Communities Advancing Research Equity for Health™ (CARE for Health™)

Advancing Clinical Research *with and for* Primary Care

Network Meeting: Open Session

December 4, 2024

NIH National Institutes of Health

Welcome

Dr. Tara Schwetz
Deputy Director for Program Coordination, Planning, and Strategic Initiatives
National Institutes of Health

CARE for Health™ Network Meeting: Purpose and Objectives

Overarching Purpose:

- Begin building the foundation for a sustained CARE for Health™ Network for primary care research across the United States

Objectives:

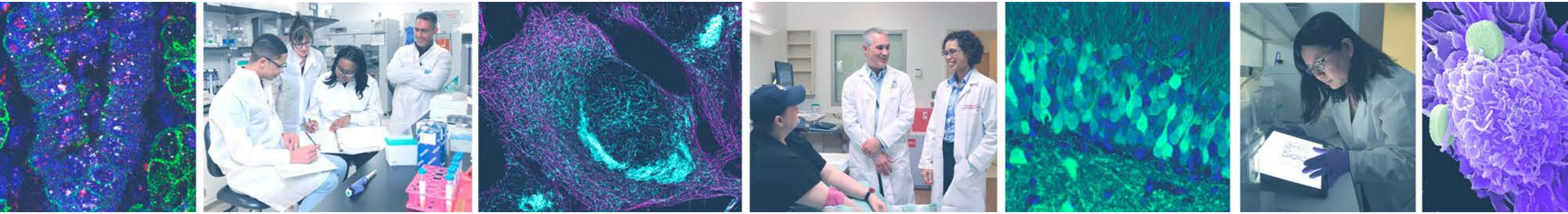
- Welcome participants
- Present NIH leadership's vision for the program
- Connect Network Research Hub investigators and community representatives to share insights and discuss potential opportunities and challenges
- Provide an orientation to the CARE for Health program's goals and milestones
- Review the current clinical studies portfolio

Open Session Agenda

Time	Segment
9:00	**Welcome by Deputy Director for Program Coordination, Planning, and Strategic Initiatives**
9:10	**Opening Remarks by the NIH Director**
9:25	**Programmatic Overview by CARE for Health™ Oversight Committee Co-Chairs**
9:50	**Overview of Clinical Studies Portfolio**: Non-pharmacologic pain management in FQHC Primary Care Clinics (BeatPain Utah)
10:35	*Break*
10:55	**Overview of Clinical Studies Portfolio:** Collaborative Care for Polysubstance Use in Primary Care Settings (Co-Care)
12:00	*Lunch Break*
1:15	**Overview of Clinical Studies Portfolio**: Treat-to-target serum urate vs. treat-to-avoid symptoms in gout (TRUST)
2:00	**Looking Ahead to Opportunities and Challenges**
3:50	**Wrap Up and Next Steps**
4:00	Adjourn Open Session

Our Vision for CARE for Health™

CARE for Health Network Meeting
December 4, 2024



Monica M. Bertagnolli, MD
Director, National Institutes of Health

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA


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



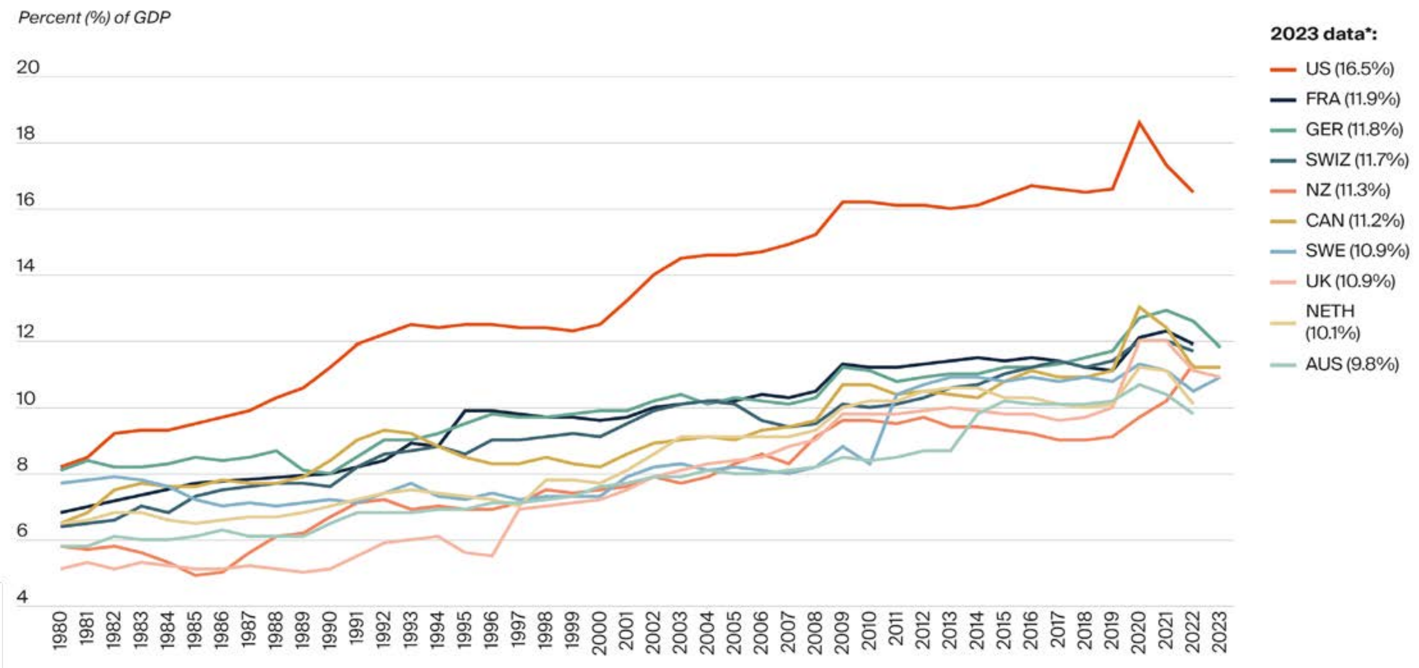
Disturbing metrics in the health of the U.S. population

Health care system performance rankings
Comparing 10 Nations

United States

Overall Rankings	10th
Access to care	10th
Care process	2nd
Admin Efficiency	9th
Equity	9th
Health Outcomes	10th

Health Care Spending as a Percentage of GDP 1980–2023



Data: OECD Health Data, July 2024. David Blumenthal et al., Mirror, Mirror 2024: A Portrait of the Failing U.S. Health System — Comparing Performance in 10 Nations

People who are not adequately represented in clinical research

- Are older
- Are uninsured
- Belong to minority groups
- Live in rural locations
- Have co-morbid conditions
- Are more likely to receive non-standard treatment

What Should NIH Do?

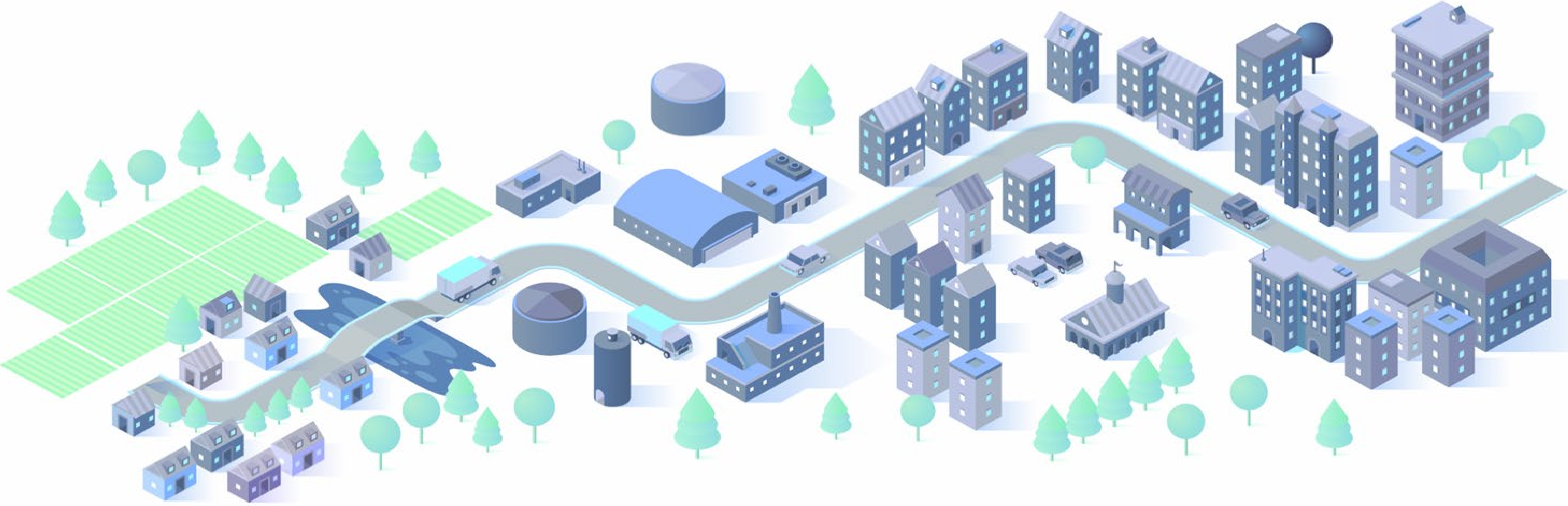
Connect research to primary care

Research

Clinical Care

Communities **A**dvancing **R**esearch **E**quity **for Health**

CARE for Health™



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CARE for Health^{TM} Pilot Phase: Inaugural Awards

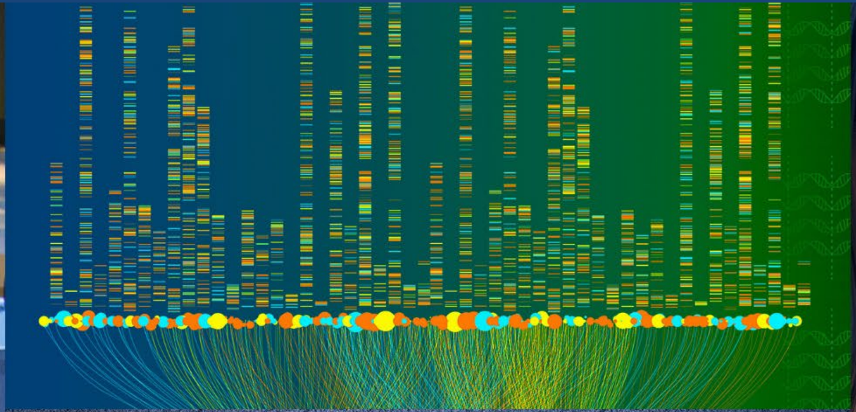
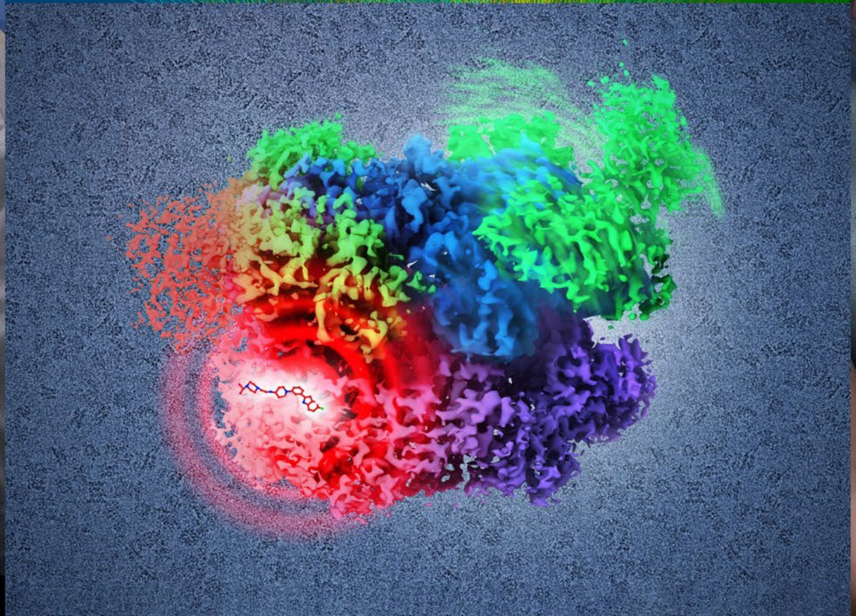
$5 million in first-year funding to support 3 Network Research Hubs

- **Oregon Health and Science University (OHSU):** The Primary Care Rural and Frontier Clinical Trials Innovation Center to Advance Health Equity (PRaCTICE) Network Research Hub
- **University of Wisconsin-Madison (UW):** The Wisconsin Research and Education Network (WREN)
- **West Virginia University (WVU)**, in partnership with the West Virginia Clinical and Translational Science Institute: The West Virginia Rural Roots to Research (WVR3) Network

Partnerships with Ongoing Clinical Trials

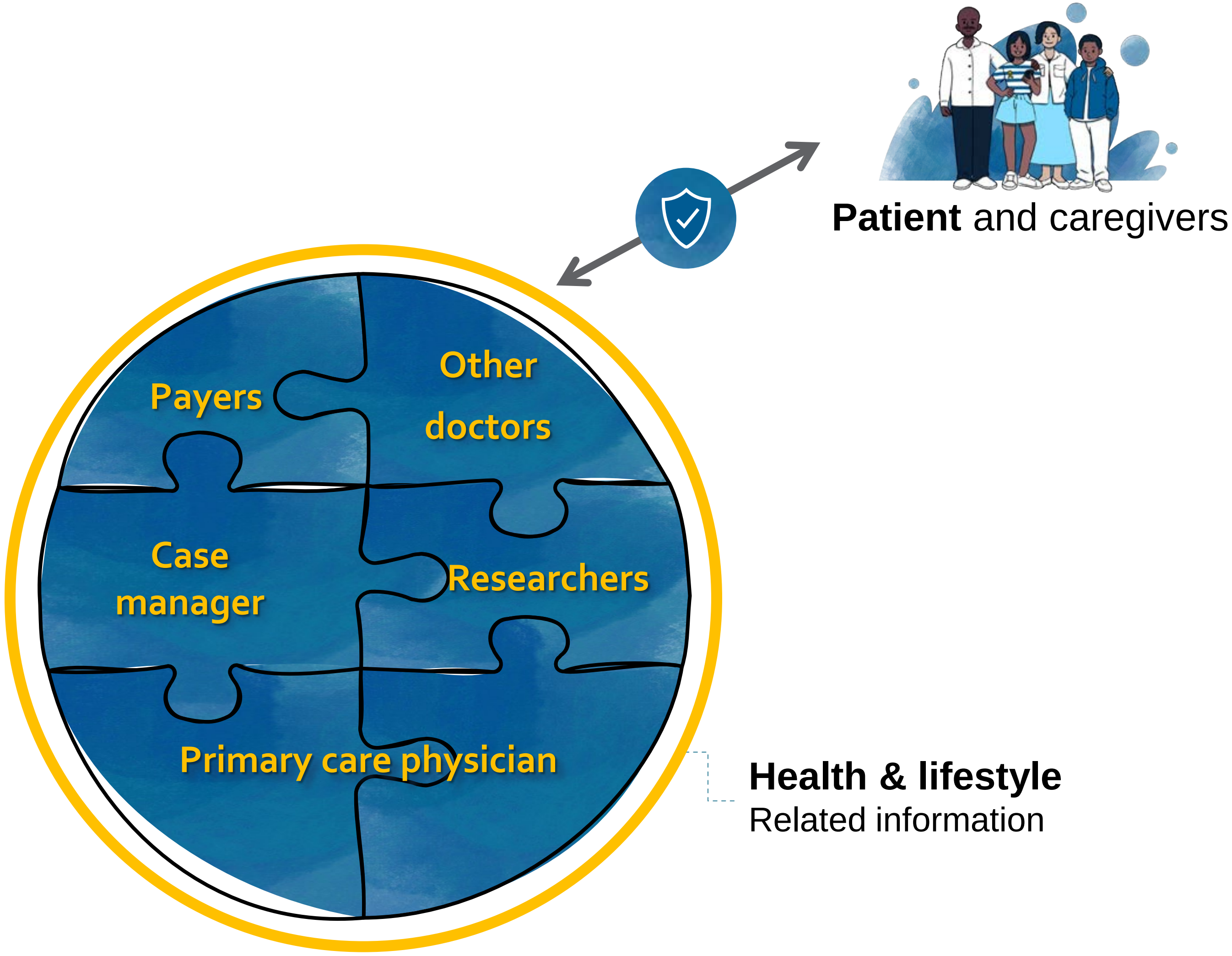
- Working with OHSU: Nonpharmacologic Pain Management in FQHC Primary Care Clinics – **Beat Pain**
- Working with OHSU and WREN: Collaborative Care for Polysubstance Use in Primary Care Settings – **Co-Care**
- Working with WV: Treat-to-Target Serum Urate Versus Treat-to-Avoid Symptoms in Gout – **TRUST**

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.


Leveraging Data from the Clinical Care Environment for Research

- Goals:
  - Bring data and information together directed and controlled by patients
  - Create a network of lifetime patient data and information at scale
- Features:
  - Patients own all their data and fully control permission of how their data is used and for what purpose.
  - Data is aggregated for patients across their lifetime – and is comprehensive from disease to wellness



Patient and caregivers

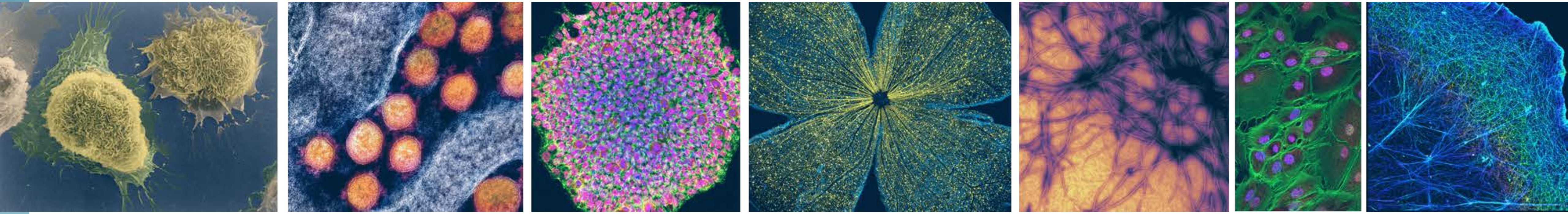
Health & lifestyle
Related information

NIH's Health Data Ecosystem

The right data, at the right time, at the right place.

- Facilitate learning health system initiatives
- Eliminate data formatting and collection redundancies
- Reduce burden for data submission
- Increase data quality and access speed to allow decision-making
- Apply AI methods to data that are as diverse as the US population

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



NIH

Turning Discovery Into Health

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Programmatic Overview

CARE for Health™ Oversight Committee Co-Chairs

CARE for Health™ Programmatic Overview

CARE for Health™ Oversight Committee

Debara Tucci, MD, MS, MBA
Co-Chair

Director, National Institute on Deafness and Other Communication Disorders (NIDCD)

Helene Langevin, MD
Co-Chair

Director, National Center for Complementary and Integrative Health (NCCIH)

Joni Rutter, PhD
Co-Chair

Director, National Center for Advancing Translational Sciences (NCATS)

In addition to the co-chairs, Oversight Committee membership include directors from NCI, NEI, NHLBI, NIA, NIAID, NIDDK, NIGMS, NIMHD, and DPCPSI (*ex officio*)

Communities Advancing Research Equity for Health™

In June 2024, NIH Director, Dr. Monica Bertagnolli, introduced the CARE for Health™ initiative

Read the announcement

NEWS RELEASES

Thursday, June 6, 2024

NIH launches $30 million pilot to test feasibility of a national primary care research network

Initiative aims to improve health outcomes by integrating research in everyday primary care settings.

