

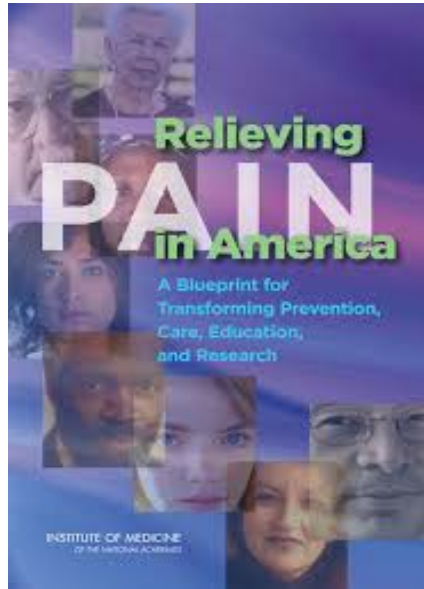
Translating Evidence-Based Interventions into Real-World Settings to Improve Pain Care

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Outline

- Background on studies
- Implementation choices and challenges
- Forming meaningful community partnerships
- NIH CARE for Health Initiative
- Lessons learned



Institute of Medicine Report, 2011

- **Pain as a Public Health Problem:** Quantifying the prevalence and economic burden of pain (then estimated at \$635 billion annually) to justify national research investment.
- **Need Better Pain Management:** Both better treatments and translation of what is known into practice
- **Pain is not “Democratically” Distributed:** Specific groups face significantly greater barriers to receiving quality care

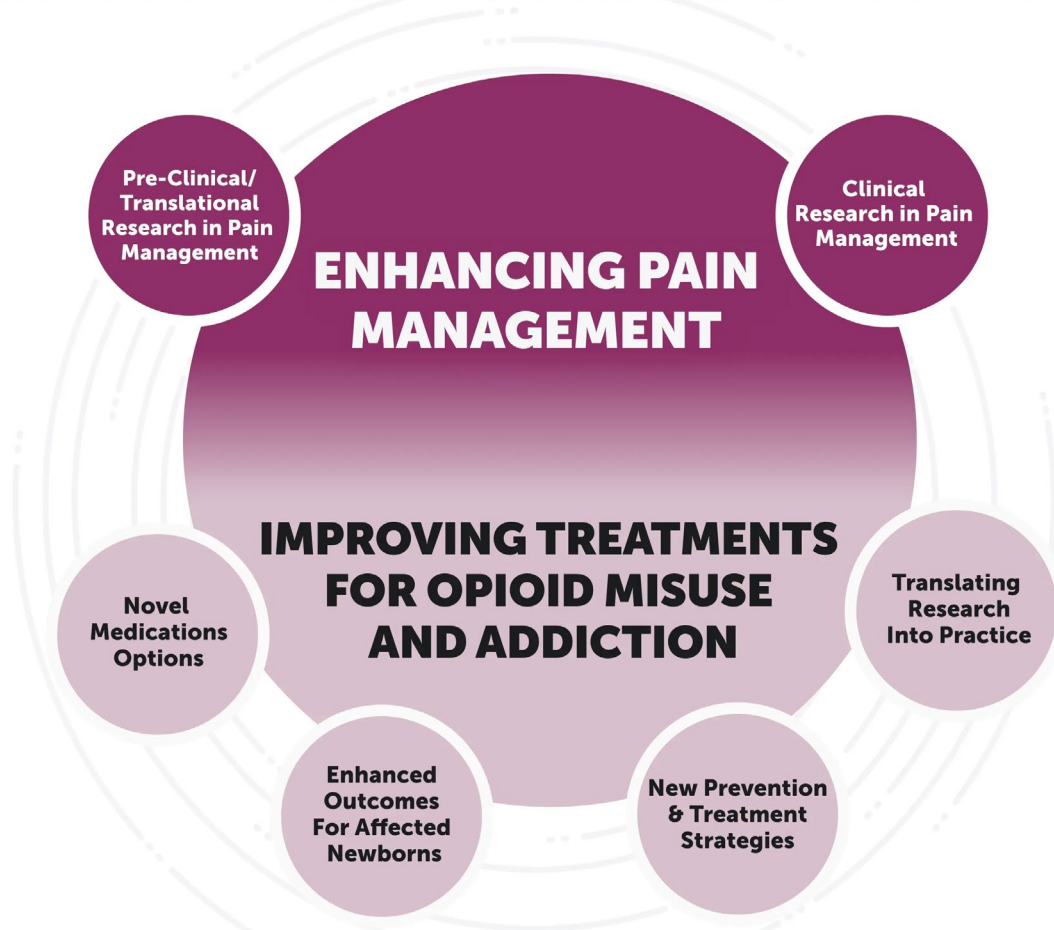


Department Health Human Services, 2016

- **Population Research:** Distinguished "High-Impact Chronic Pain" (pain that severely restricts life activities) and the need for effective population-level interventions – particularly those relevant to primary care. Also recommends improvements in pain self-management programs.
- **Increasing Access:** Address the disproportionate impacts of chronic pain by increasing access to high-quality pain care.

NIH launches HEAL Initiative, doubles funding to accelerate scientific solutions to stem national opioid epidemic

