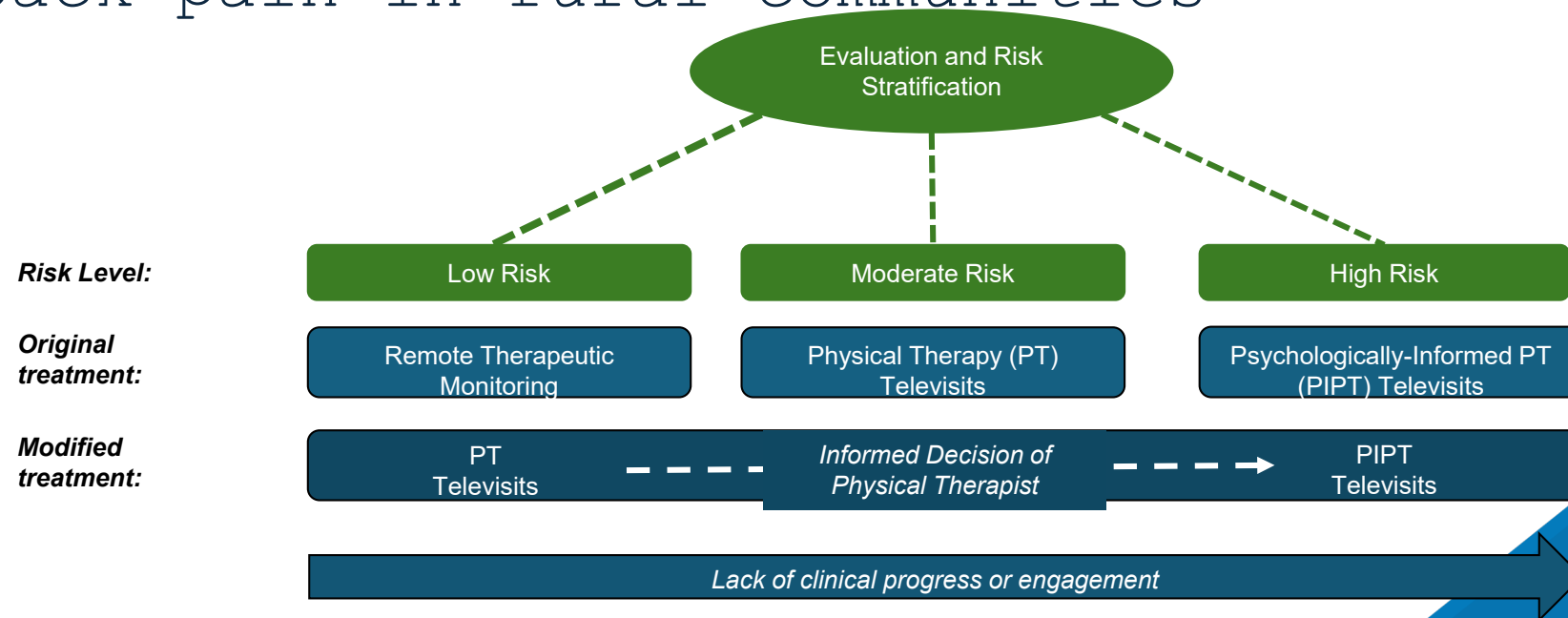
## Telehealth

- PT provided by televisits for first time during pandemic
- Reimbursed by CMS and most commercial insurances
- New code for remote therapeutic monitoring (RTM)
  - Asynchronous telerehabilitation using