The National Institutes of Health (NIH) is investing approximately $30 million in total over fiscal years 2024 and 2025 to pilot a national primary care research network that integrates clinical research with community-based primary care. The new initiative called Communities Advancing Research Equity for Health – or CARE for Health – seeks to improve access to clinical research to inform medical care, particularly for those in communities historically underrepresented in clinical research or underserved in health care. Informed by the health needs of these

EDITORIAL

Connecting lab, clinic, and community

Despite great progress in biomedical research, the health of the US population appears to be getting worse. The United States spends substantially more per capita on health care than other wealthy countries, yet US life expectancy ranks low among its peers. Mortality rates have been increasing for segments of the US population, including those in rural areas, certain racial and ethnic groups, and individuals with low socioeconomic status. A whole-of-society approach is required to address such negative trends and disparities, and the biomedical research enterprise must play a key role.

To better understand relationships between the genes we inherit and the environmental and societal factors that surround us and to deliver more evidence-driven health care, research must be integrated into clinical care and community settings, reaching patients from all walks of life. Unlike most research settings, primary care is patient- and community-centered and emphasizes health maintenance and preventive care alongside treatment and rehabilitation in a location as convenient as possible for the patient. Communities Advancing Research Equity (CARE) for Health, a new National Institutes of Health (NIH) research network in primary care settings, will expand beyond the existing capacity of clinical researchers to engage patients and communities that are currently not well represented in clinical research. By engaging more primary care providers serving more communities experiencing health disparities, the CARE for Health network will address common health issues, including obesity, mental health, perinatal care, and cancer screening.

Rather than sticking to a narrow suite of studies determined by researchers centrally, the network will offer a wider menu of studies, allowing more patients and providers more choice to participate in, and influence, those studies most relevant to their needs and the needs of their communities. Studies will place particular emphasis on evaluating new treatment and prevention approaches that are meaningful to underserved populations. The network will focus on research on disease prevention, health care implementation, and information dissemination, as well as trials with multidisease endpoints and those designed to improve the efficiency of care delivery. Primary care providers will receive support to achieve research aims, including funding and study designs that integrate research activities into clinical care workflows and embed data collection in electronic health records.

> “...the network will offer a wider menu of studies...”

The CARE for Health network will leverage many existing resources, such as Federally Qualified Health Centers, which offer services for underserved populations, and several existing NIH research initiatives and networks, including the IDeA Clinical & Translational Research Network Award program, which supports biomedical research capacity building in states that have historically low levels of NIH funding.

A second initiative will establish NIH's National Library of Medicine (NLM) as a focal point to accelerate data sharing and use and to advance health-related data science. Rapid growth in biomedical data, together with new artificial intelligence and machine learning (AI/ML) methods, promises to deliver transformative tools and research insights. NIH's Data Management and Sharing Policy requires that all new funding proposals include a data accessibility plan to promote data sharing. But full implementation of this policy requires new approaches and resources that can integrate data from basic and social science research, public health, and clinical care.

NLM will substantially increase its capacity for data hosting, including reaching beyond NIH to incorporate data from agencies across the Department of Health and Human Services. It will employ a federated architecture to allow independent research teams to deliver data in ways that reduce complexity, require minimal cost to access, and foster flexibility and agility in data exchange using open data standards. NLM will promote access to data from diverse populations to facilitate ethical and equitable development of AI/ML, expanding on current NIH programs such as Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity, and Bridge to Artificial Intelligence. NLM will also enable access to advanced analytics and computational power by fostering collaboration between computational biology, molecular biology, drug development, and translational, clinical, and social science research. Existing NIH efforts providing data science education and workforce development will expand.

These initiatives will help translate scientific discoveries into effective health care and will require not only support from NIH but commitment from the biomedical research community, other governmental agencies, health care systems, and private citizens who participate in research.

–Monica M. Bertagnolli

Monica M. Bertagnolli is director of the National Institutes of Health, Bethesda, MD, USA. monica.bertagnolli@nih.gov

10.1126/science.adq2140

CARE for Health™ Program Overview

PROGRAM GOALS

Develop **infrastructure for a primary care-focused clinical research network**

Establish a **foundation for sustained engagement with communities** underrepresented in clinical research

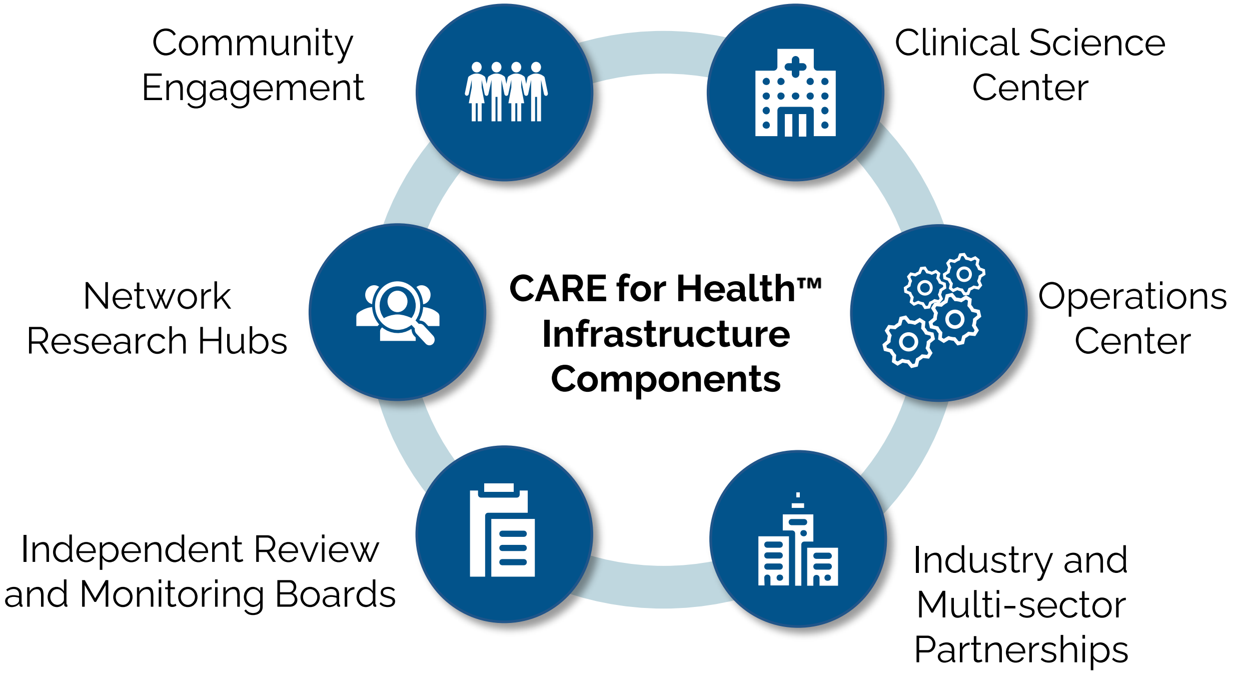
Implement **innovative study designs**

Integrate **research into routine primary care**

Facilitate **adoption of evidence-based research findings**

PROGRAM COMPONENTS

Starting as a **two-year pilot**, CARE for Health™ will develop six components to build a Network of Networks.



CARE for Health™ Infrastructure Components

Community Engagement

Clinical Science Center

Network Research Hubs

Operations Center

Independent Review and Monitoring Boards

Industry and Multi-sector Partnerships

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Outreach and Engagement to Inform Program Design

From April-June 2024, NIH hosted several listening sessions and a public workshop to launch the Communities Advancing Research Equity for Health™ (CARE for Health™) network.

Listening Sessions

Engaged **78 participants** across four sessions on:

- Early, Sustained Engagement of Patients and Community Organizations
- Clinical Research Network Capabilities
- Needs of Providers and Healthcare Systems for Research Participation
- Clinical Research Innovations to Reduce Site and Provider Burden

Perspectives reflected included:

- Research Networks
- Primary Care Providers and Organizations
- Hospital Systems
- Patient and Community Organizations
- Federal Agencies

Public Workshop

538 participants joined on June 7th to hear details on CARE for Health™ and shared their questions and suggestions for the program.

Listening Session Executive Summary: https://commonfund.nih.gov/clinical-research-primary-care/fnih-nih-listening-sessions

What We’ve Heard: Common Themes

Bridging Gaps and Building Connections

Building Sustainable and Effective Partnerships

Demonstrating Trustworthiness through Balanced & Bi-directional Partnerships

Understanding the Diverse Needs of Communities

Accounting for Provider Needs in Research Integration

Aligning Practice Needs and Research Structures

Considering the Workload of Health Care Providers

Reducing Burden with Innovative Study Design and Technology

Balancing Financial Implications of Research Involvement

Addressing Financial Sustainability

Valuing Patient and Community Contributions

Potential Synergistic Partnerships

IDeA | Clinical and Translational Research

NIH CEAL
Community Engagement Alliance

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

CTSA Clinical & Translational Science Awards Program

pcornet®
The National Patient-Centered Clinical Research Network


CARE for Health Partners

Patients, Communities

FQHCs and CHCs

Federal Agencies

Practice Based Research Networks

Industry and Multi-sector Partnerships

Professional Societies

COMMUNITY HEALTH CENTER® FQHC QUALITY

HRSA
Health Resources & Services Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

OASH | Office of the Assistant Secretary for Health

FDA U.S. FOOD & DRUG ADMINISTRATION

INDIAN HEALTH SERVICE • PHS • 1955

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

AHRQ Agency for Healthcare Research and Quality

Establishing an NIH Network for Research in Primary Care Settings

Coordinated infrastructure that embeds innovative research into routine clinical care in primary care settings to:

- Support primary care-based clinical research in mission areas **spanning prevention and treatment** and with a **focus on health equity and whole person health**
- Establish a foundation for **sustained engagement with communities underrepresented** in clinical research
- Implement **innovative study designs suitable for primary care settings** that address common health issues, inform clinical practice, and enhance dissemination and implementation

…thereby facilitating and accelerating research advances for adoption and implementation into everyday clinical care, improving health outcomes, and advancing health equity for all Americans.

Approach to Network Building

Expand enrollment efforts of existing NIH studies and develop new studies as the infrastructure is established

---

Partner with existing clinical research networks and resources, expanding with new collaborations as the network grows

---

Engage primary care sites and their community network partners on prioritizing and planning research

---

Implement study designs across the landscape of clinical trial innovations to minimize burden on patients and providers

Key Components

Practice-Based and Patient-Centered | Research Prioritization and Planning | Clinical Study Innovations | Sustained Community Engagement

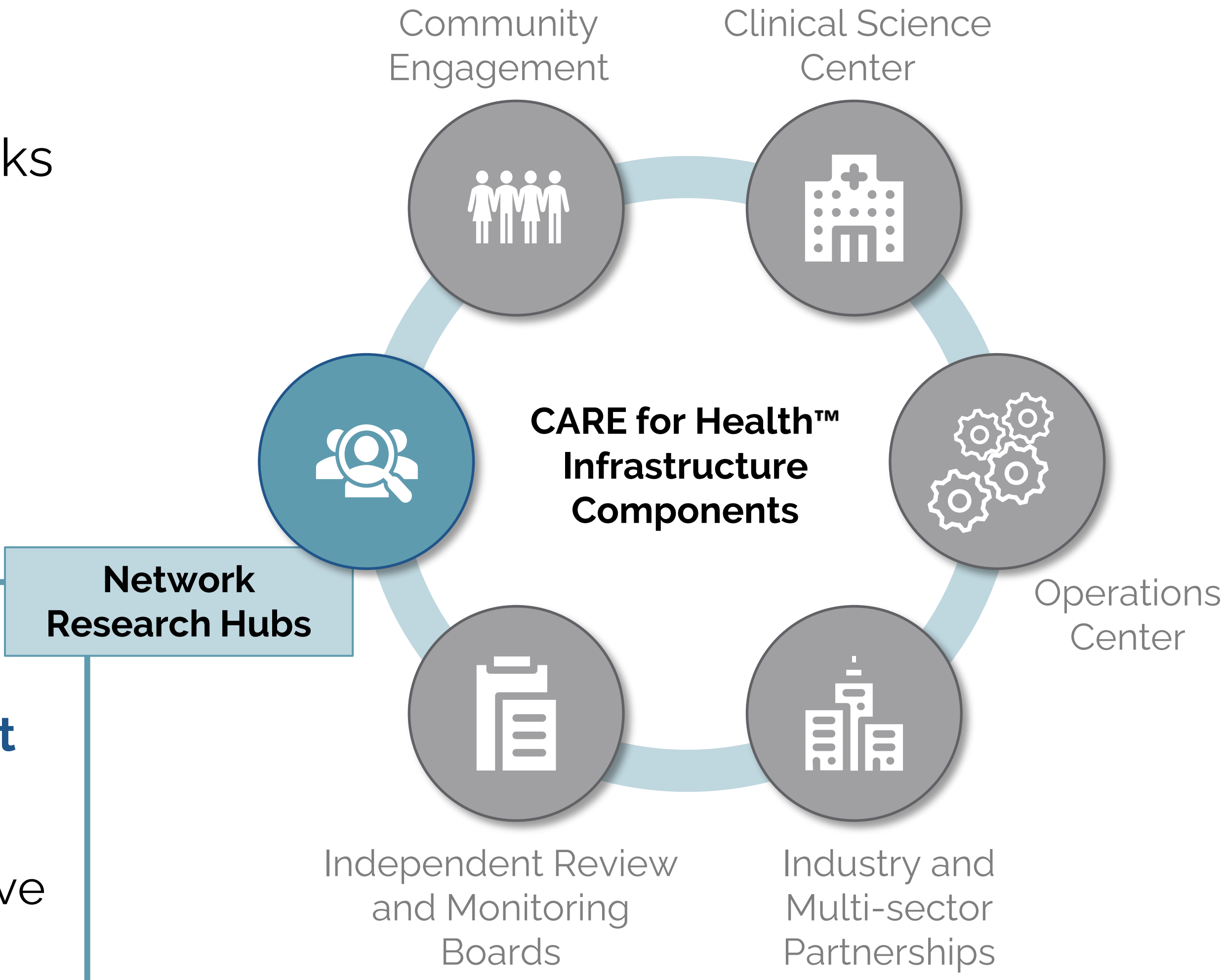
Network Research Hubs

Key Elements of Pilot Launch

- Leveraging existing clinical research Networks for rapid launch
- Focus on populations that are medically under-served and historically under-represented in biomedical research, with emphasis in initial pilot phase on rural populations

Research Opportunity Announcement (ROA):
Integrating Clinical Research into Primary Care Settings through Network Research Hubs – A Pilot (OT2)

Purpose: Invite applications for organizations to serve as "Network Research Hubs" and establish infrastructure to conduct clinical research in rural primary care settings as a two-year pilot


CARE for Health™ Infrastructure Components

Community Engagement

Clinical Science Center

Operations Center

Industry and Multi-sector Partnerships

Independent Review and Monitoring Boards

Network Research Hubs

Three Awards Have Been Made to Date

NIH Makes Inaugural Awards to Begin Building its CARE for Health™ Primary Care Research Network

The National Institutes of Health (NIH) made awards to three institutions as a first step toward creating a primary care clinical research network that will actively engage communities historically underrepresented in clinical research. This marks the kick-off of the pilot phase of the Communities Advancing Research Equity for Health™ - or CARE for Health™ program, which seeks to improve access to clinical research that informs m
awards, totaling more than $5 m
the first year will support three
Hubs as part of the developing
infrastructure.

"We eagerly anticipate collabora
communities – to tackle the hea
Monica M. Bertagnolli. "These a

NIH Common Fund
@NIH_CommonFund

The #CAREforHealth Program is underway! The program has announced the first 3 Hubs as part of a pilot project to bring #ClinicalResearch opportunities to patients in #PrimaryCare settings. Learn more: go.nih.gov/l4zyfLn

On September 24, NIH Common Fund announced the first three hub awards

Read the announcement

CARE for Health™ Research Opportunity Announcement (OTA-24-016) for Network Research Hubs: Initial Awards

Awarded Organization	Research Network Affiliation	FQHC	PBRN
Oregon Health and Science University	NIH CTSA	✓	✓*
University of Wisconsin - Madison	NIH CTSA	✓	✓
West Virginia University	IDeA-CTR	✓	✓

* Indicates >1 PBRN

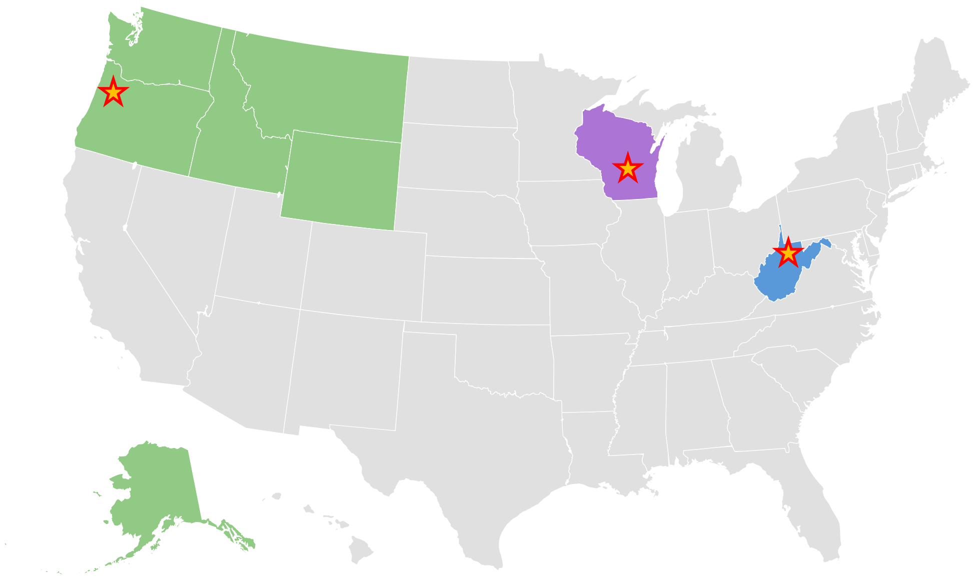
Building a Foundation for CARE for Health™ Network of Networks: Clinical Community Reach

The network research hubs will

1. Participate in clinical trials with existing NIH funded studies.
2. Engage additional clinics as part of efforts to understand communities' research priorities and preferences.

In total, the hubs will be working with over 50 clinics in Year 1.