NIH HEAL INITIATIVE RESEARCH OVERVIEW



Clinical Pain Management Research Priorities

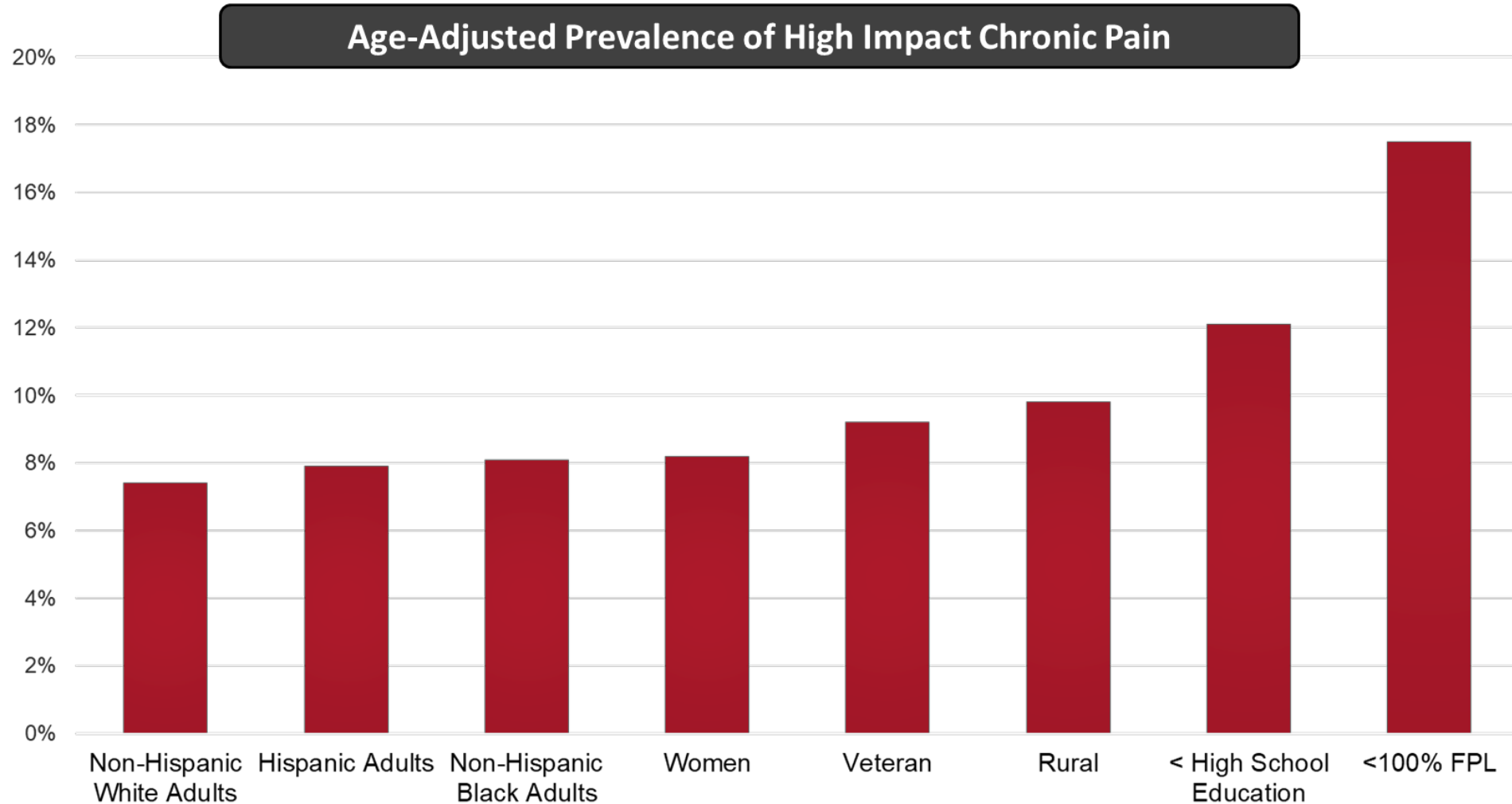
Discovery of Non-Addictive Treatments: A primary goal was to develop new, effective, and non-addictive drugs and devices for both acute and chronic pain.

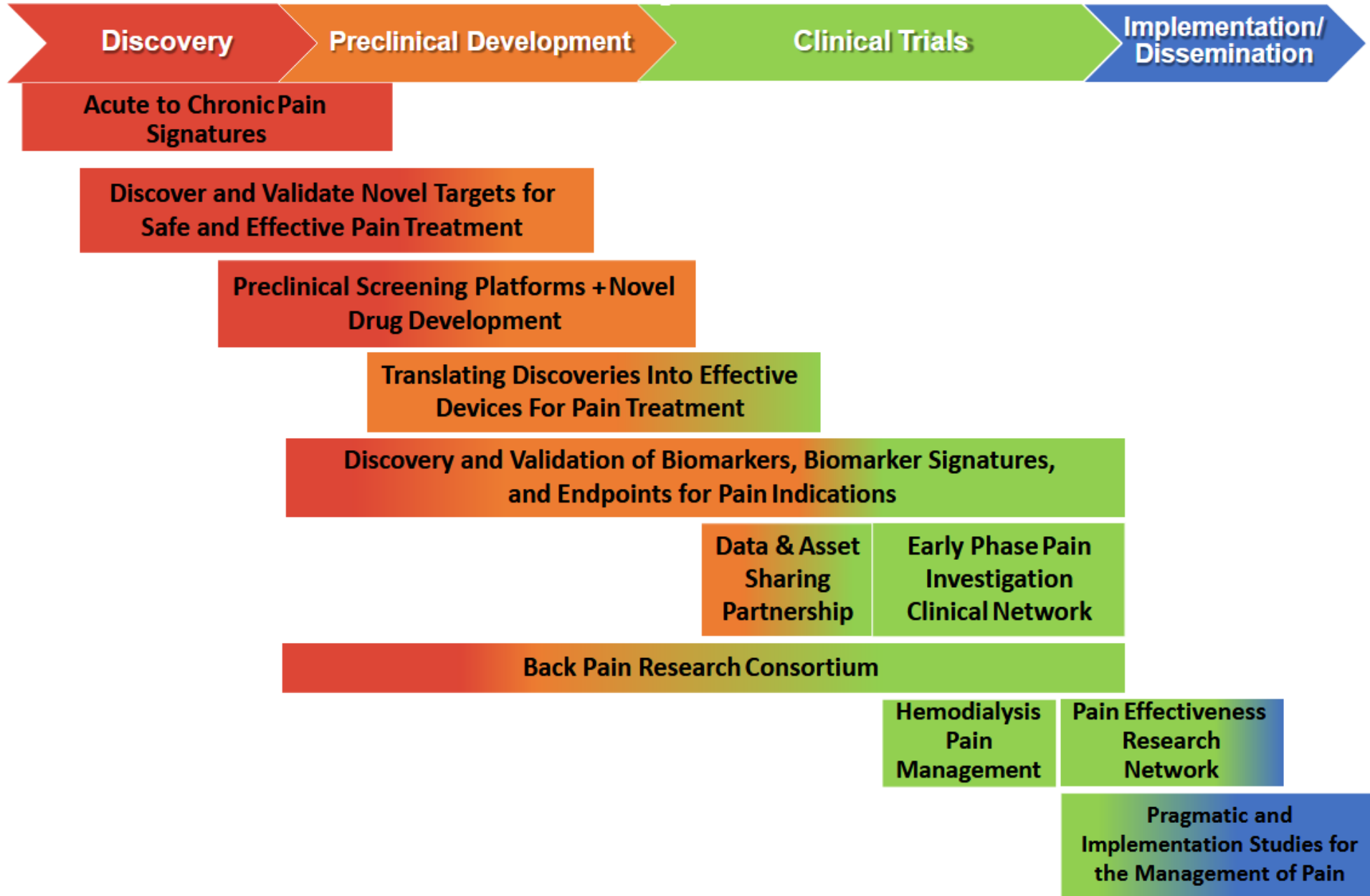
Comparative Effectiveness Research: The initiative funded large-scale trials to compare existing and new pain treatments, helping clinicians choose the best options for their patients.