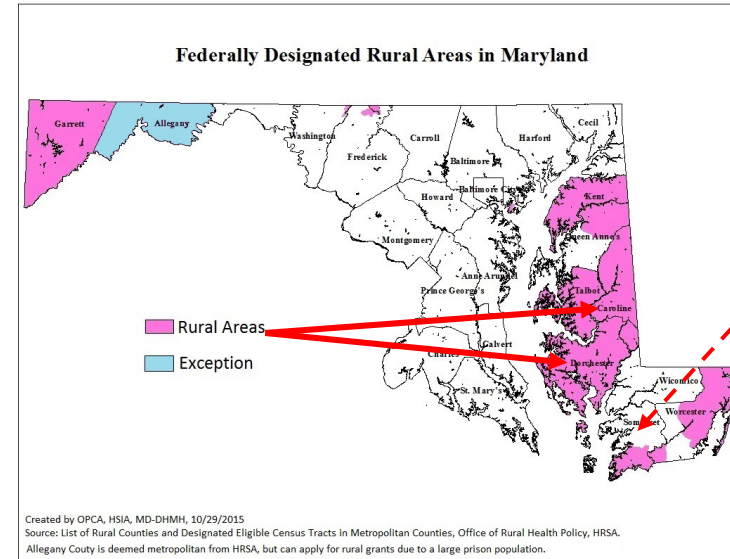
# Overall Objective

- To compare the effectiveness of a risk-informed telerehabilitation model to patient education to improve outcomes in patients with chronic low back pain in rural communities



# Study Design

- Randomized clinical trial
  - RiSC Telerehabilitation
    - Delivered by TidalHealth
  - Patient Education
    - Delivered via website
- Patients
  - 434 with chronic LBP
    - No spine surgery past 12m
    - Primary care office visit
  - 8 weeks active treatment
  - 12 months follow-up



Nearest  
PT Clinic

## Caroline County, MD

- 33,593 (pop'n est. 2023 Census)
- 80.7% White, 13.8% Black, 8.9% Hispanic
- 17.7% Age 65+ years

## Dorchester County, MD

- 32,897 (pop'n est. 2023 Census)
- 66.4% White, 29.2% Black, 6.4% Hispanic
- 23.1% Age 65+ years

# Potential Facilitators

## Recruitment Strategy

- Eligible population
  - Adults (18+ years)
  - Present to primary care with diagnosis of back pain in last 90 days
  - ODI  $\geq$  24%
  - Pain NRS  $\geq$  4/10
- Established relationship with primary care clinic
- EHR based recruitment and fidelity assessment

## Treatment Strategy

- Internet-based treatment
  - Broadband stipend (\$25/month during active treatment)
- Logistically flexible
  - No need to travel to clinic
- Materials provided
  - Home exercise equipment (e.g., mat and bands)

# Potential Barriers

## Recruitment Strategy

- Patient may not be actively seeking treatment for back pain
  - Build rapport; Identify burden of back pain; Discuss treatment options
- Recruitment by Hopkins team - lack of trust with population
  - Partnership between Tidalhealth and JH
  - Consistent branding ARBOR-Telehealth in all communications
  - Treatment provided by

## Recruitment Strategy

- EHR-based strategy
  - Technical challenges of sFTP transfer on monthly/daily basis
  - Epic programming team at partner institution

# Potential Barriers

## Treatment Strategy

- Internet-based treatment
  - Limited broadband access in rural communities
    - >90% household w/computer
    - ~85% household w/Internet
- Space needs
  - RC works to identify needs and provide solutions in advance
- Technical proficiency
  - RC walk through process in advance of first appointment
- Provider familiarity
  - Limited experience with delivery of telehealth visits
    - Will address with provider training
  - Limited experience with psychologically informed physical therapy
    - Will address with provider training

# Community Engagement

## Local Partners

- Tidalhealth
  - Research partner
  - Involved in development and implementation of program
- Maryland Rural Health Association
  - Community-based partner
  - *Educating and advocating for optimal health and wellness of rural communities and residents*

## Stakeholder Interviews

- Mixed-methods approach
  - Surveys
    - Burden of back pain
    - Experience with PT
    - Perspectives on Televisits
  - Interviews
    - Patients, Primary Care, Physical Therapy, Organizational Stakeholders