Hub's Proposed Reach



🟩 **Oregon Health and Science University**

🟪 **University of Wisconsin - Madison**

🟦 **West Virginia University**

★ Stars indicate location of submitting institution

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CARE for Health™ - Future Plans

FY24 and Early FY25

- FY24-funded Hubs initiate enrollment into existing NIH-funded studies
- Engage with funded Hubs to identify and develop clinical research priorities relevant to their practitioners and communities
- Anticipate funding additional Hubs

FY26 and Beyond

- Continue expanding and developing infrastructure components of the program
- Launch new studies developed by and for the network

FY25

- Develop the Clinical Science Center and Operations Center
- Design innovative studies tailored to practitioner- and community-identified priorities

Overview of Clinical Studies Portfolio

Discussion Overview

- Description of the study
- Overview of hub participation in study, including relevance of research question to their communities
- Discussion on challenges, adaptive strategies, and opportunities
- Open Q&A

Overview of Clinical Studies Portfolio: BeatPain

Presenters: Dr. Julie Fritz (BeatPain Utah), Representatives from PRaCTICE Network Research Hub

Moderator: Dr. Wendy Weber

NIH National Institutes of Health

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

BEATPAIN Utah

Nonpharmacologic Pain Management in Federally Qualified Health Center Primary Care Clinics

Julie M. Fritz, PhD, PT
Distinguished Professor of Physical Therapy and Athletic Training
University of Utah

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

NIH HEAL INITIATIVE

AUCH
ASSOCIATION FOR UTAH COMMUNITY HEALTH

UNIVERSITY OF UTAH
HUNTSMAN
CANCER INSTITUTE

HEALTH
UNIVERSITY OF UTAH

Pain in America

21% of U.S. adults experience chronic pain

7% experience high-impact chronic pain (i.e., chronic pain resulting in substantial restriction to daily activities)

High impact chronic pain rates are higher for rural, low income, lower education attainment

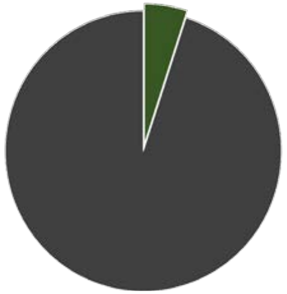
Rural residents also experience disparities in receiving evidence-based pain care

FROM: National Center for Health Statistics, National Health Survey, 2019.

FROM: Rikard SM, et al. *MMWR Morb Mortal Wkly Rep*. 2023; 72(15);379–385

AUCH
ASSOCIATION FOR UTAH COMMUNITY HEALTH

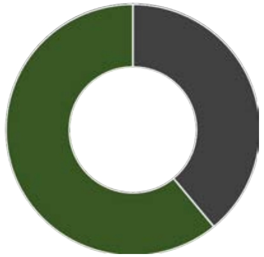
14 Utah health centers operate **69 clinics** and provide care to more than **181,000 people** annually



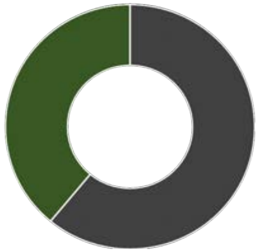
1 of every **20** Utahns

1 of every **4** uninsured Utahns

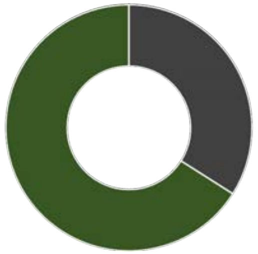
1 of every **3** Utahns living in poverty



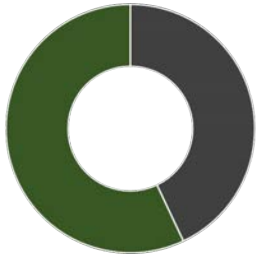
61% identity as a racial or ethnic minority



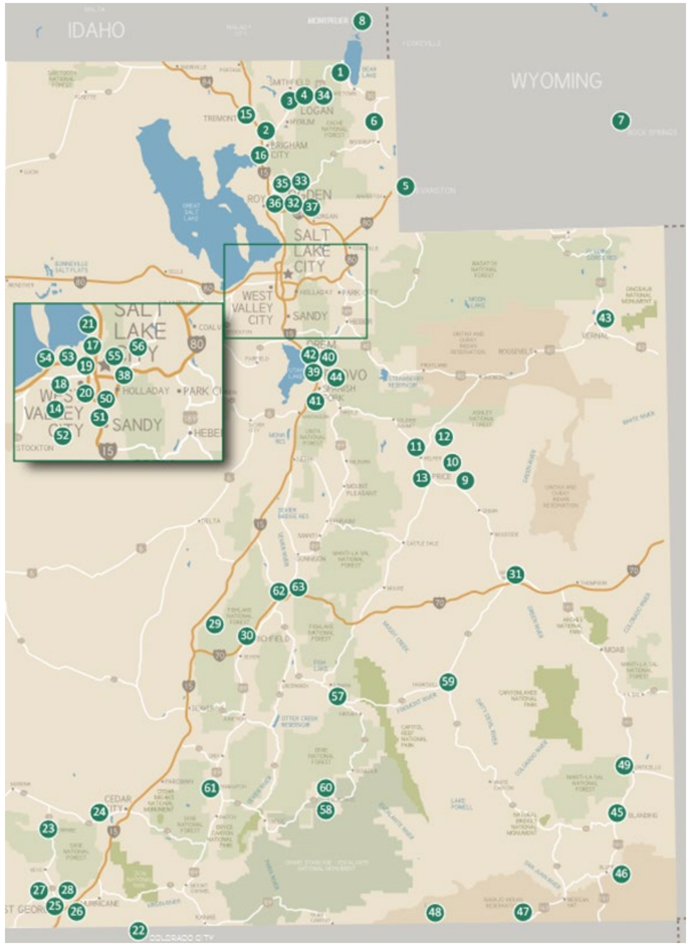
37% communicate in a language other than English



66% at or below the Federal poverty level



57% of clinics located in rural/frontier counties



BeatPain Utah

Goal: Improve pain management and reduce reliance on opioids for patients with chronic back pain in FQHCs in Utah.

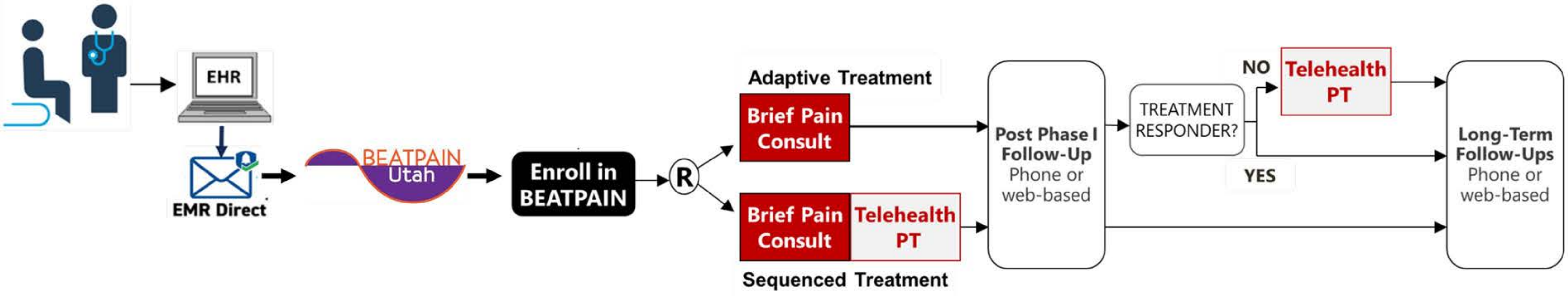
Strategy: Pragmatic Randomized Clinical Trial - Hybrid type I effectiveness-implementation design.

- ✓ Compare the effectiveness of first-line nonpharmacologic pain treatments using phone-based telehealth to overcome access barriers, improve patient-centered outcomes and reduce opioid use.
- ✓ Collect implementation outcomes for EHR-based referral process and telehealth physical therapy delivery.

Nonpharmacologic Pain Management in Federally Qualified Health Center Primary Care Clinics

SPECIFIC AIMS

1. Compare the effectiveness of brief pain teleconsult with or without telehealth PT (pain interference 1^0 outcome; opioid use 2^0 outcome).
2. Compare the effectiveness of telehealth PT as a first-line vs. a stepped care strategy as second-line care for patients do not respond to brief pain teleconsult.
3. Examine results of Aims 1 & 2 in pre-defined patient phenotypes based on gender, presence of HICP and current opioid use.
4. Explore implementation outcomes for teleconsult services (acceptability, adoption, feasibility and fidelity).



EHR

EMR Direct

BEATPAIN Utah

Enroll in BEATPAIN

R

Adaptive Treatment

Brief Pain Consult

Brief Pain Consult | Telehealth PT

Sequenced Treatment

Post Phase I Follow-Up
Phone or web-based

TREATMENT RESPONDER?

NO

Telehealth PT

YES

Long-Term Follow-Ups
Phone or web-based

TIMELINE: Baseline……Randomization……………………………………12-Week Follow-Up……………………………………………26-Week….52-Week F/U

PHASE I TREATMENT

PHASE II TREATMENT

Eligibility Criteria

Inclusion

- Visit with provider in a CHC clinic related to chronic back pain in past 90 days
- Chronic back pain based on the NIH Task Force definition
- Age 18-80
- English or Spanish-Speaking
- Access to telehealth resources (phone and/or internet access)

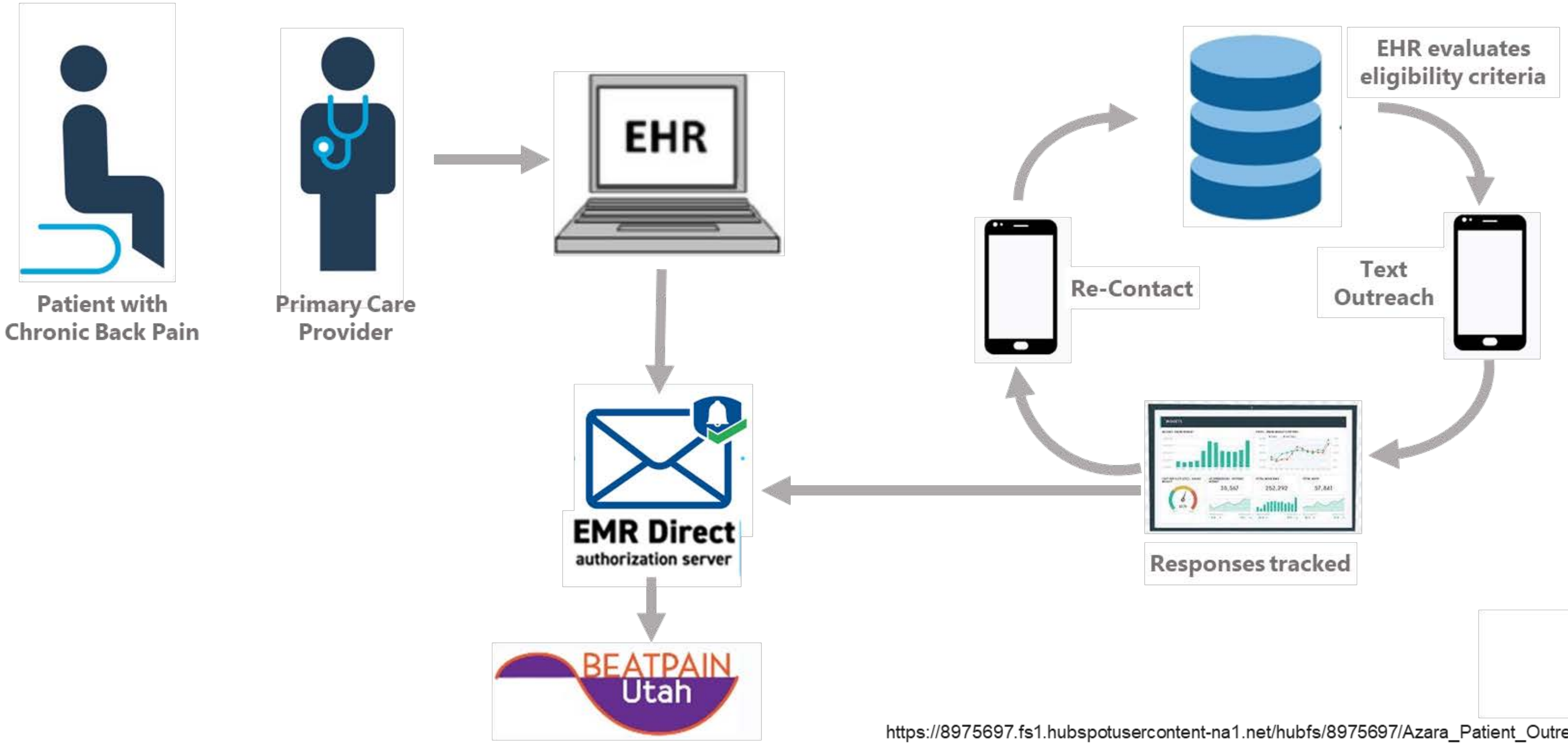
Exclusions

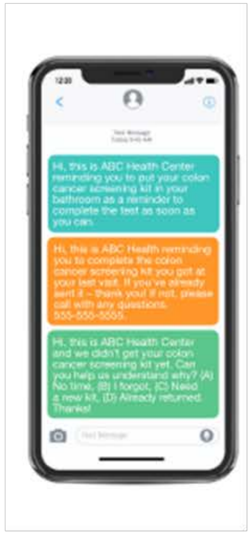
- Active substance use disorder for which the person is receiving treatment (not including peer-led support).
- Non-musculoskeletal diagnosis causing back pain including neoplasm, infection, inflammatory disease, etc.
- Spinal fracture diagnosis causing back pain.
- Co-morbid condition that restricts ability to engage in physical activity including neurologic disease or injury, paraplegia, wheelchair dependence, etc.
- Currently pregnant based on self-report
- Spine surgery in the past 6 months

Implementation Strategies

In-Clinic E-Referral

Patient Outreach Campaign




Hi, this is ABC Health Center reminding you to put your colon cancer screening kit in your bathroom as a reminder to complete the test as soon as you can.

Hi, this is ABC Health reminding you to complete the colon cancer screening kit you got at your last visit. If you've already sent it - thank you! If not, please call with any questions. 555-555-5555.

Hi, this is ABC Health Center and we didn't get your colon cancer screening kit yet. Can you help us understand why? (A) No time, (B) I forgot, (C) Need a new kit, (D) Already returned. Thanks!

azara healthcare

https://8975697.fs1.hubspotusercontent-na1.net/hubfs/8975697/Azara_Patient_Outreach_with_Connector_Brochure.pdf

Opportunities, Challenges and Adaptive Strategies

- Consistent with a pragmatic trial, our implementation strategies are designed to have flexibility around a set of core components.
- The study is completely de-centralized to facilitate implementation in rural and under-resourced settings.
- Two-way communication with clinics has been critical as situations arise with participants.
- We offer the brief consult intervention to persons who choose not to enroll or are ineligible.
- Audio-only communication for delivering the interventions has been essential
- Rural residents that are referred have proven more challenging to contact and enroll than non-rural residents.

THANK YOU

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

- Emily Bennett
- Tracey Siaperas

Care Coordination

- Shlisa Hughes

Quality Improvement

Center for HOPE

- Melissa Hall Yack

Community Engagement

- Heather Haley
- Jennyfer Morales

Program Management

BeatPain Team

- Adrianna Romero
- Juliemar Medina
- Dania Iniguez

Research Staff

- Isaac Ford
- Laura Vinci de Vanegas
- Juan Paz Delgado
- Cynthia DeFrancesco
- Whitney Rokui

Physical Therapists

Duke University

- Adam Goode

Physical Therapy

PRaCTICE Participation in BeatPain

CARE for Health$^{\text{TM}}$ Network Meeting
December 4th and 5th, 2024

PRaCTICE: BeatPain Study Participation

ORPRN
Oregon Rural Practice-Based
Research Network

OHSU
OREGON CLINICAL
& TRANSLATIONAL
Research Institute

ITHS
Institute of Translational
Health Sciences

WPRN
Collaborative Research. Innovative Care.

PRaCTICE Team

Site Principal Investigator: Sebastian Tong, MD, MPH (UW/WPRN)

Project Director: Caitlin Dickinson, MPH (OHSU/ORPRN)

Project Support:

- Laura Ferrara, MA, Project Manager (OHSU/ORPRN)
- Ben Huynh, Community Engagement Specialist (UW/WPRN)
- Mariana Solis-Wunderlich, Senior Clinical Research Assistant (OHSU/ORPRN)
- Roni Hyde, MPH, Practice Facilitator (OHSU/ORPRN)

Site Clinical Partners:

- One Community Health
- University of Wyoming Family Practice

PRaCTICE Description

Primary Care Rural and Frontier Clinical Trials Innovation Center to Advance Health Equity (PRaCTICE)

Serves as “Network Research Hub”

Establishes the infrastructure to conduct clinical research in primary care settings

Year 1, test predetermined trial in clinical settings

Engages the community in as many aspects of the work as possible

PRaCTICE Cores

Community Engagement Core. Conducts community and clinic needs assessments, implements strategies for inclusive study participation, oversees the PRaCTICE Advisory Board, and leads interaction with the ORPRN and WPRN governing boards.

Recruitment & Trials Core. Responsible for engaging with clinical sites for study recruitment and co-developing PRaCTICE studies. This core will also be responsible for overseeing study start-up, participant recruitment, and addressing recruitment barriers as they arise.

Data Coordination Core. Supports and prepares sites for EHR data queries to assess study feasibility, and support data management and acquisition for research studies. Supports reporting PRaCTICE performance data to inform continuous process improvement and PRaCTICE evaluation.

Communications & Dissemination Core. Responsible for communication with all PRaCTICE partners, including NIH, clinical sites, community partners, and PBRN partners. Responsible for study marketing to facilitate recruitment of clinical sites and participants. Advance tools developed by ORPRN and WPRN to communicate with all partners on study progress and outcomes.