Real-World Implementation: researchers focused on how to integrate evidence-based pain management into real-world healthcare settings

Health Disparities Recognized as Cross-Cutting Theme

The Impacts of Chronic Pain are Not Borne Equally

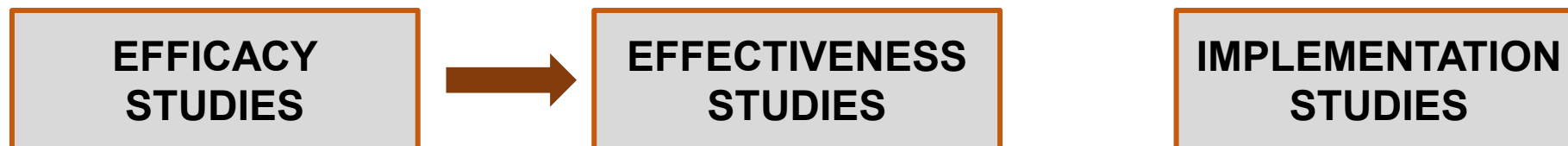




**Pragmatic and Implementation
Studies for the Management
of Pain (PRISM)**

NIH
HEAL
INITIATIVE

- **Integrate interventions with demonstrated efficacy into health care systems, and implement health care system change toward evidence-based pain management**
- **Conduct efficient, large-scale pragmatic trial or implementation science studies to improve pain management**
 - Embed the intervention under study into real-world settings
 - Collect data through the electronic records of the health care system
 - **Leverage the NIH Health Care Systems Collaboratory**
 - Focus on nonpharmacologic approaches



Designing Hybrid Trials

INTERVENTION EFFECTIVENESS

Does the field have “enough” evidence that the treatment “works”?

Is there a need for more “real-world” effectiveness data?

Are published findings generalizable to the target implementation population?

Effectiveness outcomes address the question:

Among those who got it, did they get better?

INTERVENTION IMPLEMENTATION

Understanding implementation strategies is important even in studies with effectiveness as the primary objective.

Implementation outcomes address the questions:

Did the place/people implement it?

Did everyone get it who should have gotten it?

Was it delivered as it was supposed to be?

Nonpharmacologic Pain Management in Federally Qualified Health Center Primary Care Clinics

Goal: Improve pain management by increasing access to evidence-based nonpharmacologic treatments for patients with chronic low back pain in FQHCs in Utah.