# Study Team

- Johns Hopkins
  - Richard L. Skolasky, Sc.D. (MPI)
  - Kevin McLaughlin, D.P.T. (MPI)
  - Elizabeth Colantuoni, Ph.D.
  - Stephen Wegener, Ph.D.
  - Tricia Kirkhart
- MedStar Health Research Institute
  - Kisha Ali, Ph.D.
- TidalHealth
  - Robert Joyner, Ph.D.
  - Jill Stone, D.P.T.
  - M. Patricia Chance, CRRC
  - Terri Hochmuth, D.N.P., M.S.N.-Ed, R.N.
- Maryland Rural Health Association
  - Jonathan Dayton, Director

A d a p 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   ( A I M - C P ) :  
*Lessons and Challenges Engaging Rural Populations*

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

NIH Collaboratory Steering Committee Annual Meeting

May 9, 2024



# DISCLAIMER

- I live in a city of 4 million people



# Our team

## 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

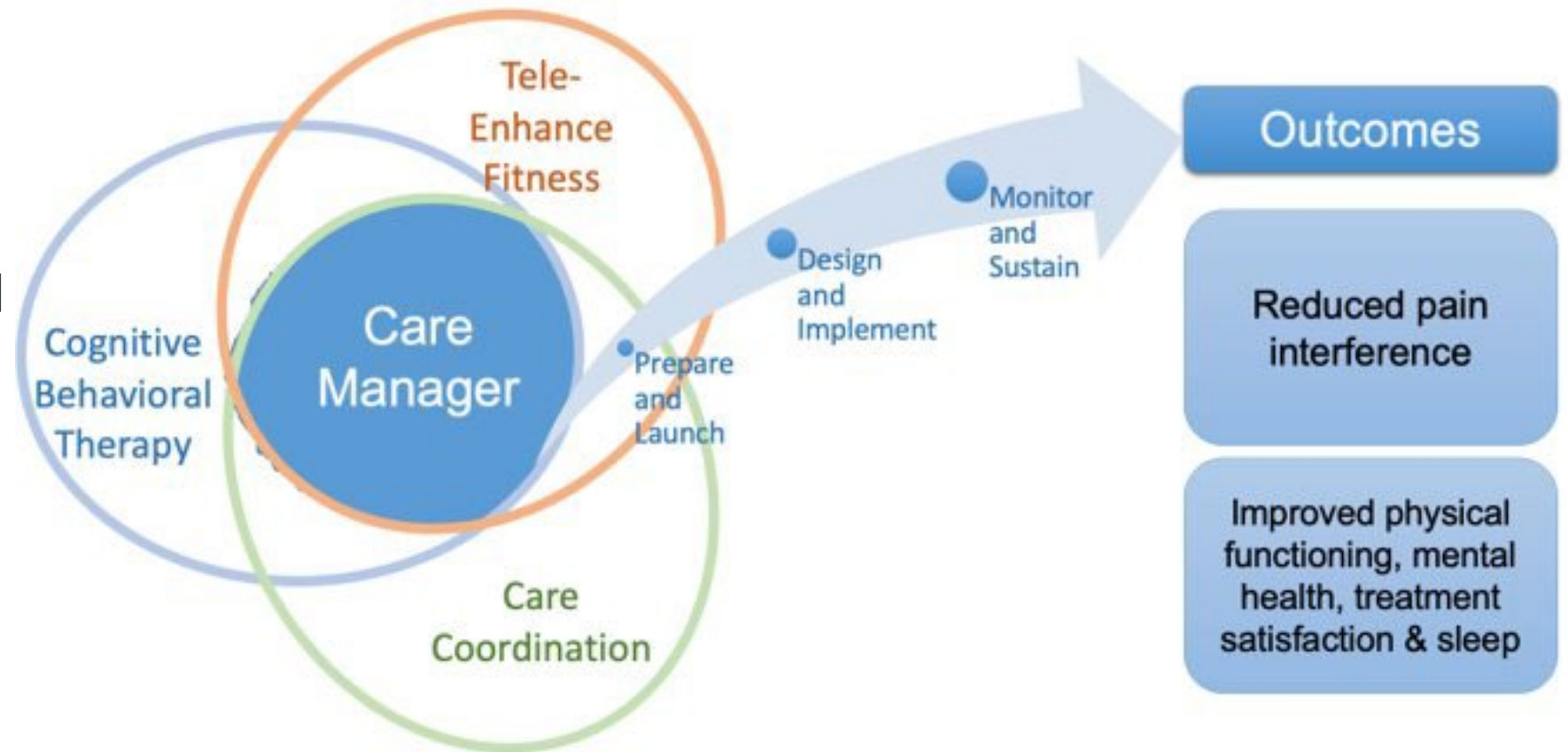
# Overall Objective

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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