Rationale for BeatPain Study Selection

- Alignment with community clinical priorities
  - Non-pharmacologic management of pain
  - Virtual health/telemedicine
  - Health equity
- Feasibility features
  - Flexible procedures for identifying and enrolling participants
  - Intervention available in two languages
  - Minimal impact on clinic staff and workflow
- Benefits to PRaCTICE/Site participation
  - Build capacity for telemedicine research
  - Increase availability of physical therapy services in rural communities

One Community Health

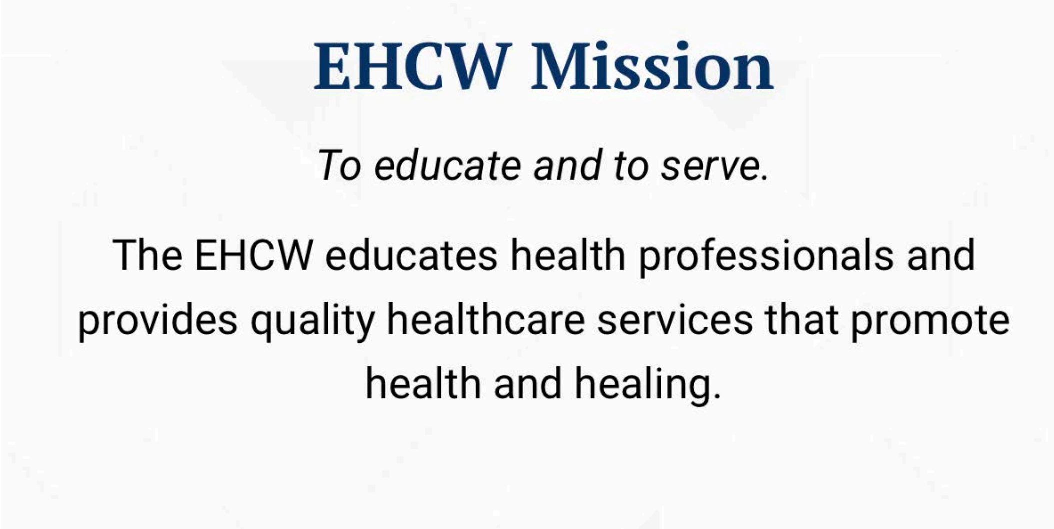
Founded in 1986 as La Clínica del Cariño Family Health Care Center

- Federally Qualified Health Center
  - Integrated medical, behavioral health, and dental services
- 4 medical clinics, 2 school based health centers, 2 mobile clinics
  - Hood River and The Dalles, Oregon
  - Stevenson and White Salmon, Washington
- Mission: Advancing health and social justice for all members of the community

ONE
COMMUNITY
HEALTH
CARING FOR ALL, CARING WITH HEART
CUIDANDO A TODOS, CUIDANDO CON EL CORAZÓN

University of Wyoming Family Practice

- Federally Qualified Health Center
- 3 medical clinics
    - Casper, Cheyenne, Laramie
- 10 physician providers, 1 physician assistant, 1 clinical pharmacist, and 1 addiction counselor



EHCW Mission

To educate and to serve.

The EHCW educates health professionals and provides quality healthcare services that promote health and healing.

UNIVERSITY
OF WYOMING
FAMILY PRACTICE

Opportunities, Challenges and Adaptive Strategies II

- Consistent with a pragmatic trial, our implementation strategies are designed to have flexibility around a set of core components.
- The study is completely de-centralized to facilitate implementation in rural and under-resourced settings.
- Two-way communication with clinics has been critical as situations arise with participants.
- We offer the brief consult intervention to persons who choose not to enroll or are ineligible.
- Audio-only communication for delivering the interventions has been essential
- Rural residents that are referred have proven more challenging to contact and enroll than non-rural residents.

Overview of Clinical Studies Portfolio: Co-Care

Presenters: Drs. Jane Liebschutz and Jennifer McNeely (Co-Care), Representatives from PRaCTICE and WREN Network Research Hubs

Moderator: Dr. Larissa Aviles-Santa

NIH National Institutes of Health

National Drug Abuse Treatment Clinical Trials Network

HEAL

NIH · Helping to End Addiction Long-term®

CO-CARE

Collaborative Care for Polysubstance Use in Primary Care Settings (Co-Care)
CTN-0139

Lead Investigators: Jennifer McNeely, Jane Liebschutz

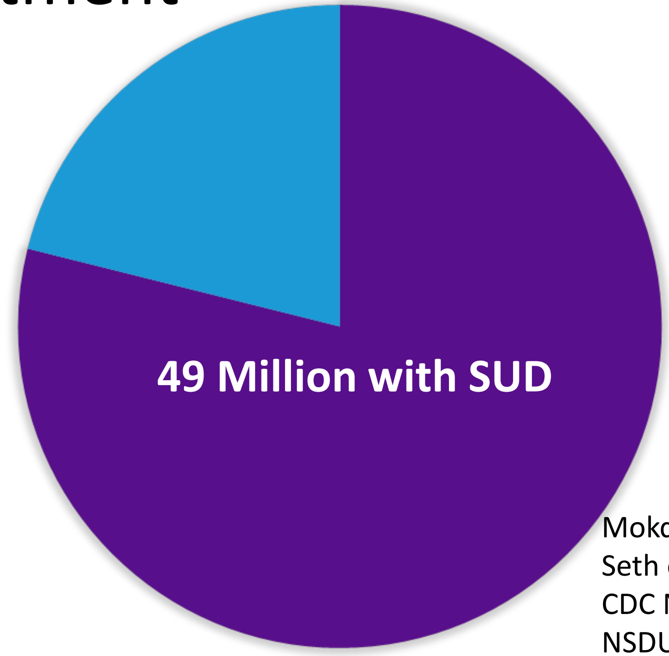
CARE FOR HEALTH NETWORK MEETING

DECEMBER 4, 2024

The addiction treatment gap

- Substance use leads to more death and disability than any other preventable condition
  - Alcohol is the 3rd leading cause of preventable death in the US
  - 108,000 drug overdose deaths last year in the US

- Less than 1 in 4 people with SUD receive addiction treatment



Mokdad et al., *JAMA* 2000
Seth et al., *MMWR* March 2018
CDC NCHS, May 2024
NSDUH 2023

Addressing substance use in primary care

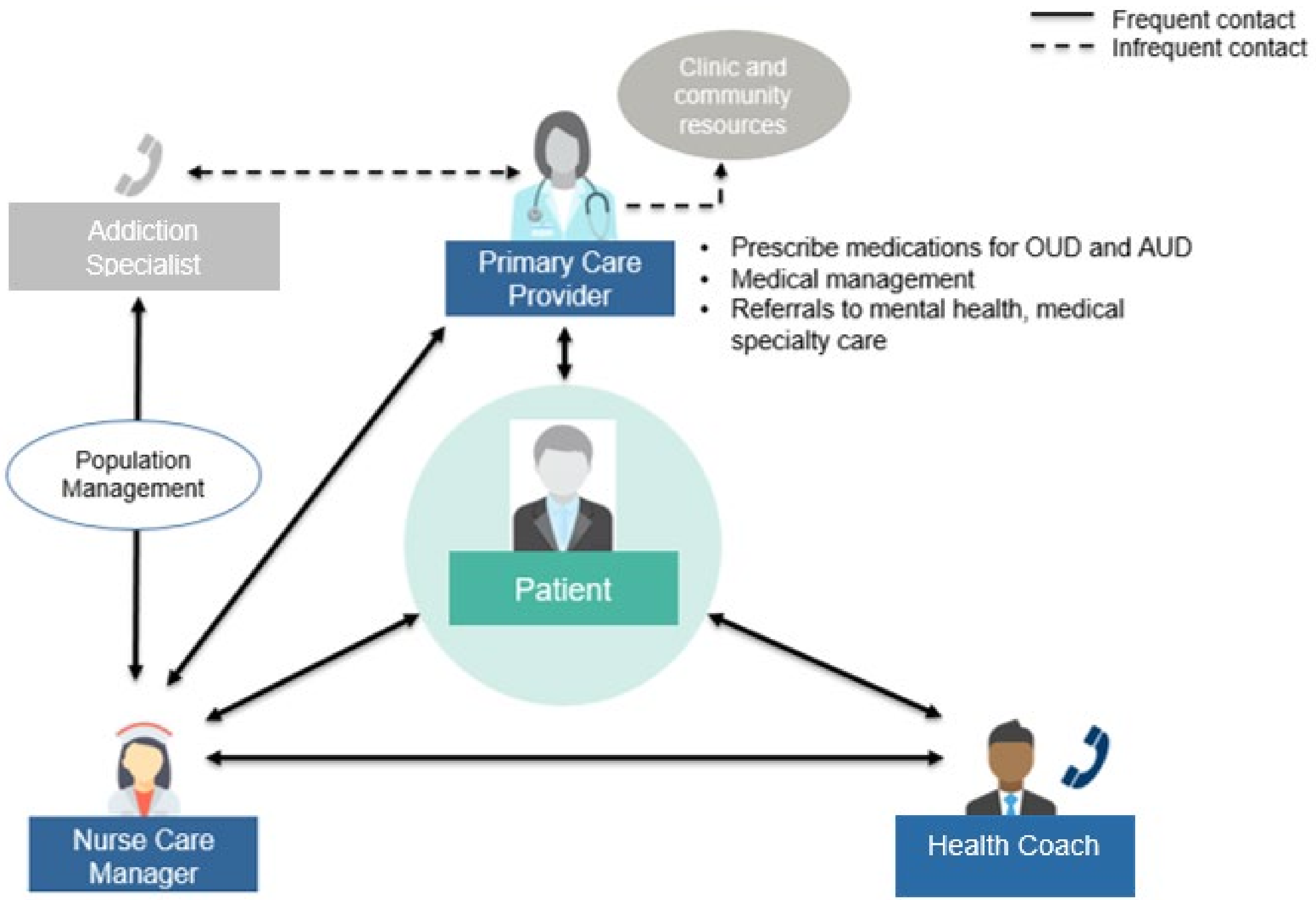
- ➢ High prevalence of substance use in primary care settings
  - ~25% with risky use, 5-15% with SUD (higher in safety net clinics)
- ➢ Untreated SUD impacts care for all health and mental health conditions
- ➢ Barriers to introducing new treatment practices within primary care are well known, and demand new approaches

Cherpitel and Ye, *Drug and Alc Dep* 2008
Roche et al., *Drug and Alc Dep* 2005
Hallgren KA et al., JSAT 2020

Central Research Question

Can a collaborative care model engage adult primary care patients in evidence-based treatment for substance use disorders, leading to **reductions in substance use** and **improved health outcomes**?

Co-Care Adapted Collaborative Care Model



Frequent contact

Infrequent contact

Clinic and community resources

Addiction Specialist

Primary Care Provider

- Prescribe medications for OUD and AUD
- Medical management
- Referrals to mental health, medical specialty care

Population Management

Patient

Nurse Care Manager

- Management of medications for OUD and AUD
- Contingency management
- Linkage to mental health and addiction treatment
- Care management

Health Coach

- Patient-centered counseling
- Motivational enhancement therapy
- Cognitive behavioral therapy

Study Objectives

Primary Objective

- *Examine the efficacy of Co-Care, in comparison to EUC (Enhanced Usual Care), for reducing* ***days of opioid, stimulant, and heavy alcohol use****.*

Hypothesis: Patient participants in the Co-Care condition, in comparison to those in EUC, will have reduced total days of use in Months 4-6.

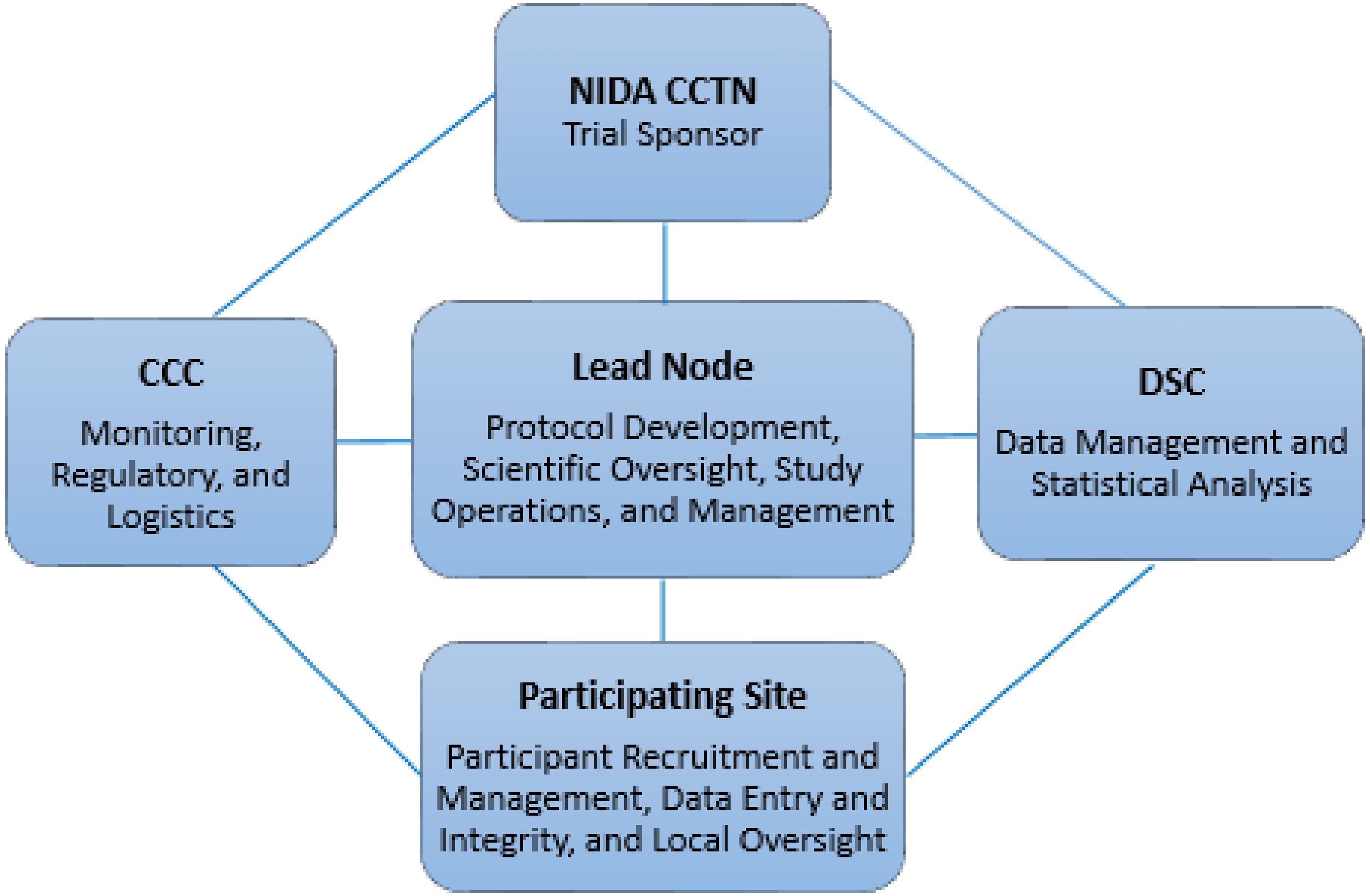
Secondary Objectives

- ***Patient-level outcomes****: examine the effect of the intervention on patient-reported progress in treatment and recovery, substance use, health, quality of life, and service utilization outcomes*
- ***PCP-level outcomes****: prescribing of medications for addiction treatment, attitudes and knowledge regarding substance use and substance use medications*

Study Design

- ➢Clinical trial at 5 sites → 7 sites
- ➢Safety net clinics: Federally Qualified Health Centers (FQHCs) and similar
- ➢Cluster randomized at the level of PCP
- ➢Enrolls adult patients with polysubstance use disorder
- ➢Sample size:
  - PCPs: N=100
  - Patients: N=300-400 (Target = 350)
- ➢Patients receive 6 months of collaborative care intervention
- ➢Outcomes measured over 12 months

CTN-0139 Study Structure



NIDA CCTN
Trial Sponsor

CCC
Monitoring, Regulatory, and Logistics

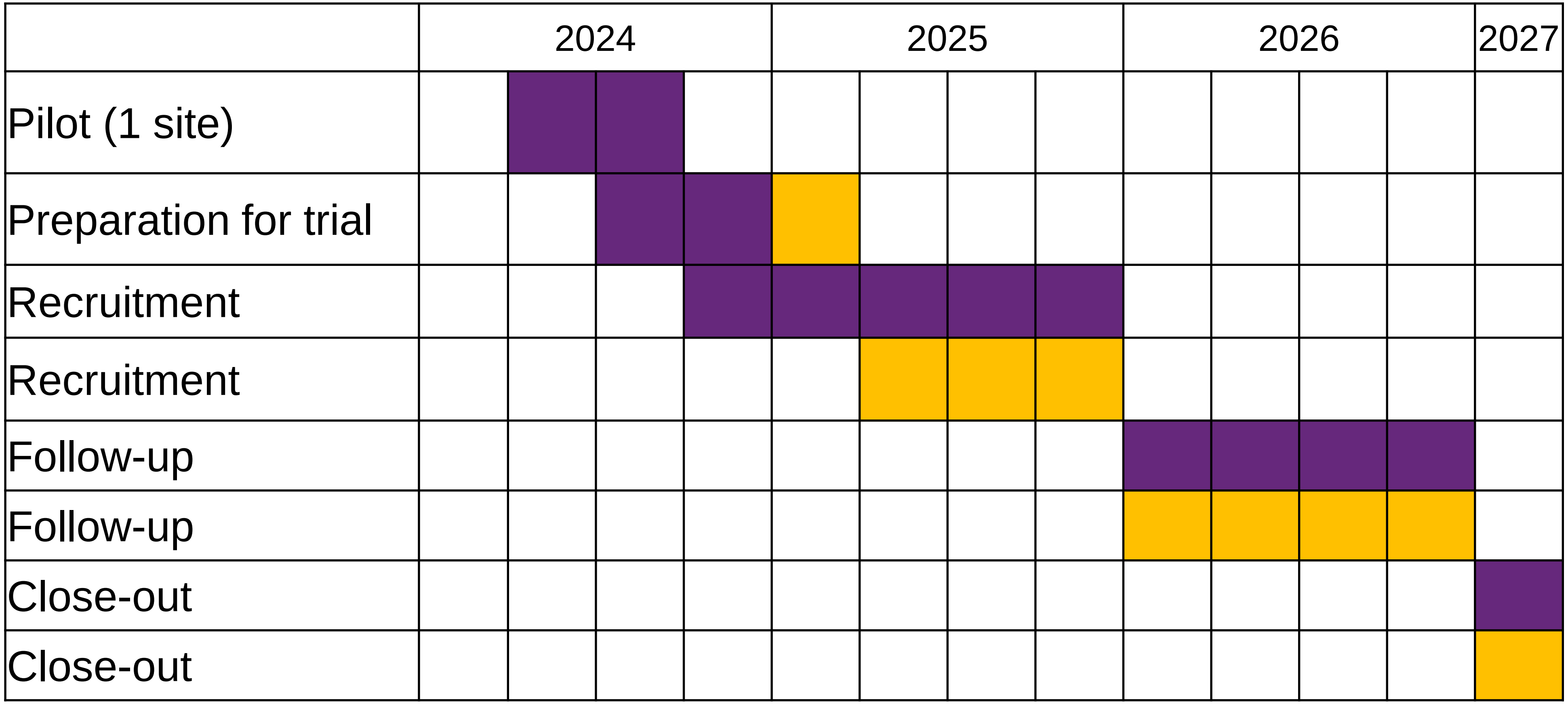
Lead Node
Protocol Development, Scientific Oversight, Study Operations, and Management

DSC
Data Management and Statistical Analysis

Participating Site
Participant Recruitment and Management, Data Entry and Integrity, and Local Oversight

Timeline

🟪 Original Sites
🟨 CARE for Health Sites



	2024				2025				2026				2027
Pilot (1 site)		🟪	🟪										
Preparation for trial			🟪	🟪	🟨								
Recruitment				🟪	🟪	🟪	🟪	🟪					
Recruitment						🟨	🟨	🟨					
Follow-up									🟪	🟪	🟪	🟪	
Follow-up									🟨	🟨	🟨	🟨	
Close-out													🟪
Close-out													🟨

WREN Participation in Co-Care

CARE for Health™ Network Meeting

Overview of WREN Participation in Co-CARE

Wisconsin Research and Education Network (WREN)