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

NIH
HEAL
INITIATIVE



AUCH

ASSOCIATION FOR UTAH COMMUNITY HEALTH

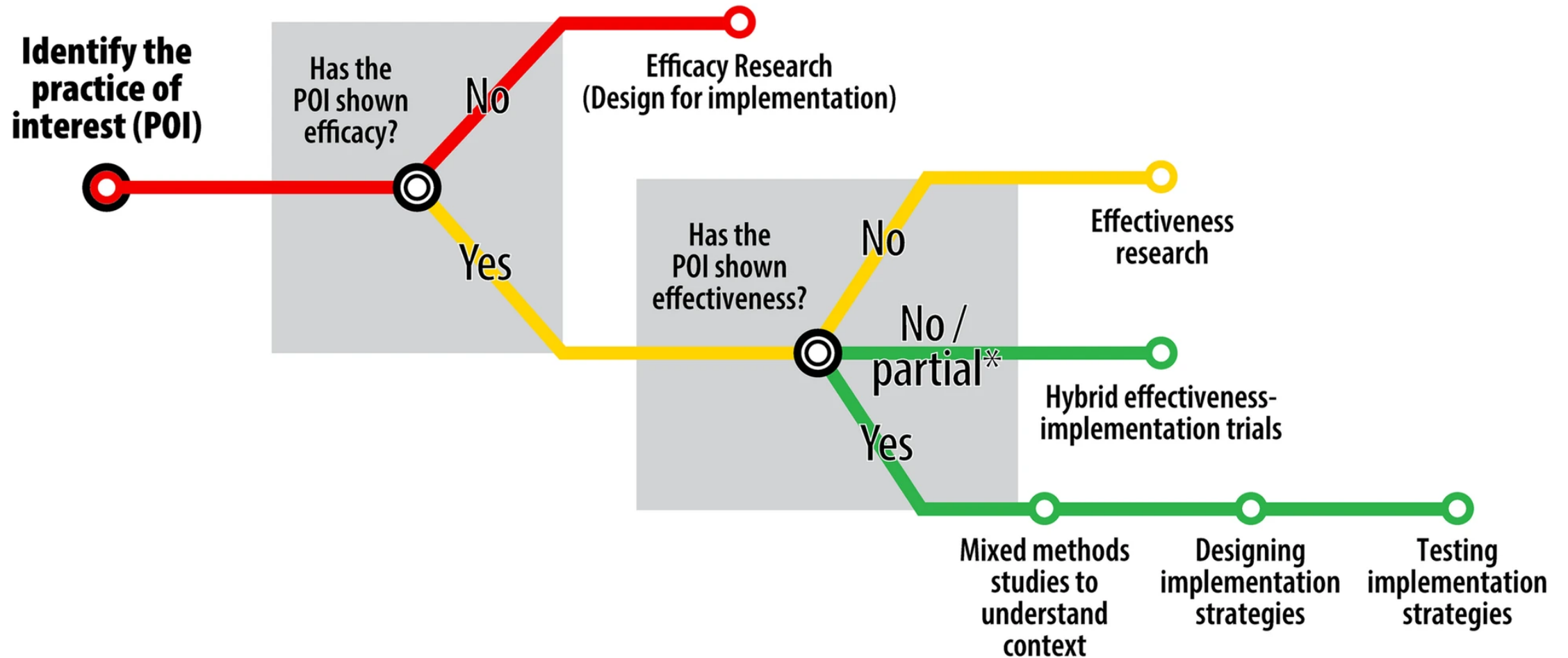
UNIVERSITY OF UTAH



HUNTSMAN
CANCER INSTITUTE



HEALTH
UNIVERSITY OF UTAH

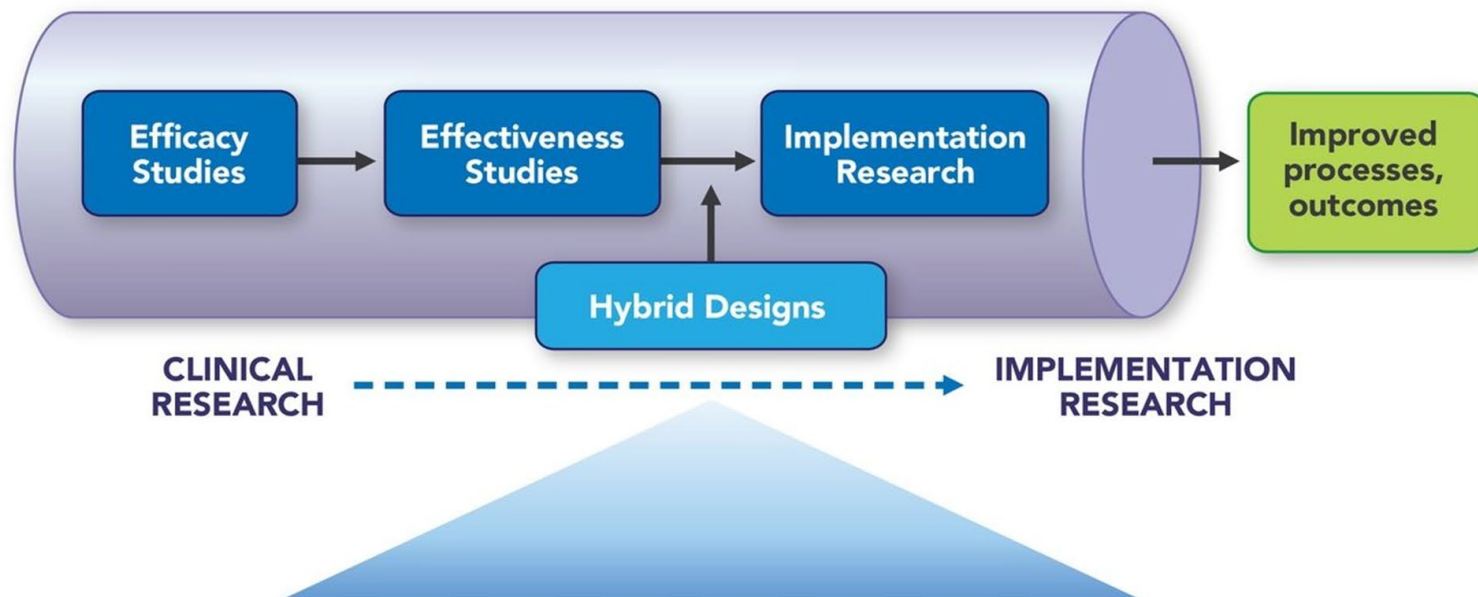


* In many cases it is appropriate to move forward with hybrid trial in absence of effectiveness evidence to accelerate implementation. In cases where effectiveness evidence may not generalize to other settings, hybrid trials are appropriate to examine both effectiveness and implementation into different contexts and settings

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD,* Mark Bauer, MD,† Brian Mittman, PhD,‡
 Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD‡



The speed of moving research into routine adoption could be improved by considering *hybrid designs* that combine elements of effectiveness and implementation research.

Doesn't wait for "perfect" effectiveness data before moving to implementation research.

Can study how clinical outcomes relate to levels of adoption and fidelity.

Hybrid Type I:

Goal: test clinical intervention while gathering information on implementation

Primary Aim: is the clinical intervention effective in these settings/patients?

Secondary Aim: barriers/ facilitators to implementation

Hybrid Type II:

Goal: test clinical intervention balanced with studying implementation

Primary Aim: is the clinical intervention effective in these settings/patients?

Secondary Aim: does the implementation method show promise?

Hybrid Type III:

Goal: test implementation intervention while gathering information on effectiveness

Primary Aim: What methods facilitate implementation? Which core components are critical?

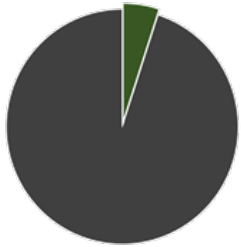
Secondary Aim: is the clinical intervention effective in these settings/patients?



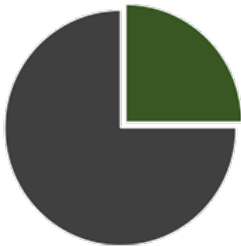
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14 Utah community health centers operate 69 clinics and provide care to more than 181,000 people annually



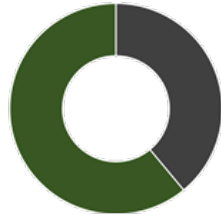
1 of every 20 Utahns



1 of every 4 uninsured Utahns



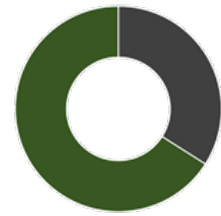
1 of every 3 Utahns living in poverty



61% identity as a racial or ethnic minority



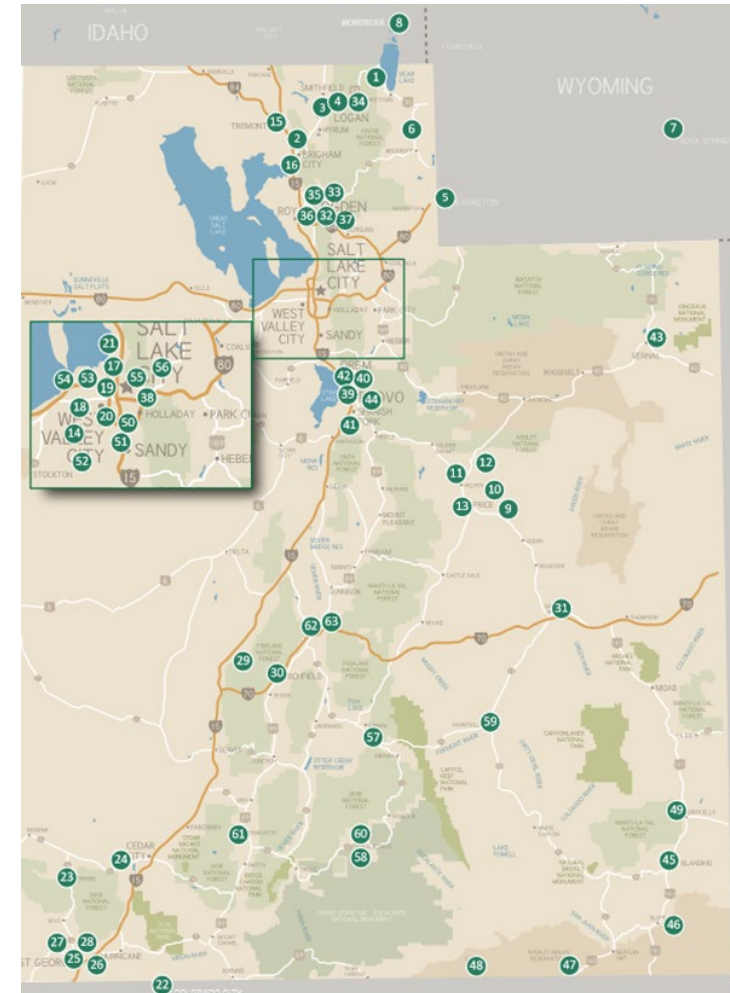
37% communicate in a language other than English



66% at or below the Federal poverty level



57% of clinics located in rural or frontier counties



Partnering for Community Engagement and Sustainability

Mission: Bring communities and researchers together to **create long-term solutions** to prevent cancer, chronic and infectious disease, and improve health in all populations.

Key Partners

Academic
Research Center



Primary Care
Association



Utah Community
Health Centers



Key Partnership Characteristics

- Shared Goals
- Mutual Respect of Expertise
- Shared Resources and Data

Key Engagement Activities

- Patient and Study Advisory Committees
- Clinic Workflow Analyses and Usability Assessments
- Adaptations to Implementation Strategies

Lessons Learned

- Research Topics Have to Be a Priority for Partners
- Importance of Bridging Capacity
- Leverage Partnership Expertise to Overcome Challenges
- Sustainability

Community-Engaged Dissemination & Implementation (CEDI) Framework



BeatPain Utah

Goal: Improve pain management by increasing access to evidence-based nonpharmacologic treatments for patients with chronic low back pain in FQHCs in Utah.