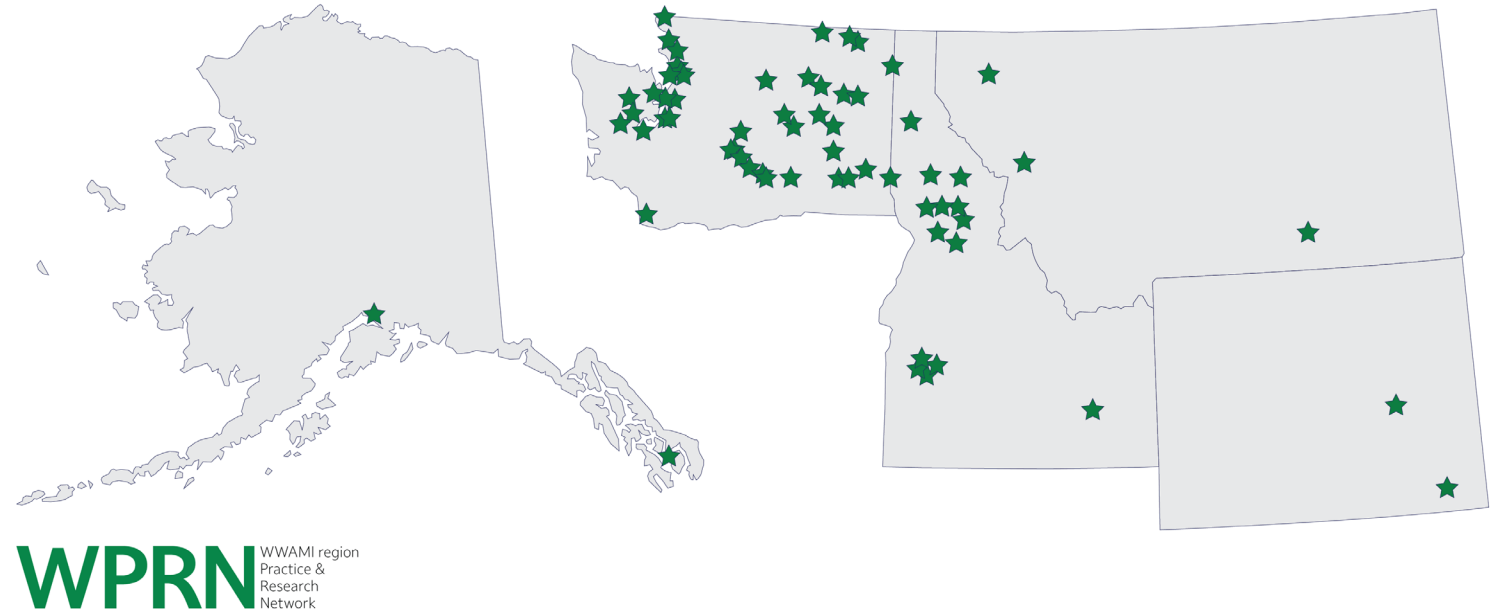


# Intervention components

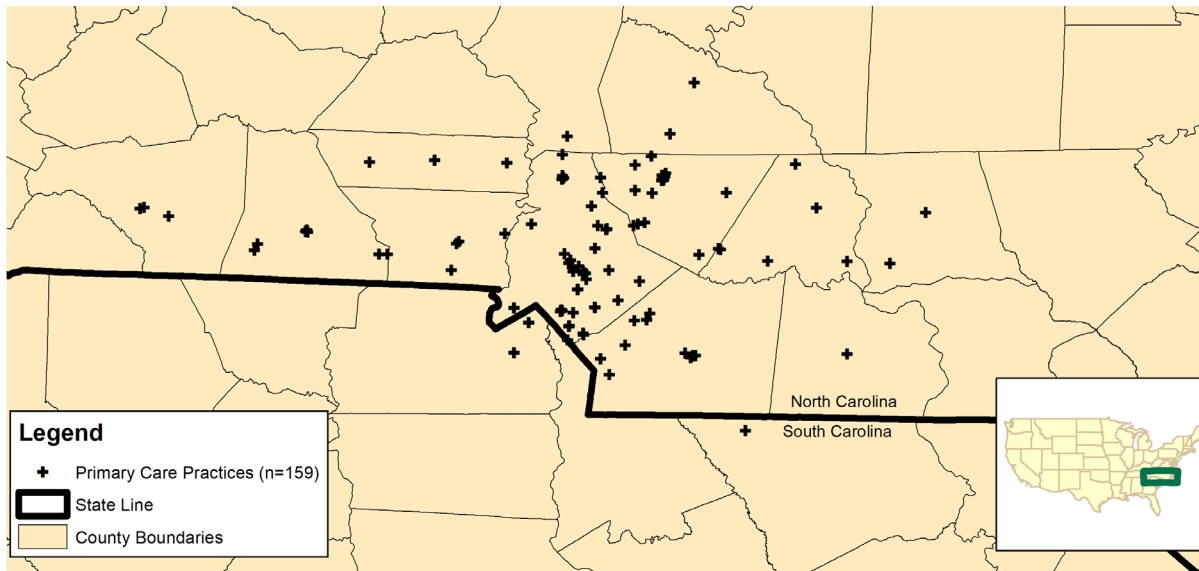
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Individual component	Description
Care Coordination	<ul style="list-style-type: none"><li>• Assessing patients for social service, behavioral health and specialty care needs</li><li>• Linking patients with community resources</li><li>• Tracking and 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>

# Settings



Primary Care Practice Locations for the Mecklenburg Area for Partnership for Primary Care Research (MAPPR)



# Challenges and Proposed Solutions

Category	Challenge	Proposed Solutions
Workforce	Nursing workforce shortage	<ul style="list-style-type: none"> <li>Flexibility in care manager background</li> </ul>
	Overall workforce shortage	<ul style="list-style-type: none"> <li>Defer site participation</li> <li>Discuss intervention as strategy to alleviate workforce shortage</li> </ul>
Trust / Polarization	Urban-rural divide	<ul style="list-style-type: none"> <li>Use local staff for most contact</li> <li>Staff and investigators who represent or understand rural issues</li> <li>Build on existing relationships</li> </ul>
	Framing of research outcomes / variables / interventions (e.g. CBT -> "in your head"; gender vs. sex)	<ul style="list-style-type: none"> <li>Open listening / discussion</li> <li>Build on existing relationships</li> </ul>
Regulatory	Lack of familiarity	<ul style="list-style-type: none"> <li>Open discussions / conversations</li> </ul>
	Different expectations	<ul style="list-style-type: none"> <li>Flexibility in trial design, identifying core elements of intervention</li> </ul>

# THANK YOU!

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

Sebastian Tong MD MPH  
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# Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention (RAMP)

Katie Hadlandsmyth, PhD

Associate Professor

Department of Anesthesia

Carver College of Medicine

University of Iowa



# Disclosures

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- No relevant financial relationships to disclose.
- Off-label use will not be discussed in this presentation.
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The views expressed in this talk are those of the authors and are not necessarily endorsed by the NINR, NIH, U.S. Department of Veterans Affairs, or the United States Government.