December 4-5, 2024

Hub Introduction: Meeting Participants

Principal Investigators

Sarina Schrager, MD, MS

Mary Henningfield, PhD

Earlise Ward, PhD

Yao Liu, MD, MS*

WREN Team

Alyssa Turnquist

Meagan Sulikowski, MSW

Community Partners

Michael Britt

Elizabeth Walter

CTSA Representatives

Bernadette Gillick, PhD

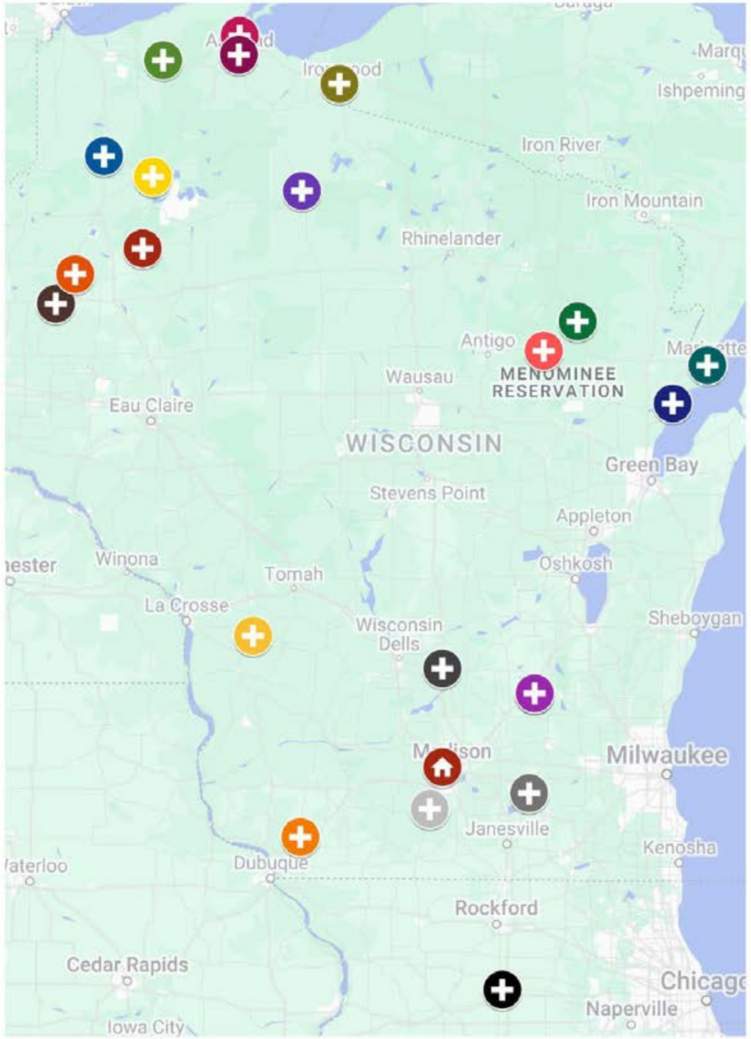
Leigh Ann Mrotek, PhD

Whitney Sweeney, PhD

*Not in attendance

Collaborators

- Hub- WREN
- NorthLakes Community Clinic -Ashland (RUCA 7)
- NorthLakes Community Clinic -Birchwood (RUCA 10)
- NorthLakes Community Clinic -Cumberland (RUCA 10)
- NorthLakes Community Clinic -Hayward (RUCA 10)
- NorthLakes Community Clinic -Hurley (RUCA 7)
- NorthLakes Community Clinic -Iron River (RUCA 8)
- NorthLakes Community Clinic -Lakewood (RUCA 10)
- NorthLakes Community Clinic -Marinette (RUCA 4)
- NorthLakes Community Clinic -Minong (RUCA 10)
- NorthLakes Community Clinic -Oconto (RUCA 7)
- NorthLakes Community Clinic -Park Falls (RUCA 10)
- NorthLakes Community Clinic -Turtle Lake (RUCA 10)
- NorthLakes Community Clinic -Washburn (RUCA 8)
- NorthLakes Community Clinic -White Lake (RUCA 8)
- The Platteville Clinic at Southwest Health (RUCA 4)
- Scenic Bluffs Community Health Centers (RUCA 10)
- UW Health Beaver Dam Clinic Family Medicine Clinic (RUCA 4)
- UW Health Beaver Dam Clinic Internal Medicine Clinic (RUCA 4)
- UW Health Belleville Clinic Family Medicine Clinic (RUCA 2)
- UW Health Fort Atkinson Clinic Family Medicine Clinic (RUCA 4)
- UW Health Portage Clinic Family Medicine Clinic (RUCA 4)
- UW Health Rochelle Clinic Family Medicine Clinic (RUCA 4)



WREN
WISCONSIN
Research & Education Network
for our health

Rural clinics/Health systems

- UW Health
    - 5 rural clinics
- Northlakes Community Clinics
    - 14 rural clinics
- Scenic Bluffs Health Center, Inc.
    - 2 rural clinics
- Southwest Health Family Medicine & Clinics
    - 1 rural clinic

WREN has worked with many other clinics

- Some indicated not enough time to officially sign up for the hub
- I-TRUST includes clinics nationwide

Study Selection Process

WREN
WISCONSIN
Research & Education Network
for our health

- WREN study criteria:
  - Is the study question relevant and important for primary care clinics, patients, and communities?
  - Do the methods ensure that negative impacts on patient care are avoided?
  - Does the study design minimize burden on clinic staff?
  - Is the study appropriately funded?
- WREN reviewed list of NIH studies and identified four as potentially feasible in rural primary care clinics
- Network clinics were asked to rank the four trials
- **Co-Care to address polysubstance use disorder was selected as the best match**

Areas of Research listed in our proposal

Research questions co-developed with clinics and communities

Substance use disorders and harm reduction

Mental health

Patient-centered care through shared decision-making

Loneliness and social isolation

Health inequities and disparities that are priorities of communities

WREN Research Network Participation part 1

Anticipated benefits

- Assistance to enhance treatment of polysubstance use disorder
  - Training and experience can translate to implementation in practice
- Ability to engage in research

Features that make the study feasible in Hub site practice settings

- Remote aspects of addiction medicine specialist and health coach
- Ability for some patient assessments to be self-assessments/remote
- Funding for FTE for research activities (eg, practice manager)
- Coverage of costs for contingency management
- Realistic enrollment goals

WREN Research Network Participation part 2

Clinics

- UW Health Portage
- UW Health Fort Atkinson (Tentative)
- Scenic Bluffs (FQHC)

Geographic distribution

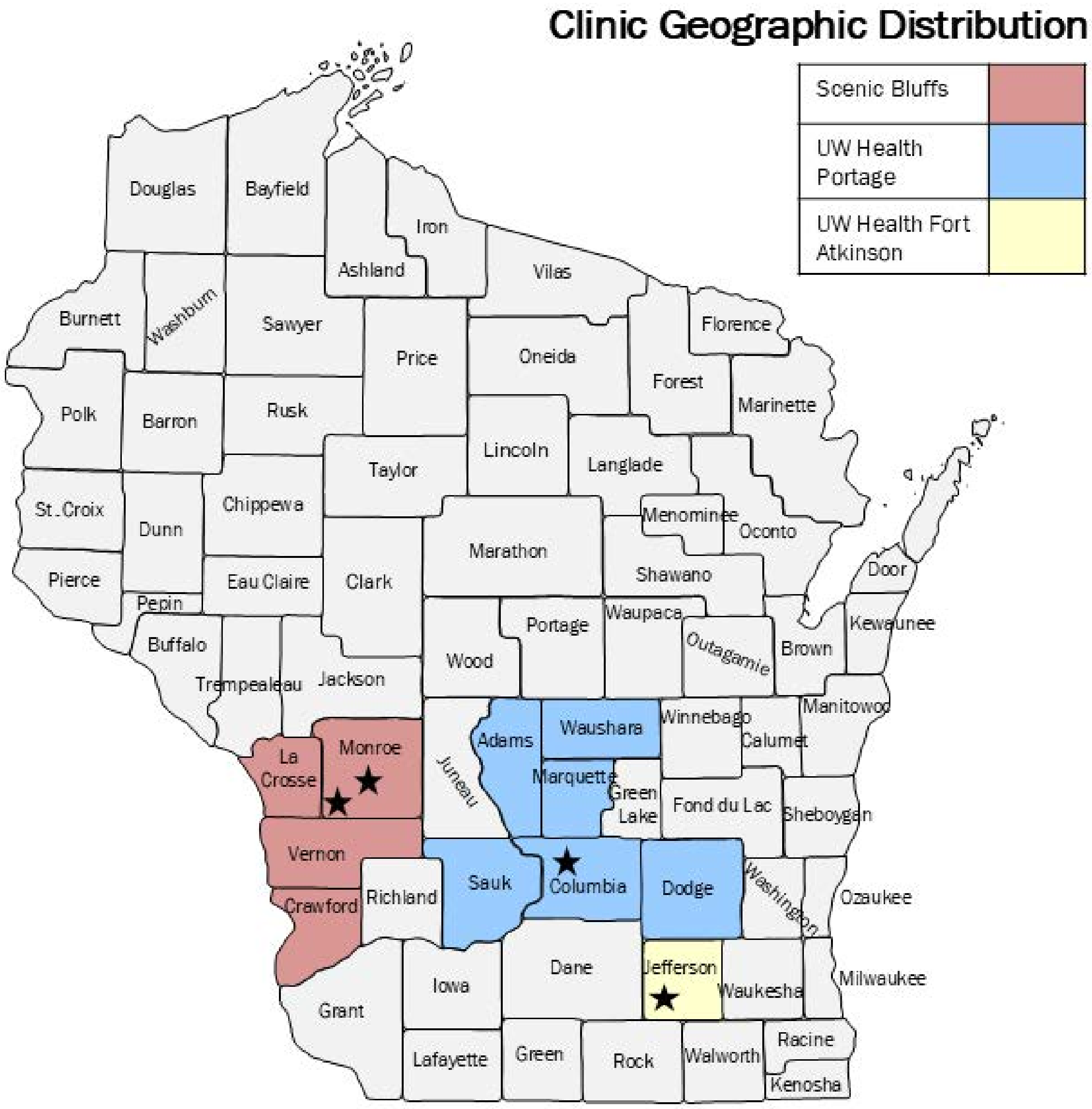
- Service areas of these rural clinics span multiple counties

Demographics

- Primarily white
- Some rural counties are particularly disadvantaged
- Alcohol use is a particular issue for Wisconsin residents

Anticipated enrollment

- UW Health (2 clinics) – 10 clinicians; 40 patient participant
- Scenic Bluffs (2 clinics) – 5 clinicians; 20 patient participant



PRaCTICE Participation in Co-Care

CARE for Health^{TM} Network Meeting
December 4th and 5th, 2024

PRaCTICE: Co-Care Study Participation

ORPRN
Oregon Rural Practice-Based Research Network

OREGON CLINICAL & TRANSLATIONAL Research Institute
OHSU

ITHS
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WPRN
Collaborative Research. Innovative Care.

Primary Care Rural and Frontier Clinical Trials Innovation Center to Advance Health Equity (PRaCTICE)

A network research hub collaboration between the Oregon Rural Practice-based Research Network (ORPRN) and the WWAMI region Practice and Research Network (WPRN)

	ORPRN	**WPRN**
Year Established	2002	2005
Region	Oregon (>50% in rural/frontier practices)	Washington, Wyoming, Alaska, Montana, Idaho
Clinical Partners	168 primary care practices	140 primary care practices
Governing Body	14-member advisory board of rural clinicians and clinical partners	10-member steering committee of primary care clinicians from across region
Underrepresented Populations Served	• Rural/frontier • American Indian, Hispanic • Low income • Uninsured • Peoples with disabilities	• Rural/frontier • Asian, Hispanic • Low income • Uninsured

PRaCTICE Cores II

Community Engagement Core. Conducts community and clinic needs assessments, implements strategies for inclusive study participation, oversees the PRaCTICE Advisory Board, and leads interaction with the ORPRN and WPRN governing boards.

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Rationale for Study Selection

- Alignment with community clinical priorities
  - Growing importance of polysubstance use beyond just opioid use disorder
  - Health equity
- Feasibility features
  - Flexibility in roles
  - Can be aligned with existing workflows at clinic
- Benefits to PRaCTICE/Site participation
  - Patient benefit from access to evidence-based SUD treatment
  - Train clinical staff to provide SUD services that would last beyond study (clinical trial that is also implementation!)
  - Deepen engagement of Site with PRaCTICE/academic partners

Winding Waters Medical Clinic

Wallowa County, Oregon

- Medical Care
  - 8 primary care providers
  - 4 registered nurses
  - 3 physical therapists
  - 1 naturopath/acupuncturist
- Mental Health Care
  - 7 mental health providers
- Dental Care
  - 4 dentists
  - 5 dental hygienists

Mission:

To improve the health of our communities

Vision:

The best health for all

Values:

Accountability
Collaboration
Empowerment

Image source: Winding Waters

Study Team

Site Principal Investigator: Claire Simon, MD – UW/WPRN

PRaCTICE Project Manager: Laura Ferrara, MA – OHSU/ORPRN

Clinical Champion: Mike Farley, PharmD – Winding Waters

Clinic Manager: Keli Dennis, COO – Winding Waters

Nurse Care Manager: TBD

Research Coordinator: Mariana Solis-Wunderlich – OHSU/ORPRN

Research Assistant: TBD

Adapting to Rural Primary Care Settings

Sensitivity to bandwidth: Recognizing that we're working in small but mighty settings, every person plays multiple roles – and roles are distinct amongst clinics.

Flexibility in study roles: Understanding the core functions of each clinical role, and who can support functions (regardless of title).

Limited local resources: Primary care clinics may have to take on more, rely less on referrals.

Timeline/expectations: Realizing that activities take longer; fewer people to do the work.

Cultivating local research prowess: Taking time to bring locals up to speed, developing new opportunities in communities. Goal is to create savviness in research implementation in non-traditional settings.

Sustainability of personnel: Making a commitment to rural primary care settings to support research. *How to address misalignment with funding (e.g., NIDA CTN 0139 until 2027 vs. CARE for Health until September 2025)?*

Study Roles

- Nurse care manager
  - On-site, full member of clinical team, 100% effort
- Clinical champion
  - Practicing PCP in the study clinic, part-time effort
- Practice manager
  - Member of existing staff, part-time effort

In the primary care clinic

- Health coaches
  - Centralized resource
- Addiction psychiatrist
  - Centralized resource

Remote

Clinical Champion

Clinical Champion plays a key role in integrating the intervention into the clinic, supporting PCPs and Nurse Care Manager

Needs of the trial:

- To reach recruitment targets, sites should have 10+ PCPs participating
- Clinical Champion role cannot be done by a PCP participant
- In small practices, goal is to recruit all eligible PCPs, to increase sample size

Strategy in rural settings:

- A clinical pharmacist (or other non-PCP clinician) may serve as the Clinical Champion, so that all eligible PCPs can participate

Nurse Care Manager

Difficulty hiring for the Nurse Care Manager position in rural areas

Needs of the trial:

- Nurse needs to be on site at each study clinic

Strategies in rural settings:

- Search for internal candidates
- Hire nurse in each region/system, to reduce travel
- Emphasize unique benefits of this position: gaining expertise in SUD treatment, research experience, addressing an important unmet need

Transportation barriers for patients

Patients may need to travel long distances to get to the clinic

Already in place for the trial:

- ➢No required in-person visits for study assessments
  - Electronic surveys can be completed on cell phone/tablet or computer
  - Remote collection of urine toxicologies
  - Patients may receive a cell phone for study participation
  - Travel reimbursement for contingency management visits
- ➢Health coaching is fully remote
- ➢Nurse Care Manager may do televisits

Challenges and Strategies

Challenges

- Initial UW Health clinic hired a nurse care manager and were no longer a good fit
- Completion of regulatory activities in an accelerated timeline
- Hiring for WREN Program Manager and Research Coordinator in progress
- Potential challenges in travel to rural clinics during winter conditions
- Hiring the Nurse Care Manager is more challenging for rural areas
- Challenges not necessarily unique to rural areas:
  - Time needed for training busy clinicians can be challenging
  - Defining the clinic champion role

Strategies

- Flexibility in clinic champion role as goal is to maximize number of clinicians who can enroll patients

Opportunities

- Co-Care offers flexibility to expand research to rural clinics
- Some past research efforts were limited to inclusion of patients with opioid-use disorder because of funding requirements
  - Co-Care expands to polysubstance use disorder, including alcohol use
- Overall potential to increase care for patients with SUD
- Potential to demonstrate benefits of contingency management, which could be practice-changing

Overview of Clinical Studies Portfolio: TRUST

Presenters: Dr. Hyon Choi (TRUST), Representatives from WVR3

Moderator: Dr. Erin Iturriaga

Treat-to-Target Serum **U**rate versus Treat-to-Avoid **S**ymptoms in Gout: A Randomized Controlled **T**rial (TRUST)

TRUST Background & Rationale

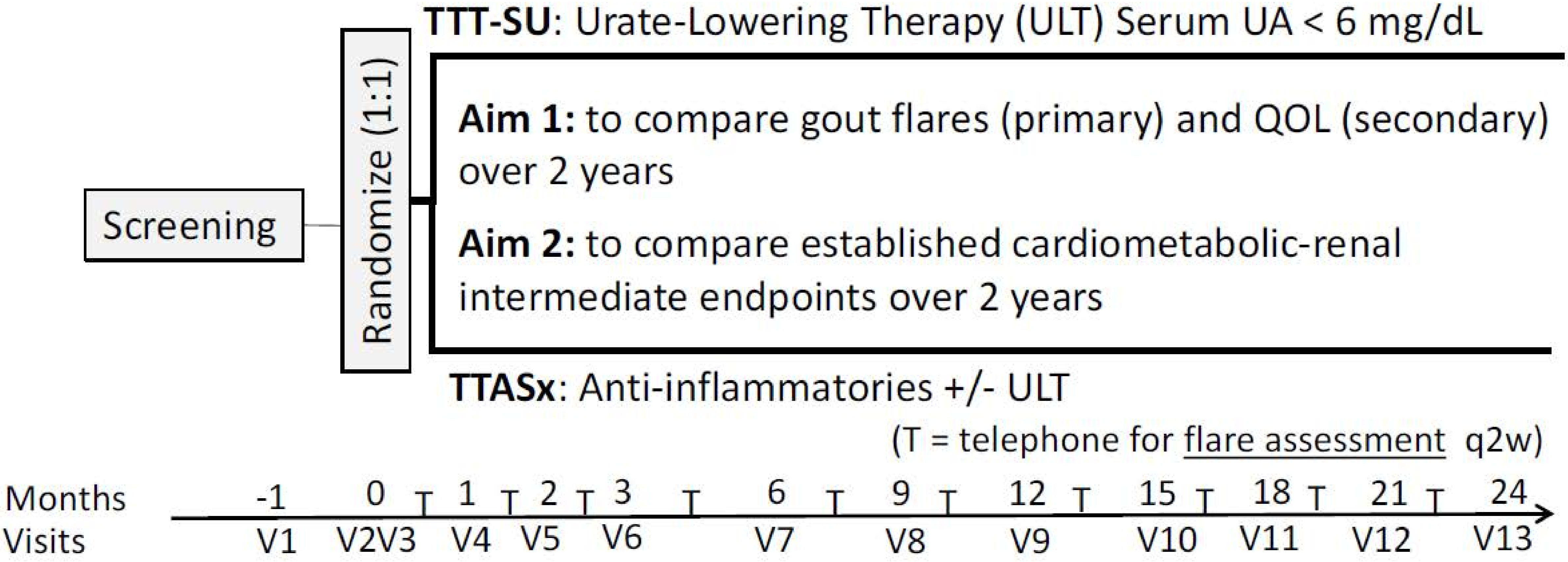
- **Rheumatology guidelines** emphasize a treat to target serum urate (TTT-SU) approach (e.g., SU <6 mg/dL, a urate sub-saturation point); however, SU is not even measured in the vast majority of gout patients in primary care practice, where >90% of gout care occurs.
- **ACP guidelines** highlighted the lack of high-level evidence comparing a TTT-SU approach with treat to avoid symptoms (TTASx), resulting in guidelines that dueled with the ACR.
- The TRUST aims to generate high-level evidence to resolve the guideline conflict by mobilizing rheumatologists and PCPs.