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

- ✓ Compare the effectiveness of first-line nonpharmacologic pain treatments using 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.

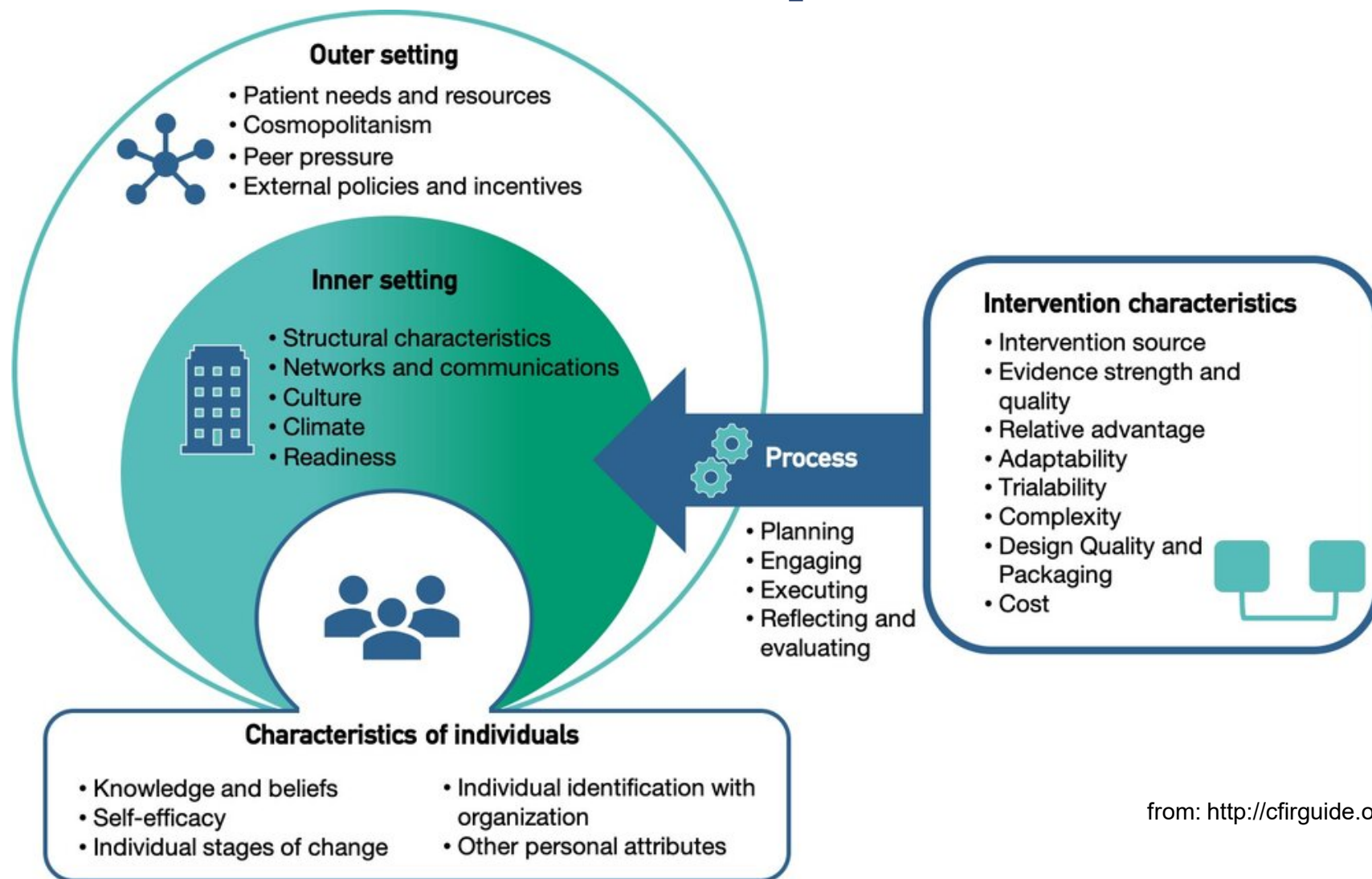
Implementation Framework

Consolidated Framework for Implementation Research

CFIR provides a menu of constructs across 5 domains associated with effective implementation.

Provides a guide to assess barriers and facilitators to prepare for implementation:

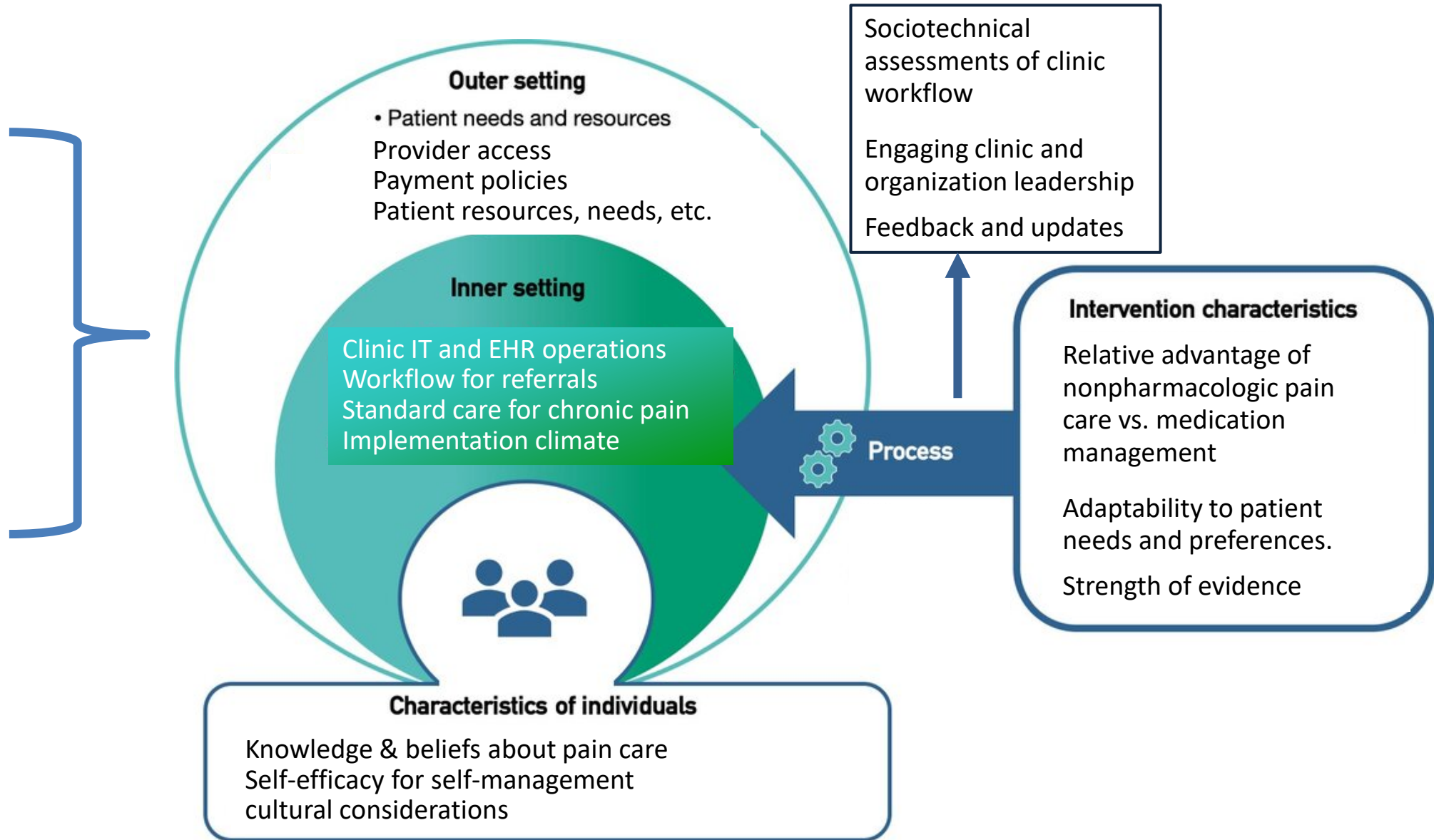
- 1) Outer Setting
- 2) Inner Setting
- 3) Intervention Characteristics
- 4) Characteristics of Individuals
- 5) Process of Implementation