# Acknowledgements

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**Co-PIs:** Diana Burgess, PhD and Roni Evans, DC, PhD

**Research Team:** Co-Investigators: Robin Austin, John Ferguson, Alex Haley, Brent Leininger, Marianne Matthias, Brent Taylor, Stephanie Taylor; Consultant: Greg Serpa

**Project staff:** Ann Bangerter, **Lee Cross**, Emily Hagel Campbell, **Mallory Mahaffey**

## Known Barriers for Rural Veterans Utilizing CIH for pain

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- Lack of awareness and knowledge among clinicians and patients
- Need for clinician referral
- Support to successfully engage in CIH self-management
- Demand for CIH providers often outstrips supply
- Lack of availability of CIH/Whole Health pain care services outside of main VA medical centers

# Rural Veterans: Applying Mind-Body Skills for Pain (RAMP)

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**Goal:** To improve pain management and reduce opioid use among rural patients in the VA healthcare system

- The RAMP program is a cohesive, scalable multi-component CIH intervention that addresses Veterans' needs and overcomes existing barriers to pain care
- RAMP is designed to be implemented within the VA through its nationwide Whole Health System initiative
- We will collaborate with Veteran patients, VA health system partners, and Veteran serving community partners

# RAMP Study Overview

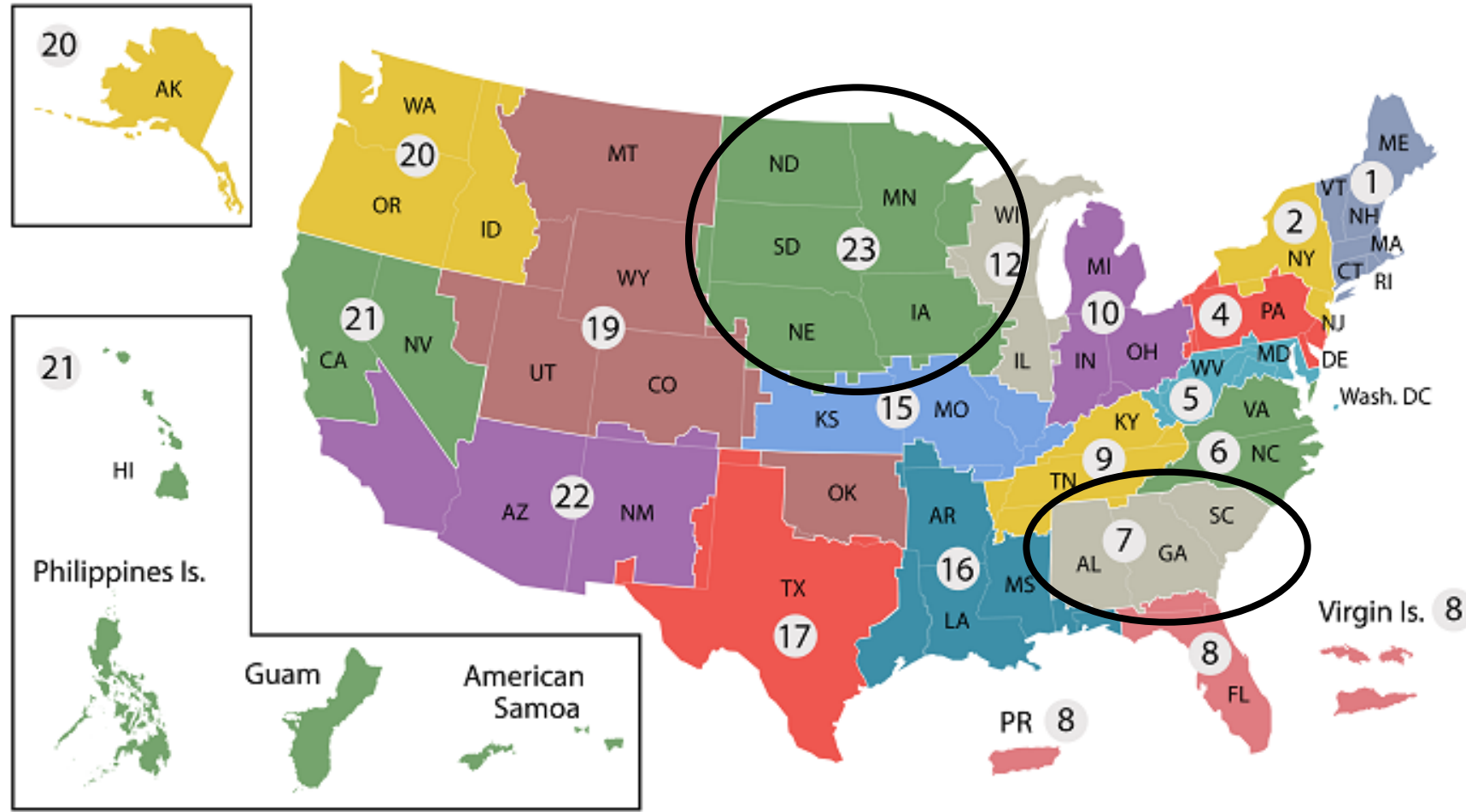
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**Phase 1 UG3 (2 years): Engagement activities** including developing & working with multi-level advisory panels (n = 35-50) & pilot study (n = 40)