Study Aims

Aim 1) To conduct an RCT **(Tr**eat-to-Target Serum **U**rate versus Treat-to-Avoid **S**ymptoms in Gout: A Randomized Controlled **T**rial [TRUST]**)** with blinded endpoint assessment, comparing TTASx with TTT-SU in gout patients with hyperuricemia for gout flares and QoL as endpoints.

Aim 2) (Optional) To test the effects of lowering SU on key extra-articular intermediate endpoints, including kidney function, glycemic status, and blood pressure among gout patients enrolled in the TRUST trial.

TRUST Schema (N=650 gout patients from PCP practices)



Screening

Randomize (1:1)

TTT-SU: Urate-Lowering Therapy (ULT) Serum UA < 6 mg/dL

Aim 1: to compare gout flares (primary) and QOL (secondary) over 2 years

Aim 2: to compare established cardiometabolic-renal intermediate endpoints over 2 years

TTASx: Anti-inflammatories +/- ULT

(T = telephone for flare assessment q2w)

Months	-1	0	T	1	T	2	T	3	T	6	T	9	T	12	T	15	T	18	T	21	T	24
Visits	V1	V2V3		V4		V5		V6		V7		V8		V9		V10		V11		V12		V13

TRUST Study Population (650 gout patients from PCP practices)

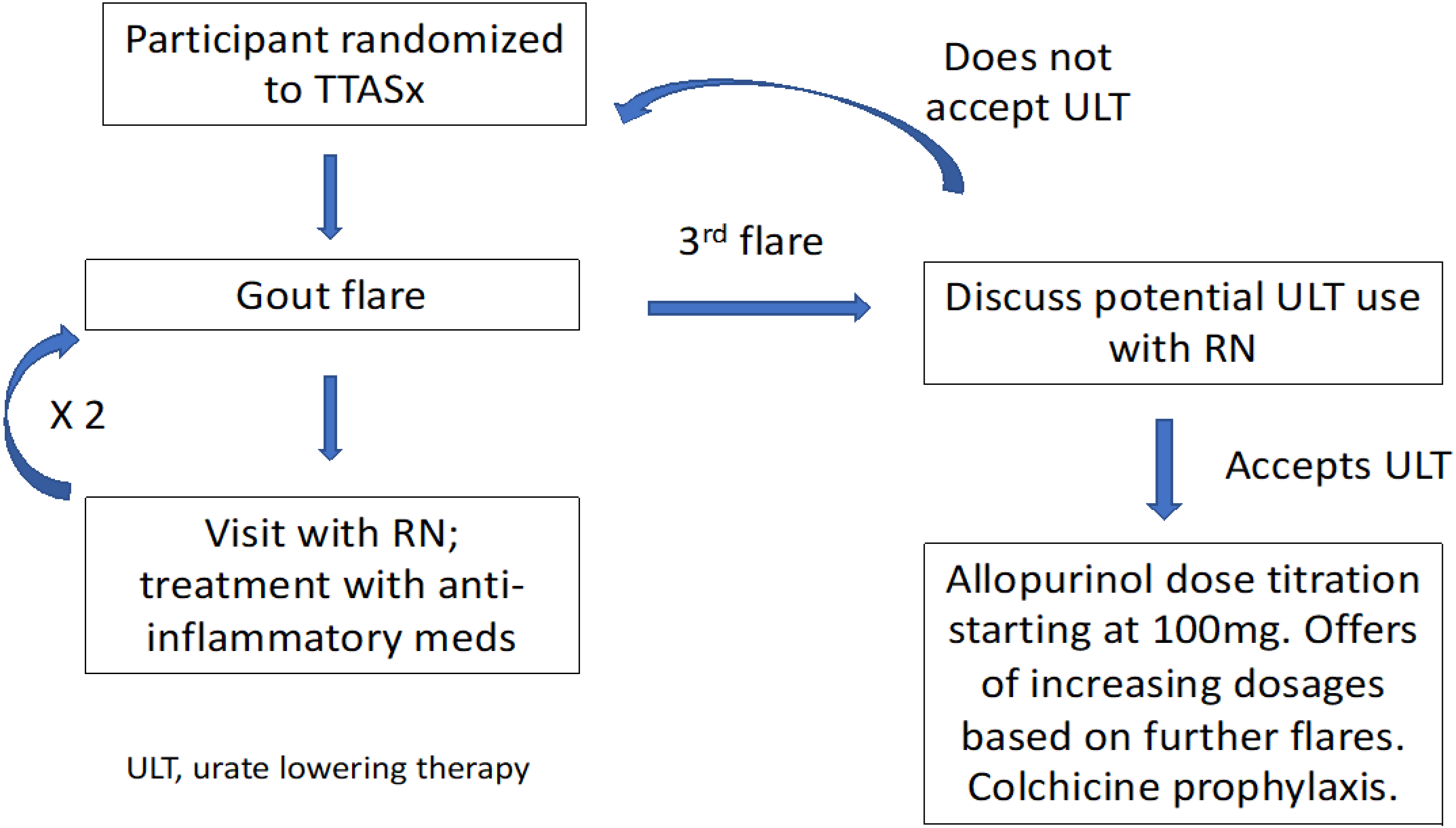
Inclusion criteria	Age 18+, fulfilling ACR/EULAR gout criteria, 1+ gout flares in last 12 months, SU ≥ 6mg/dl
Exclusion criteria	CKD Stage 3B or worse (eGFR < 45ml/min), 2+ episodes of renal colic in prior 5 years, ALT > 3x upper limits of normal, pregnancy (planned or current, breastfeeding, use of 6MP or azathioprine, unlikely to survive 2 years, currently using > 200mg/d of allopurinol, unable/unwilling to give written informed consent

SU, serum urate; eGFR, estimated glomerular filtration rate; CKD, chronic kidney disease; ULT, urate lowering therapy. All inclusion criteria must be met to be potentially eligible and no exclusion criteria can be present.

Titration Schedule in TTT-SU Arm

Allopurinol		Febuxostat	
Visit	Dose Titration	**Visit**	Dose Titration
Baseline	100 mg	**Baseline**	40 mg
Week 4	200 mg	**Week 4**	80 mg
Week 8	300 mg	**Week 8**	80 mg
Week 12	400 mg	**Week 12**	80 mg
Week 16	500 mg	**Week 16**	80 mg
Week 20	600 mg	**Week 20**	80 mg
Week 24	700 mg	**Week 24**	80 mg
Week 28	800 mg	**Week 28**	80 mg

Schedule/Approach in TTASx Arm



Participant randomized to TTASx

Gout flare

Visit with RN; treatment with anti-inflammatory meds

X 2

3rd flare

Discuss potential ULT use with RN

Does not accept ULT

Accepts ULT

Allopurinol dose titration starting at 100mg. Offers of increasing dosages based on further flares. Colchicine prophylaxis.

ULT, urate lowering therapy

Status and Relevant Items

- **Study status**: <10% recruitment to date with 4 sites activated over the past 2 months, while WVU (CARE) activation is pending
- **Primary Care**: recruited exclusively from primary care practice
- **Central Adm**: single IRB, randomization, extensive nurse and study staff training, central data collection, support for patient compensation, medication, and lab costs
- **Telehealth:** majority of visits = virtual visits; use of electronic reporting of flares (primary endpoint)

WVR3 Participation in TRUST Section

West Virginia
Rural Roots
to Research

WVR3 Participation in TRUST

Date: December 4, 2024
Presenter: Sally Hodder

Introduction of Key Meeting Participants

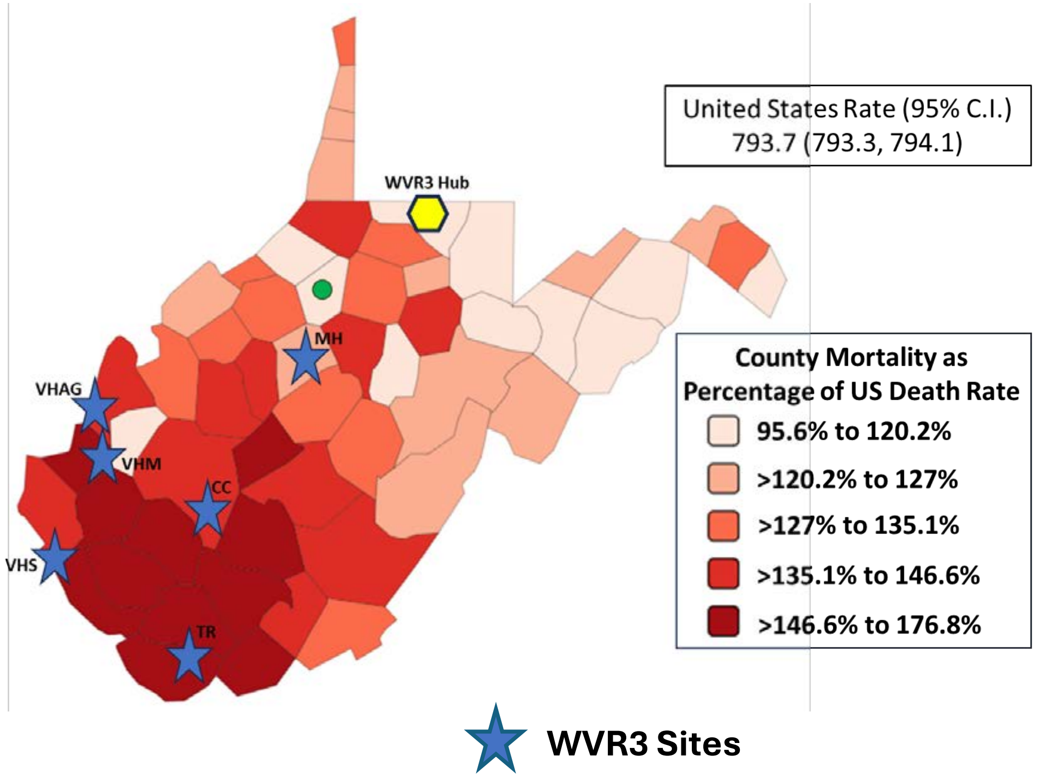
- In person:
  - Hub PI: Dr. Sally Hodder
  - Operations Lead, Clinical Studies Core: Shelley Welch
  - Project Manager: Maggie Childers-Kakos
  - Community Representative: Amber Crist
  - Site Sub-I: Dr. Korey Mitchell
- Virtual
  - Administrative Core Director: Paul Fetty
  - Community Engagement & Outreach (CEO) Core Director: Dr. Stephenie Kennedy-Rea
  - Data Analytics Core Director: Wes Kimble
  - Clinical Studies Core Director: Dr. Rebecca Reece

Rationale for TRUST Study Selection

- Relevance to clinic population
  - West Virginia (WV) has third oldest population in the nation
  - Gout is a frequent chronic disease managed in rural primary care practices
  - Gout associated with co-morbidities that are highly prevalent in WV
- Anticipated benefits
  - Study results may provide guidance on optimal management of gout and on impact of urate lowering on cardiovascular, metabolic, and renal events
  - Engage rural practice providers, staff, and communities in conduct of clinical trials
- Feasibility features of TRUST trial
  - Enthusiastic primary care clinic providers and staff
  - Collaborative, knowledgeable TRUST team at Massachusetts General Hospital
  - Straight forward randomized clinical trial design
  - Experienced regulatory and clinical trial coordinator support from hub
  - 40 foot mobile clinical trials unit (MAVERICK)

WVR3 Research Network Characteristics

Site Locations with County Mortality Rates



Source: HDPulse: An Ecosystem of Minority Health and Health Disparities Resources. National Institute on Minority Health and Health Disparities. 2018-2022 data. Created 11/13/2024. Available from https://hdpulse.nimhd.nih.gov

WVR3 Clinical Site Characteristics

Target Enrollment	Site	Clinic Pts. Average Age	African American Race %	Hispanic Ethnicity %	% of Site Patients in RUCA 4-10
15	Cabin Creek (CC)	64.4 years	<1	<1	28
5	Minnie Hamilton (MH)	66 years	1	0	83
10	Tug River (TR)	59 years	32	0	50
3	Valley Health-Apple Grove (VHAG)	53 years	<1	<1	41
10	Valley health-Milton (VHM)	64 years	<5	<2	29
3	Valley Health-Stepptown (VHS)	63 years	<1	0	41

Challenges & Adaptive Strategies

- Challenges
  - Timeline for IRB approval has delayed anticipated start of enrollment
  - Clinical sites with variable research experience
  - Participant transportation

- Adaptive strategies
  - In-person kick-off meeting held October 3 and Hub team visited all sites October 29-31, 2024.
  - Sites have conducted electronic medical record assessments of potentially eligible participants in anticipation of IRB approval.
  - With IRB approval, site providers and staff will introduce study to potential participants via phone
  - Use of the MAVERICK mobile clinical trials unit to bring trained study coordinators and equipment (e.g., refrigerated centrifuge) to the sites
  - Hub study coordinator access to sites' EMR (after executed BAA) to assist with chart review, source documentation (e.g., flare management), and to ensure use of proper order sets.
  - Transportation budget for customized transportation arrangements

Mobile Clinical Trials Unit (MAVERICK)

Opportunities, challenges, and adaptive strategies

- Recruit more than the target (~45)?
- Extension of follow-up for long-term outcomes
- Secondary endpoints and ancillary studies
- Develop adaptive strategies collaboratively with the central and other TRUST sites

Opportunities

- Community engagement activities (surveys, focus groups) underway to understand facilitators of trial enrollment in rural primary care settings.
- Optimization of site performance through use of environmental scan of current site clinical study processes to identify opportunities for efficiencies
- Real-time identification of problematic issues with subsequent delivery of solutions to problematic issues as they arise (WVR3 Solution Center).
- Identification of interested clinic staff for further training in research, thereby leveraging the existing clinical trial coordinator development program supported by NIH (i.e., IDeA State Consortium for Clinical Research Resource Center).
- Potential expansion to other West Virginia Practice-Based Research Network sites within health systems participating in WVR3 could potentially enhance TRUST study enrollment.
- Site investigators and staff enthusiastic to develop future trials to benefit the unique patient population of rural WV.

Looking Ahead to Opportunities and Challenges

Representatives from PRaCTICE, WREN, and WVR3

Moderator: Dr. Michael Chiang

NIH National Institutes of Health

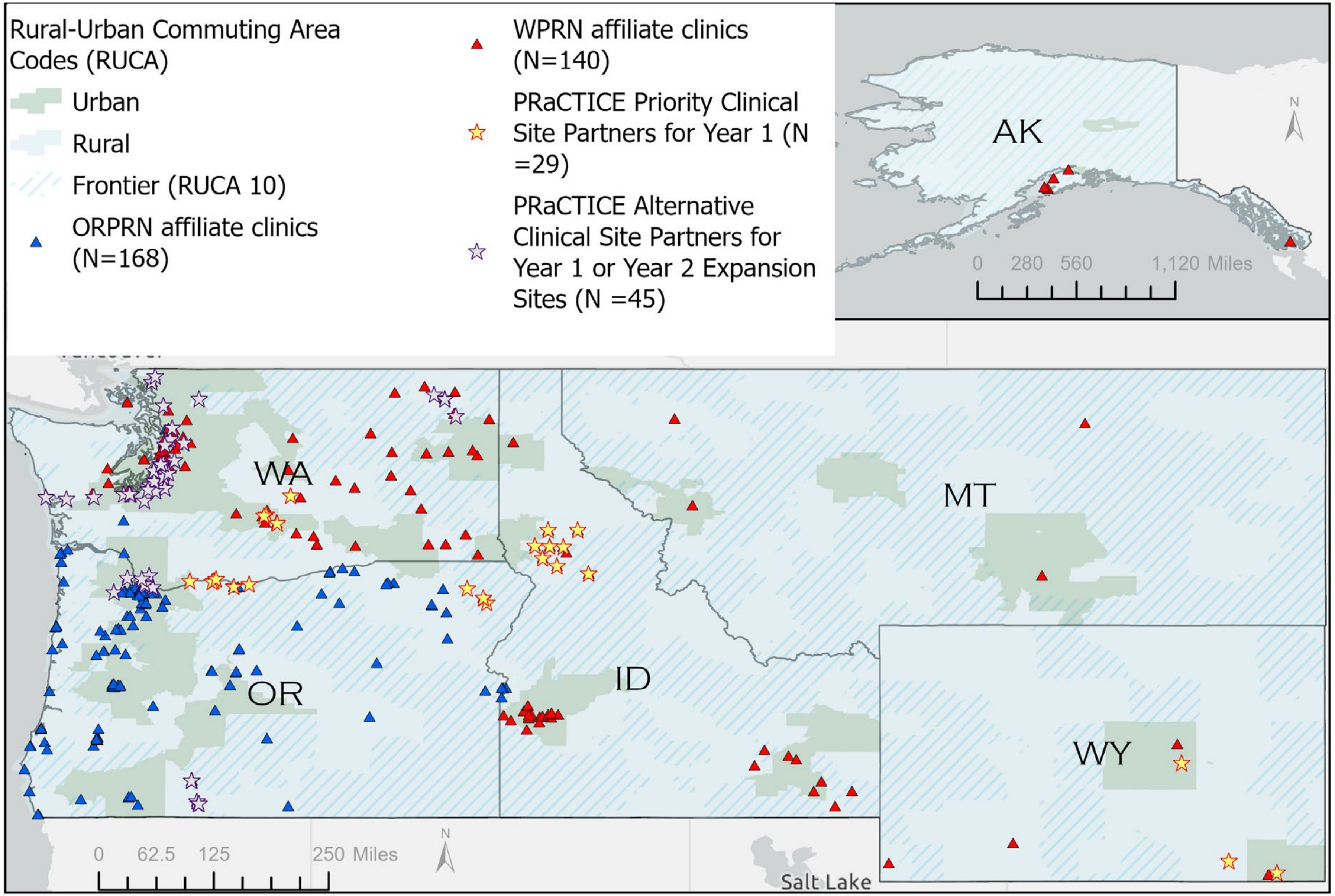
PRaCTICE Overview

Primary Care Rural and Frontier Clinical Trials Innovation Center to Advance Health Equity (PRaCTICE) II