Implementation Process

- IMPLEMENTATION MAPPING**
- 1) Conduct needs assessments for implementation in clinics and patients
 - 2) Identify determinants of change for clinics and patients
 - 3) Select implementation methods
 - 4) Finalize protocols to implement pain telehealth interventions
 - 5) Define implementation outcomes



Implementation Mapping

“Implementation Mapping provides a systematic process for developing strategies to improve the adoption, implementation, and maintenance of evidence-based interventions in real-world settings.”

IMPLEMENTATION MAPPING				
STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Needs Assessment	Identify Performance Objectives/ Determinants	Select Implementation Strategies	Produce Implementation Materials	Define Implementation Outcomes

WHO?

Identify Implementers and Understand Needs & Assets

WHAT and WHY?

Determine Who Needs to do What for Change to Happen

HOW?

Choose and Operationalize Implementation Strategies for all Implementers

IS IT WORKING?

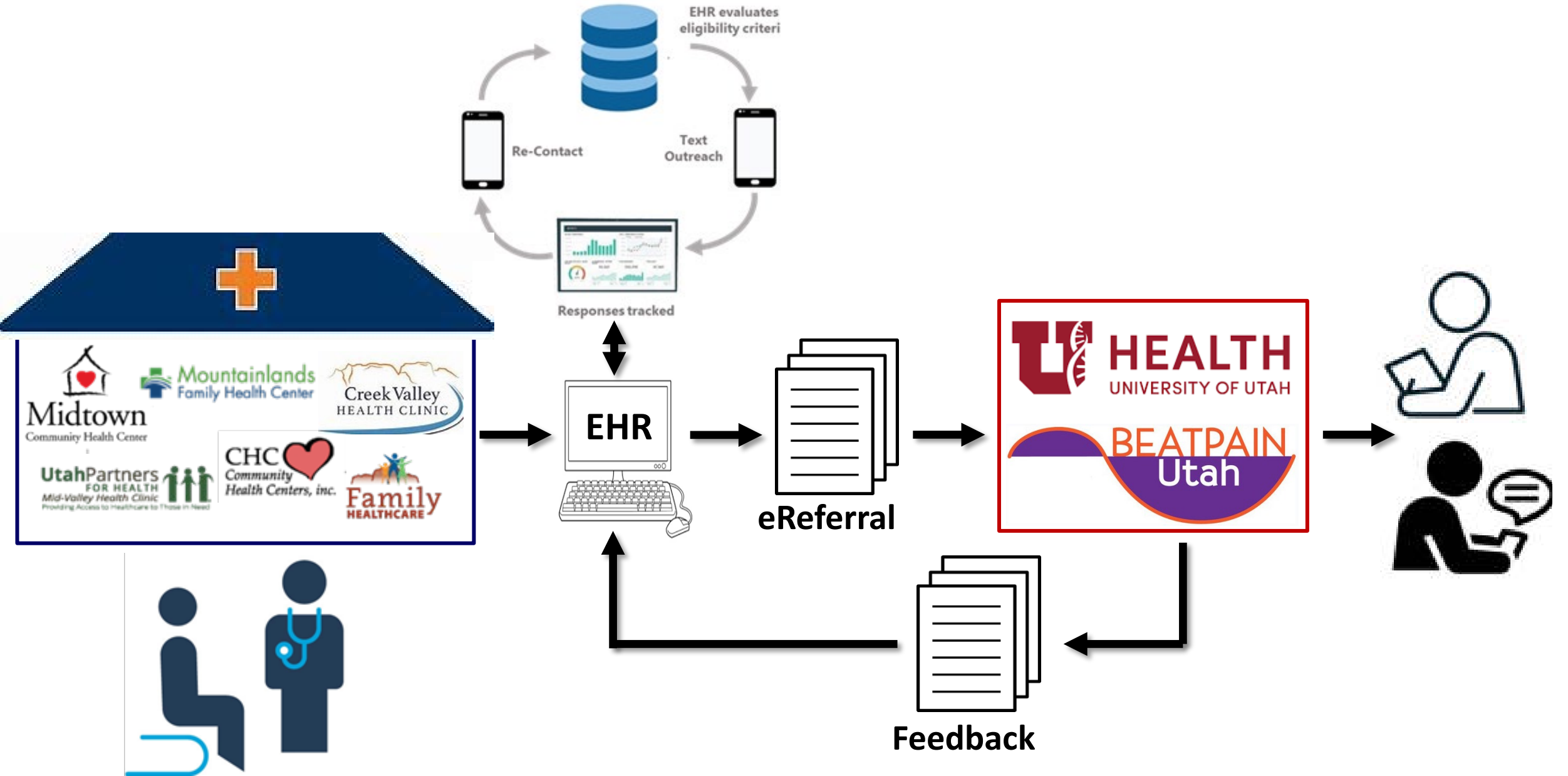
Evaluate Outcomes

FROM: Fernandez M, et al. Implementation mapping: using intervention mapping to develop implementation strategies. *Front Public Health*. 2019;7:158.