**Phase 2 UH3 (3 years): Hybrid Type II Effectiveness Implementation Pragmatic Clinical Trial**

1. Assess **effectiveness** of cohesive mind-body intervention delivered by Whole Health coaches via telehealth (RAMP), at improving pain and secondary outcomes among rural VA patients with chronic pain (n = 500)
2. **Implementation.** Work iteratively with multiple levels of advisors (patients, community partners, VA healthcare system leaders and staff; n = 35-50) to co-develop, evaluate intervention implementation strategies used in the trial and adapt these strategies to scale up RAMP within the national VA healthcare system
  - a. **Mixed-methods assessment** of facilitators/barriers, RAMP use, etc.
  - b. **Co-creation** of plausible implementation strategies to scale up RAMP
  - c. **Budget impact analysis**

# Recruiting from VISN 23 and VISN 7



# Advisor Engagement Plan

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## Patient Partners

- RAMP Engagement Panel and other ongoing Veteran Engagement Panels

## Community Partners

- Non-VA Community Organizations (VFWs, American Legions, national organizations serving marginalized groups, etc.)

## VA Health Care System Partners

- National VA Program Office Leaders
- VA Medical Center Leaders & Staff
- VA Community Based Outpatient Clinics





# Patient and Community Organization Panels

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## Community Advisor Panel (CAP)

- Alaska Veterans Organization for Women (AVOW: Alaska)
- The Unquiet Professional (National)
- Invisible Wounds Project (Minnesota)
- The Warrior Alliance (Georgia)
- Alabama Veteran (Alabama)
- Veteran and Military Support Alliance (Maryland)

## Veteran Engagement Panel (VEP)

- 11 Veterans confirmed
  - 1 tentative (max: 12)
  - 55% women
  - 45% from minoritized racial and ethnic groups
  - Range of ages (36 – 74)
  - Range of geographic locations

# Internal Advisors- National to Local

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- Whole Health
  - Building the infrastructure for WH coaches to deliver RAMP
  - National approval and local buy-in
- Pain Management
  - National approval
  - Connection with local programs (e.g., Telepain)
- Office of Rural Health
  - National support
  - Local resources (e.g., GROVE)



## Discussion Question

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### **1. What are some creative strategies for enhancing participation rates among representatives from community organizations, to participate in an engagement panel?**

This has been a challenge for our study, and we have tried:

- Using our Veteran/patient experts to connect us with organizations
- Casting a wide net and reaching out to a lot of organizations
- Referrals from participating organizations to other organizations

# Questions