A network research hub collaboration between the Oregon Rural Practice-based Research Network (ORPRN) and the WWAMI region Practice and Research Network (WPRN)

	ORPRN	**WPRN**
Year Established	2002	2005
Region	Oregon (>50% in rural/frontier practices)	Washington, Wyoming, Alaska, Montana, Idaho
Clinical Partners	168 primary care practices	140 primary care practices
Governing Body	14-member advisory board of rural clinicians and clinical partners	10-member steering committee of primary care clinicians from across region
Underrepresented Populations Served	• Rural/frontier • American Indian, Hispanic • Low income • Uninsured • Peoples with disabilities	• Rural/frontier • Asian, Hispanic • Low income • Uninsured

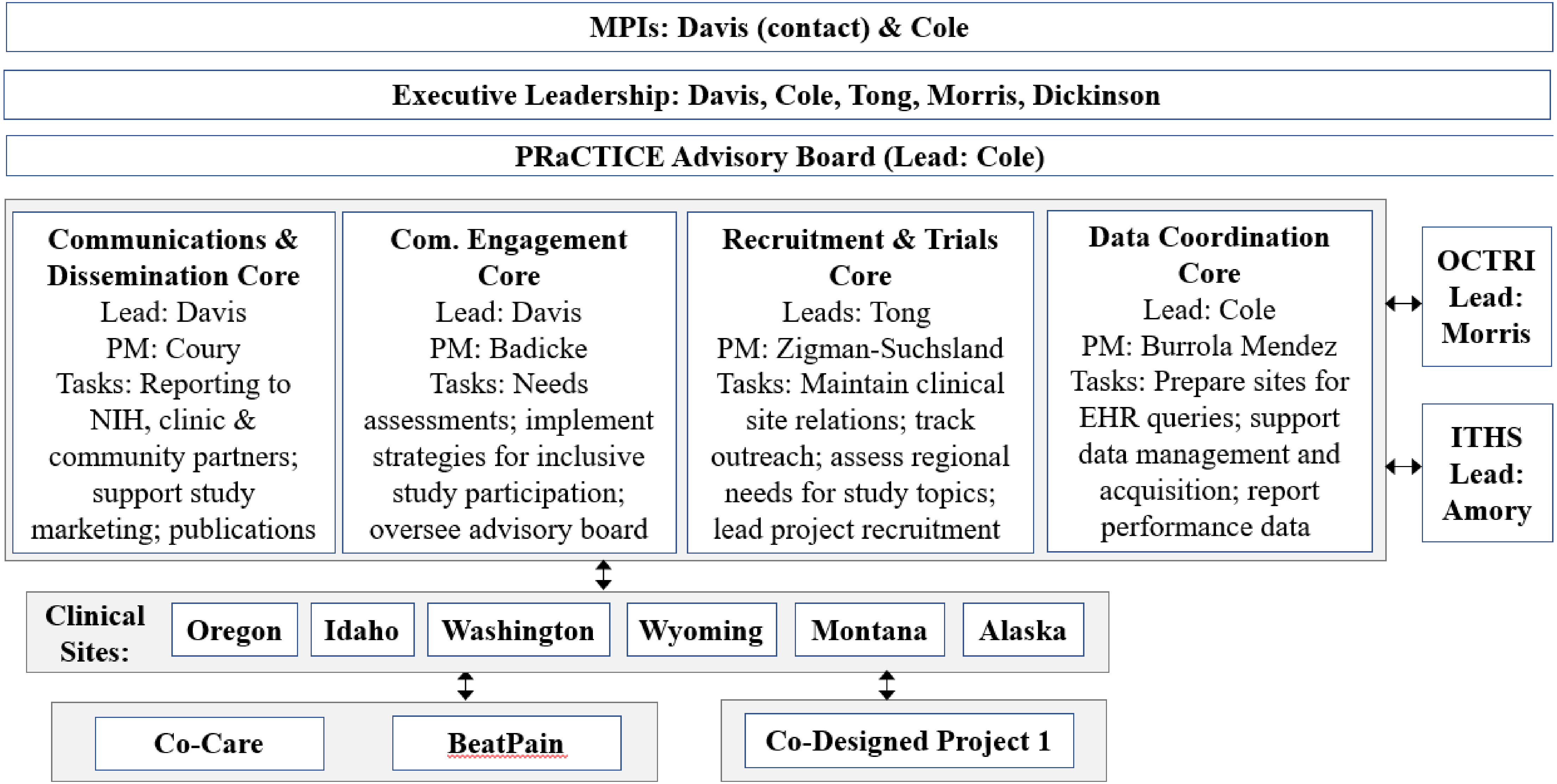
PRaCTICE clinical sites and 6-state service region



Why be part of CARE for Health™?

- **Underrepresentation in clinical research** = results have limited generalizability leading to evidence gaps and compounding health disparities
- Need to extend research participation opportunities to communities underrepresented in clinical research and to integrate opportunities into **settings where people seek care**
- Ability to be more **responsive to clinical site partners** – populations they serve + priority topics for study

NRH structure and organization



MPIs: Davis (contact) & Cole

Executive Leadership: Davis, Cole, Tong, Morris, Dickinson

PRaCTICE Advisory Board (Lead: Cole)

Communications & Dissemination Core
Lead: Davis
PM: Coury
Tasks: Reporting to NIH, clinic & community partners; support study marketing; publications

Com. Engagement Core
Lead: Davis
PM: Badicke
Tasks: Needs assessments; implement strategies for inclusive study participation; oversee advisory board

Recruitment & Trials Core
Leads: Tong
PM: Zigman-Suchsland
Tasks: Maintain clinical site relations; track outreach; assess regional needs for study topics; lead project recruitment

Data Coordination Core
Lead: Cole
PM: Burrola Mendez
Tasks: Prepare sites for EHR queries; support data management and acquisition; report performance data

OCTRI Lead: Morris

ITHS Lead: Amory

Clinical Sites: **Oregon** **Idaho** **Washington** **Wyoming** **Montana** **Alaska**

Co-Care **BeatPain**

Co-Designed Project 1

Overview of clinical partners and catchment demographics

FQHC Site	# Clinics	Population Demographics		
		% Rural	% Hispanic	% Below FPL
BeatPain				
One Community Health	8	85	42	75
University of Wyoming Family Medicine Clinic	3	22	20	82
Co-Care				
Winding Waters Health Center	4	100	10	28

Specific NRH features and strengths

98 research studies between 2019 – 2024

- 33 active studies

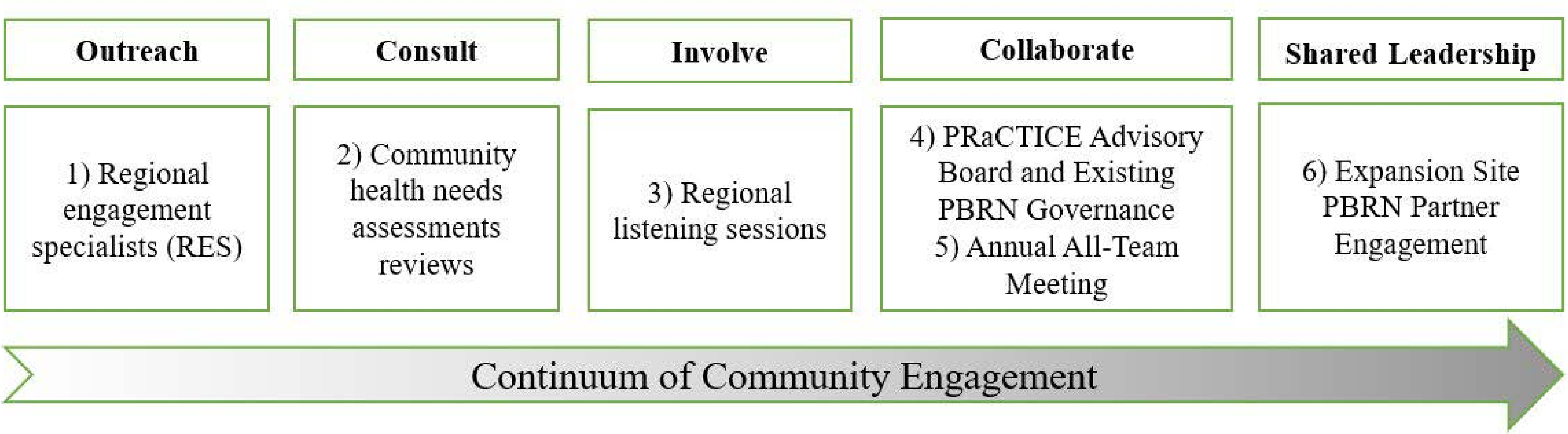
308 clinic partners

- 166 clinic partners currently engaged
- 59,249 participants recruited for currently engaged studies

27 manuscripts published in the last 12 months

8 grants funded; 26 submitted as collaborating network in last 12 months

Strategic approach to community engagement



Outreach	Consult	Involve	Collaborate	Shared Leadership
1) Regional engagement specialists (RES)	2) Community health needs assessments reviews	3) Regional listening sessions	4) PRaCTICE Advisory Board and Existing PBRN Governance 5) Annual All-Team Meeting	6) Expansion Site PBRN Partner Engagement

Continuum of Community Engagement

OHSU OREGON CLINICAL & TRANSLATIONAL Research Institute

ORPRN Oregon Rural Practice-Based Research Network

WPRN Collaborative Research. Innovative Care.

ITHS Institute of Translational Health Sciences

WREN Overview

The Wisconsin Research and Education Network (WREN)

- Founded in 1987, WREN is one of the oldest and most respected practice-based research networks (PBRNs) in the United States
- Our mission is to promote and conduct primary care research and education in partnership with primary care clinicians and the communities they serve
- As a primary care PBRN, WREN engages clinics in quality improvement activities and evidence-based research

We have collaborated with

- 59 communities
- 35 counties
- 80 clinics
- 37 health systems
- Urban, suburban, rural clinics
- Federally qualified health centers (FQHCs)

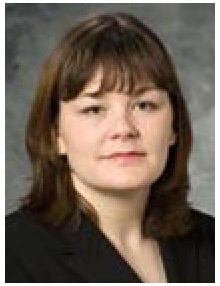
We distribute our newsletter to >1,200 constituents

The WREN Team

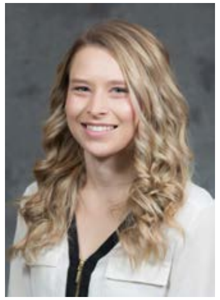
WREN WISCONSIN Research & Education Network *for our health*

Sarina Schrager, MD, MS
Medical Director

Mary Henningfield, PhD
Associate Director

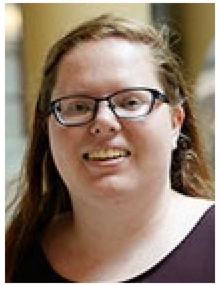


Lisa Sampson, MBA
Program Manager

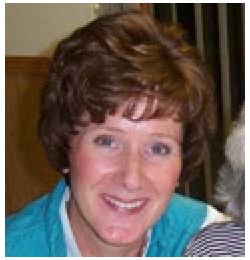


Alyssa Turnquist, BS
Research Coordinator

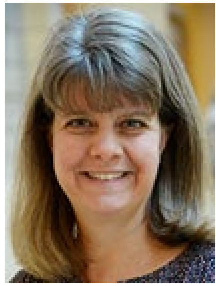
Keelin McHugh, BA
Research Coordinator



Meagan Sulikowski, MSW
Outreach Program Manager



Denise Grossman
Program Associate



Alice Yuroff, PhD
Research Coordinator

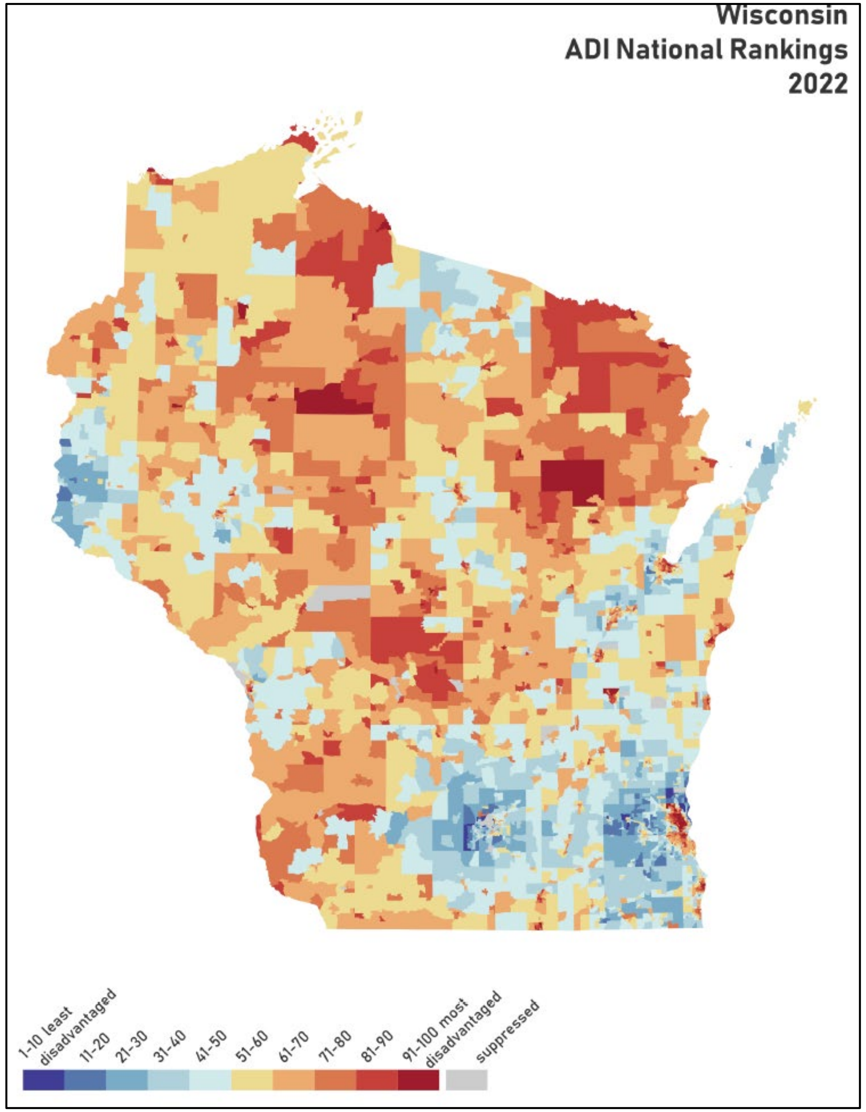
The WREN Advisory Council

- Reviews study proposals and ideas to provide feedback regarding likely interest among primary care providers and feasibility
- Provides vision and direction to help steer the conversation about what matters to primary care practices and the communities they serve
- Represent WREN in their home practices and communities, sharing research, educational and healthcare initiative opportunities with peers and colleagues, encouraging participation

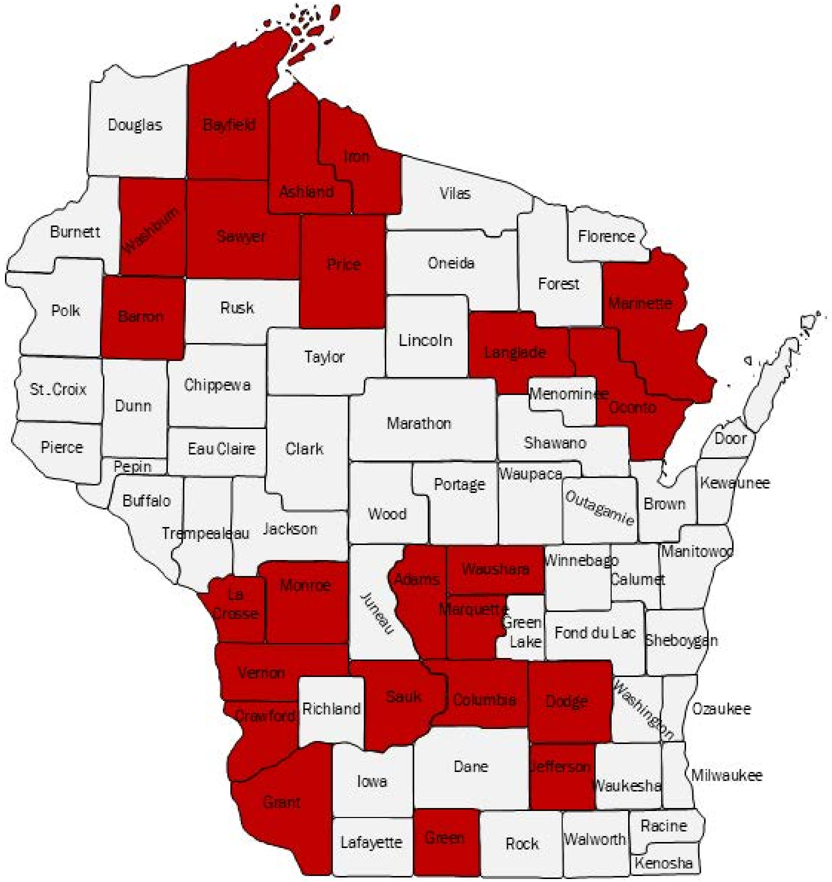
Insights on Participation in CARE for Health™

- **Relationships!**
  - All had past engagement with WREN
    - UW Health clinics
    - NorthLakes Community Health Center (FQHC)
    - Scenic Bluffs Health Center, Inc (FQHC)
    - Southwest Health Family Medicine
  - WREN Advisory Council member has leadership role of FQHCs in Wisconsin
  - Interest in research and scholarly work
- Specific interest in initiatives for rural communities
- Awareness of Care for Health and wanting to promote research in primary care
- Interest in Co-Care and substance use disorders

WREN Rural Clinics Serve Large Catchment Areas



Counties in the WREN hub



- Mainly white
- Many clinics serve areas of disadvantage
- Area of Deprivation index includes domains of income, education, employment, and housing quality

Features and Strengths of WREN

- Relationships and reputation
- Research experience
  - Long history of successful recruitment of study participants
  - Completion of nearly 100 studies over the past 10 years alone
  - Experience with a variety of study designs and methods
  - Flexibility and problem solving to overcome challenges
  - Robust support by the UW-Madison DFMCH and the UW-Madison ICTR
  - Strong leadership structure
- Engagement with Meta-LARC
- Experience includes work with out-of-state clinics (eg, I-TRUST)
- Potential for expansion to other states

Strategic Approach to Community Engagement

Overall goal of co-designed research

- Listen to community members and clinics
- Community engagement plans must be customized for rural communities
- Takes time to establish relationships, have discussions about community needs, and expand opportunities for residents of rural areas to participate in research.