Walker TJ, et al Using Implementation Mapping to develop and test an implementation strategy for active learning to promote physical activity in children: a feasibility study using a hybrid type 2 design. *Imp Sci Commun*. 2022;3:26

	Potential Barrier	Implementation Strategies	Lessons Learned
Primary Care Staff and Providers	<ul style="list-style-type: none"> Clinic staffing and patient volumes require minimal disruptions to work flows 	<ul style="list-style-type: none"> Have an in-clinic and population health strategy to offer participation to patients 	<ul style="list-style-type: none"> EHR reminders not feasible, text messaging a better option
	<ul style="list-style-type: none"> Providers and staff have strong commitment to the patients served 	<ul style="list-style-type: none"> Feedback on patient status is critical, must serve Spanish-speakers, have an option for those not wishing to be part of study 	<ul style="list-style-type: none"> Communication back to providers needs to be consistent, frequent
	<ul style="list-style-type: none"> In-clinic EHR systems differ in capabilities and performance 	<ul style="list-style-type: none"> Provide initial and ongoing training to place e-referrals 	<ul style="list-style-type: none"> Clinical bioinformatics expertise that is used to working with varied EHR systems
Therapists/ Study Team	<ul style="list-style-type: none"> Patients receiving care in CHCs and the CHCs themselves have needs that differ from academic settings 	<ul style="list-style-type: none"> Team members with language skills and commitment to working with community partners 	<ul style="list-style-type: none"> Provide staff training on partnership and engagement model
	<ul style="list-style-type: none"> Limited experience with telehealth and decentralized procedures 	<ul style="list-style-type: none"> Training on effective communication strategies 	<ul style="list-style-type: none"> Communication skills essential for team members
Patients	<ul style="list-style-type: none"> Access challenges extend well beyond geography 	<ul style="list-style-type: none"> Flexible scheduling, adapting PT protocols for audio-only delivery, low bandwidth platform, shorter sessions 	<ul style="list-style-type: none"> Respect for participants' time, being flexible, builds trust
	<ul style="list-style-type: none"> Patients' pain beliefs and coping preferences may be mismatched to evidence-based principles 	<ul style="list-style-type: none"> PT protocols provided with principles of motivation-and-problem solving (MAPS) 	<ul style="list-style-type: none"> MAPS helps build intrinsic motivation and self-efficacy for active coping

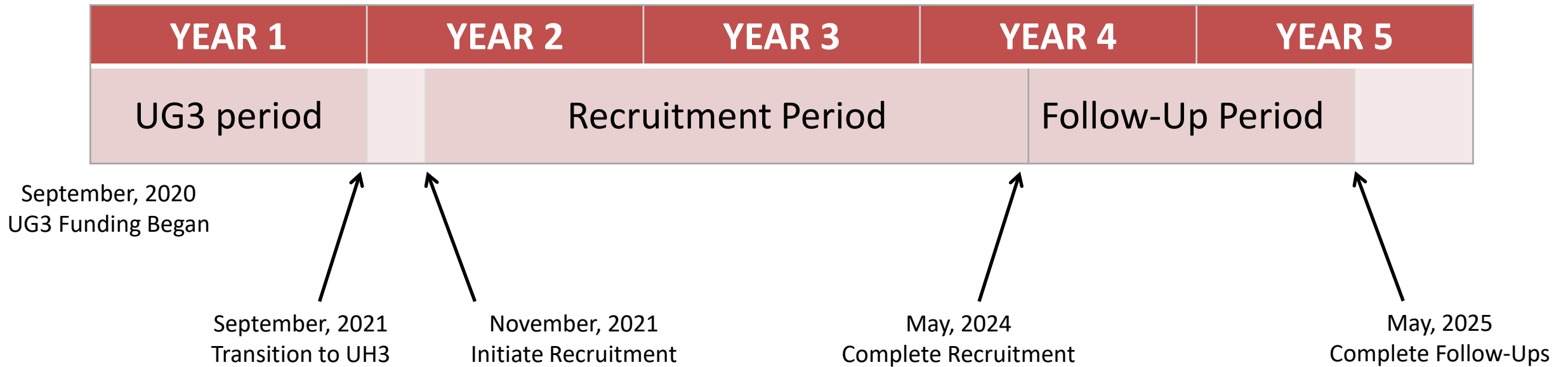
Implementation Strategies





BeatPain Utah

Original Study Timeline





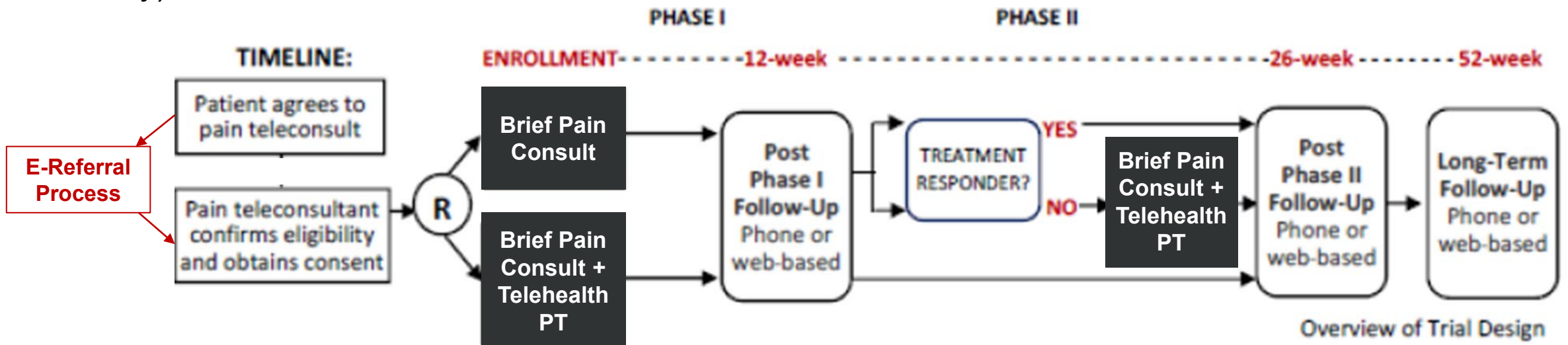
Unexpected Challenges

- ✓ COVID required switching from in-person to remote engagement efforts with partnering clinics.
- ✓ Clinic staffing and capacity fluctuated
- ✓ Focus on testing and vaccine roll-outs
- ✓ Research fatigue

BeatPain Utah

UH3 Study Aims

1. Compare the effectiveness of brief pain teleconsult with or without telehealth PT (pain impact (PEG) as primary outcome; opioid use as a secondary 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 effectiveness 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).





Lessons Learned During UH3

- ✓ COVID continued to be a challenge, evolving attitudes towards text messaging about research
- ✓ CARE for Health and working with rural communities
- ✓ Recruiting and engaging representative participants

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.