Engagement among clinics

- Build learning collaborative among clinics
- WREN Advisory Council provides expertise and input on research questions and implementation of practice-based research studies

Community-based engagement

- Partnerships with the Wisconsin Network for Research Support (WINRS) at UW-Madison, experts in community engagement
- Rural community advisory board

WVR3 Overview

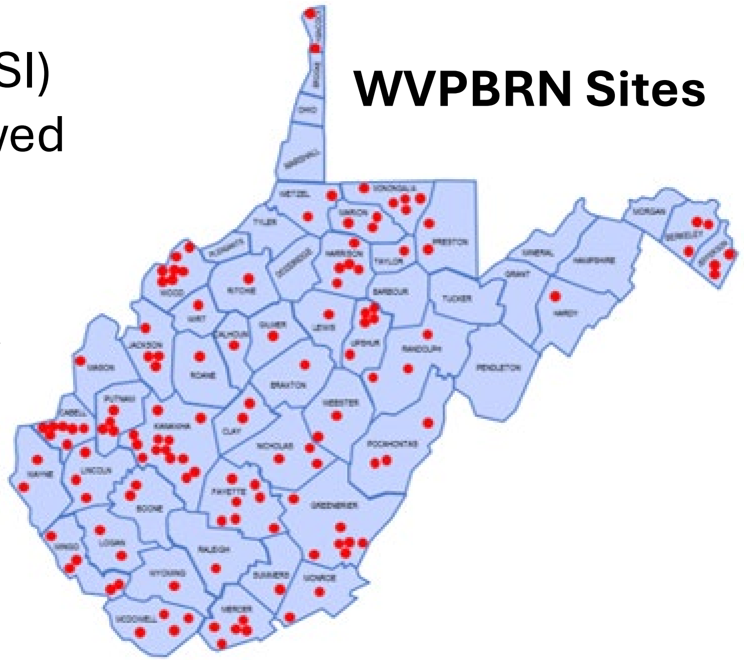
Hub History

- **2012**: West Virginia Clinical and Translational Science Institute (WVCTSI) funded as NIH IDeA Center for Translational Research in 2012, (renewed 2017 and 2022).

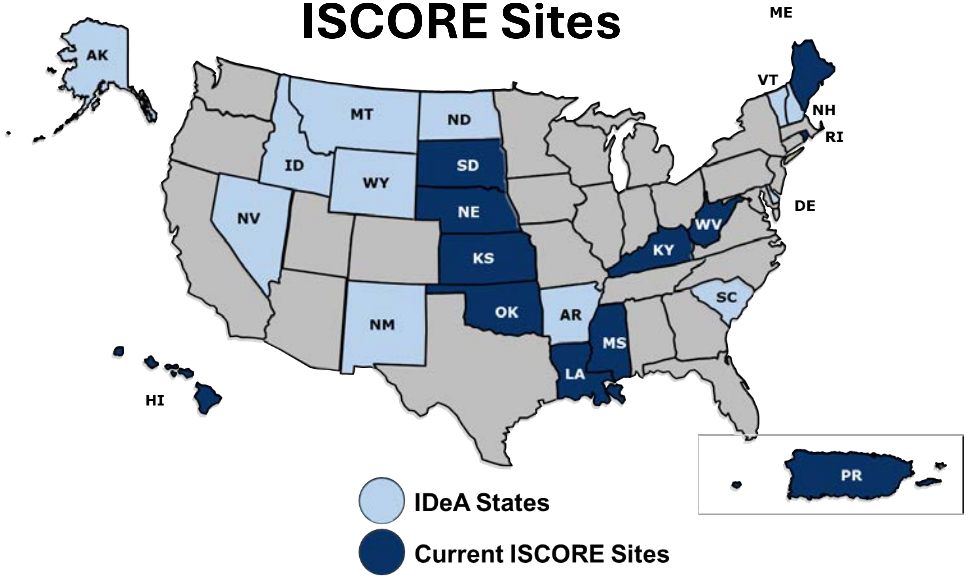
- **2013**: Established the West Virginia Practice-Based Research Network (WVPBRN). WVR3 sites recruited from WVPBRN.

- **2017**: Established Clinical Trials Center of Excellence

WVPBRN Sites



ISCORE Sites

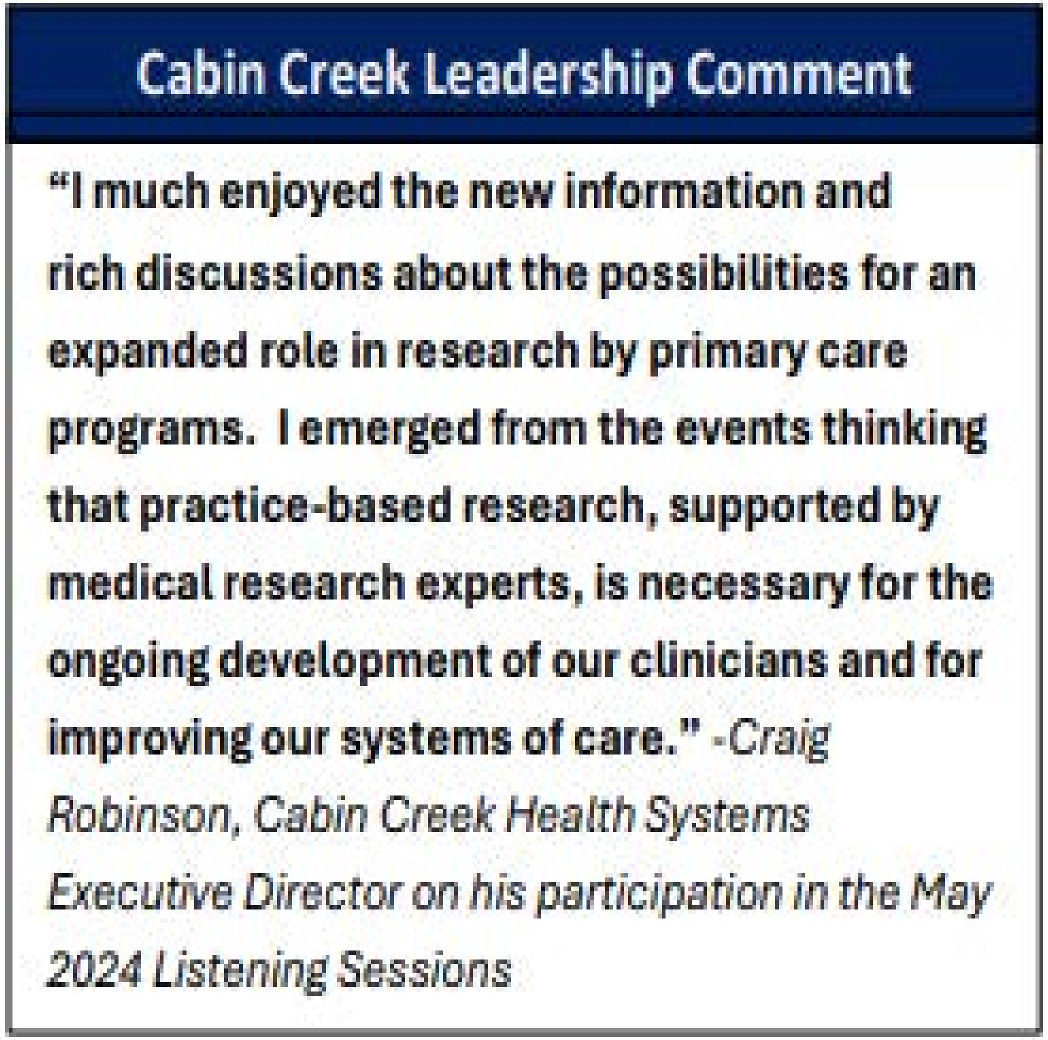


- **2020**: Created IDeA States Consortium for Clinical Research (ISCORE) – 13 trial sites in 11 states/Puerto Rico

- **2023**: ISCORE Resource Center funded by NIH.

Why CARE for Health

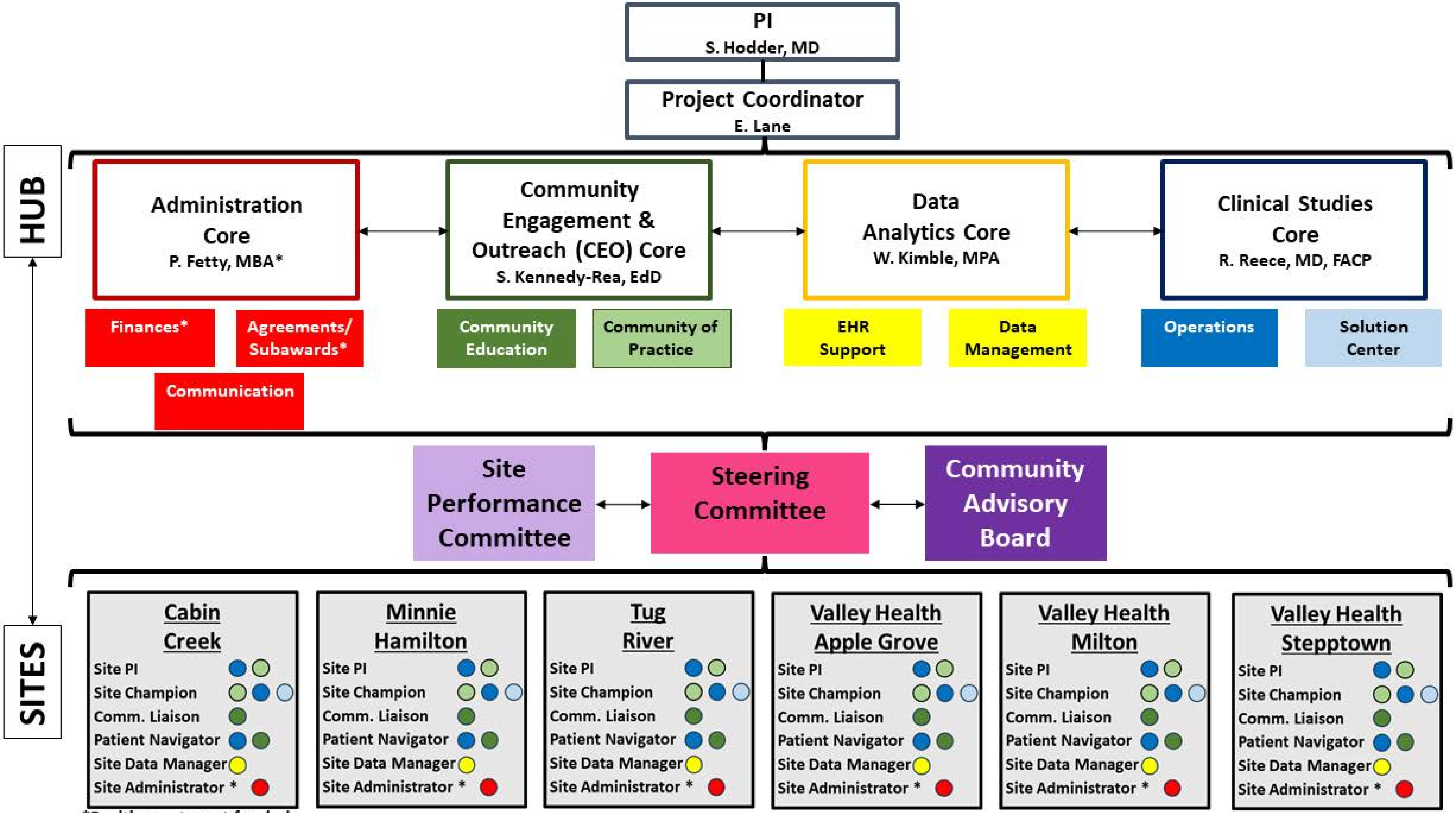
- West Virginia has among the highest prevalence in U.S. of co-morbidities and poorest health outcomes
- WVPBRN engaged in research
  - 52 completed projects (last 5 years)
  - 82% of participating health systems have participated in at least 1 study
  - 32 publications
- Sessions conducted with community members, including the May 2024 Listening Session held in partnership with the National Academies of Medicine, Science, and Engineering, demonstrate strong support for clinical research



Cabin Creek Leadership Comment

"I much enjoyed the new information and rich discussions about the possibilities for an expanded role in research by primary care programs. I emerged from the events thinking that practice-based research, supported by medical research experts, is necessary for the ongoing development of our clinicians and for improving our systems of care." -*Craig Robinson, Cabin Creek Health Systems Executive Director on his participation in the May 2024 Listening Sessions*

WVR3 Organizational Structure



PI
S. Hodder, MD

Project Coordinator
E. Lane

HUB

Administration Core
P. Fetty, MBA*
- Finances*
- Agreements/ Subawards*
- Communication

Community Engagement & Outreach (CEO) Core
S. Kennedy-Rea, EdD
- Community Education
- Community of Practice

Data Analytics Core
W. Kimble, MPA
- EHR Support
- Data Management

Clinical Studies Core
R. Reece, MD, FACP
- Operations
- Solution Center

Site Performance Committee

Steering Committee

Community Advisory Board

SITES

Cabin Creek
Site PI 🔵 🟢
Site Champion 🟢 🔵 🔵
Comm. Liaison 🟢
Patient Navigator 🔵 🟢
Site Data Manager 🟡
Site Administrator * 🔴

Minnie Hamilton
Site PI 🔵 🟢
Site Champion 🟢 🔵 🔵
Comm. Liaison 🟢
Patient Navigator 🔵 🟢
Site Data Manager 🟡
Site Administrator * 🔴

Tug River
Site PI 🔵 🟢
Site Champion 🟢 🔵 🔵
Comm. Liaison 🟢
Patient Navigator 🔵 🟢
Site Data Manager 🟡
Site Administrator * 🔴

Valley Health Apple Grove
Site PI 🔵 🟢
Site Champion 🟢 🔵 🔵
Comm. Liaison 🟢
Patient Navigator 🔵 🟢
Site Data Manager 🟡
Site Administrator * 🔴

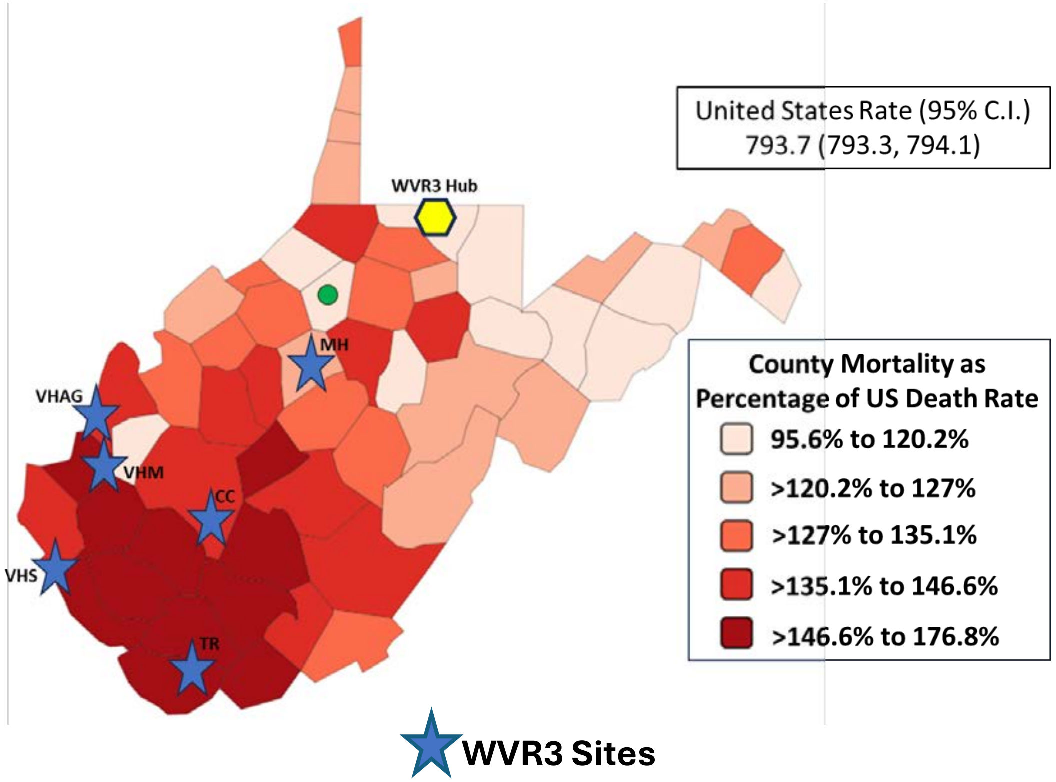
Valley Health Milton
Site PI 🔵 🟢
Site Champion 🟢 🔵 🔵
Comm. Liaison 🟢
Patient Navigator 🔵 🟢
Site Data Manager 🟡
Site Administrator * 🔴

Valley Health Stepptown
Site PI 🔵 🟢
Site Champion 🟢 🔵 🔵
Comm. Liaison 🟢
Patient Navigator 🔵 🟢
Site Data Manager 🟡
Site Administrator * 🔴

*Position not grant funded

WVR3 Health Sites

Site Locations with County Mortality Rates



Source: HDPulse: An Ecosystem of Minority Health and Health Disparities Resources. National Institute on Minority Health and Health Disparities. 2018-2022 data. Created 11/13/2024. Available from https://hdpulse.nimhd.nih.gov

WVR3 Clinical Site Characteristics

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Network Features & Strengths

- WVCTSI has a lengthy association with WVR3 health systems whose sites are also existing West Virginia Practice-Based Research Network sites.
- Hub staff is experienced in all aspects of clinical trial operations.
- Hub has track record of successfully managing clinical studies (RECOVER cohort and Immulina trial in long-COVID) among 13 sites in 10 states and Puerto Rico
- MAVERICK Mobile Clinical trials unit provides spaces for clinical trial visits and equipment that is not available at all sites (i.e., refrigerated centrifuge, appropriate sample storage).

Network Features & Strengths II

- **Each WVR3 Site has a funded Community Liaison**
- **WVR3 cWVR3 Community Forums**
- **Community members will be invited to join WVCTSI Community Advisory Board**
  - Community Forums will be held at each WVR3 site.
  - Three have been scheduled out of the six total.
- **Community of Practice (COP)**
  - WVCTSI Project ECHO will be used to disseminate best practices.
  - The Solution Center intake form will be used to guide the COP ECHO sessions.
- **WVR3 Communication Initiative**
  - Iterative health communication research designed to engage rural communities in the process of developing more effective clinical trial messaging
    - Phase 1: Community Perspectives on Clinical Trials Survey
    - Phase 2: Clinical Trial Message Development
    - Phase 3: Practice Integration

Looking Ahead: Lessons Learned from Other Programs and Networks

Panel Discussion

Moderator: Dr. Rohan Hazra

Lessons Learned Panelists

Nakela Cook, MD, MPH
PCORNet, Patient-Centered Outcomes Research Institute

Aimee Eden, PhD, MPH
AHRQ PBRNs

Erin Iturriaga, DNP, MSN, RN
IDeA Clinical and Translational Research (CTR) programs

Francisco Leyva, MD, PhD, ScM
Clinical and Translational Science Awards

Vanessa Marshall, PhD
Community Engagement Alliance (CEAL)

Rachele Peterson, MBA, MS
All of Us Research Program

Wendy Weber, ND, PhD, MPH
NIH Pragmatic Trials Collaboratory

Lessons Learned: Discussion Questions

- What is **the greatest opportunity to increase community / primary care reach of research networks**, especially one that increases capacity with limited resources?
- What was **the most significant challenge your network/program experienced** that you think CARE for Health™ might encounter? What did you do to solve it?
- What **single piece of advice would you offer** to CARE for Health™?

Thank you for joining us!

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