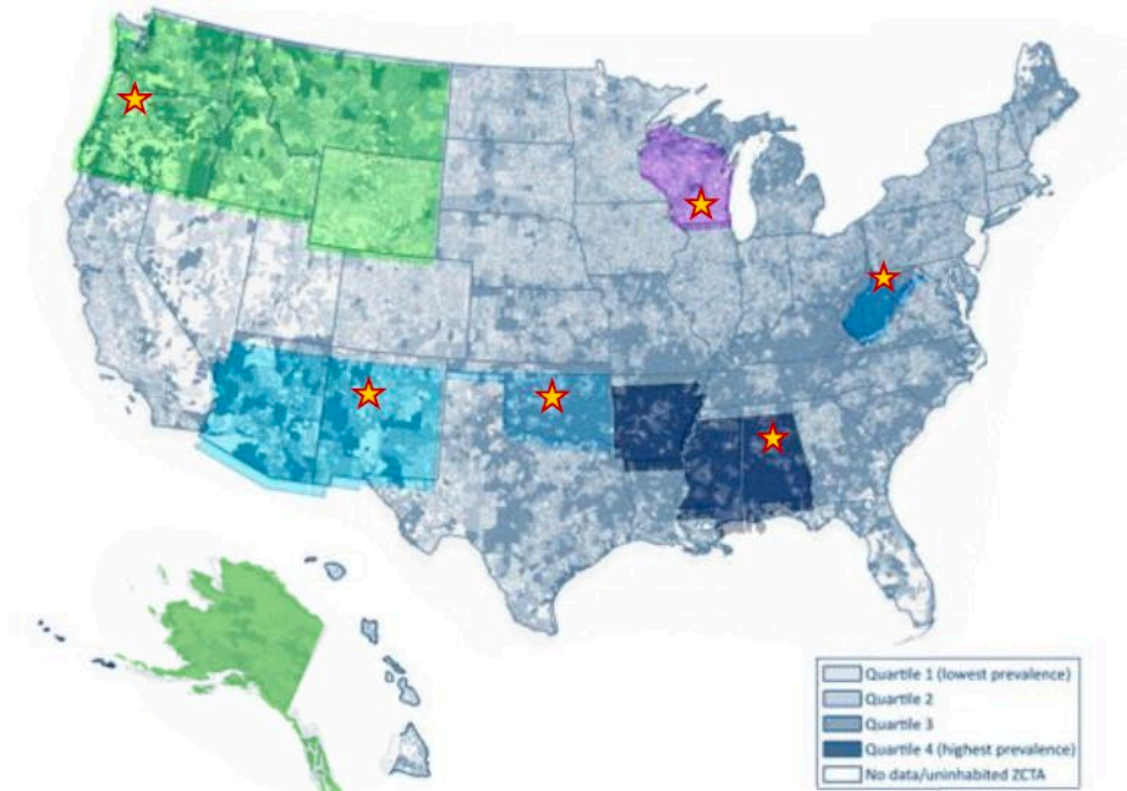
The United States continues to experience major declines in health and the life expectancy of its population significantly lags behind that of other developed countries.

To address this challenge from a research perspective, there is a critical need to:

- 1) extend research opportunities to where patients live, work, and seek medical care such that the research focuses on issues facing the frontlines of medicine;
- 2) design studies that address clinical conditions of critical importance to primary care practitioners and patients, and generate findings readily implemented in primary care settings;
- 3) facilitate research participation across the nation, with the ultimate goals of: accelerating research advances and adoption into everyday clinical care, improving health outcomes, and advancing access to clinical research for all Americans.



6 Primary Care Clinical Research Network Hubs awarded and engaging rural primary care sites across **14 states**



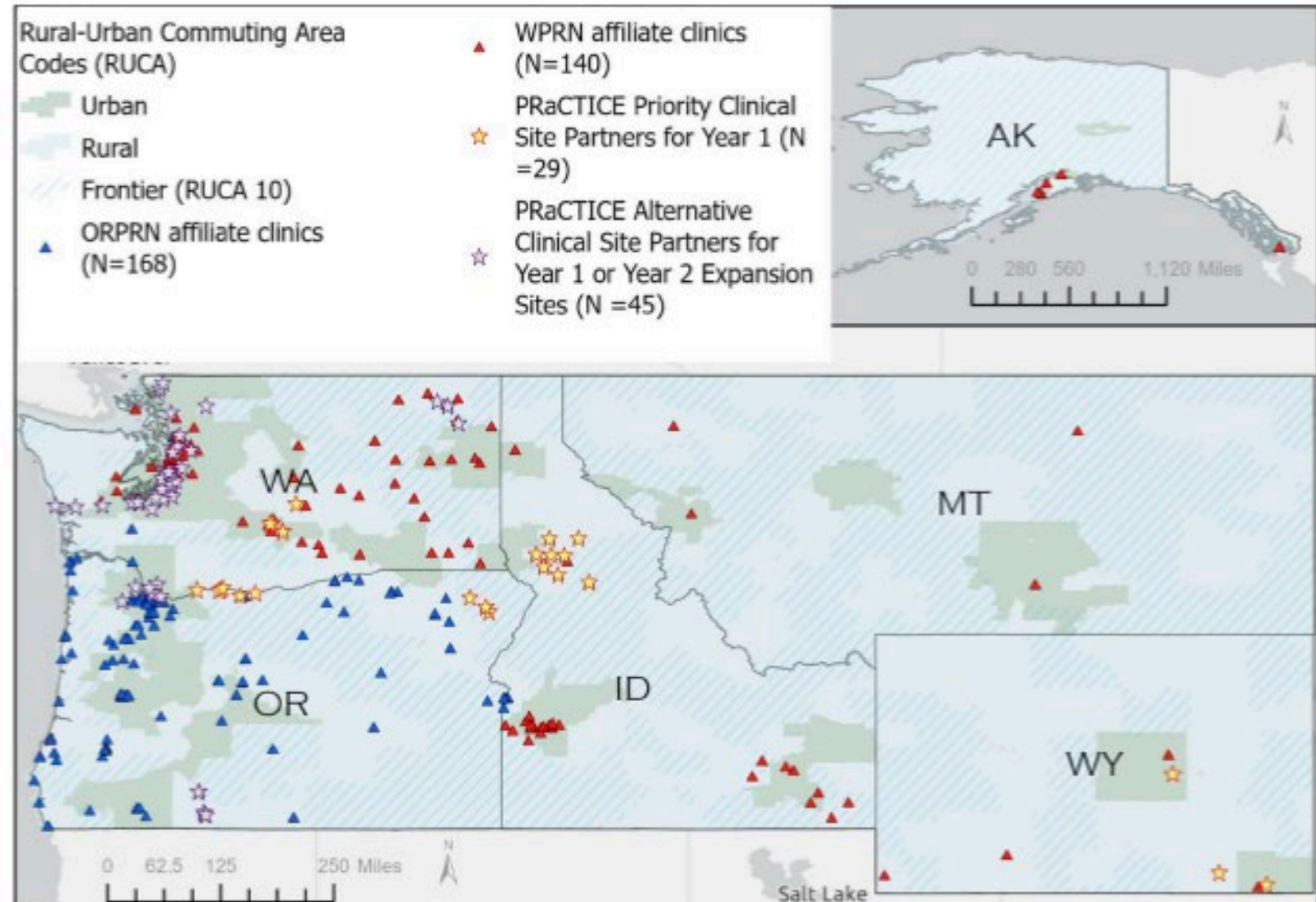
- Oregon Health and Science University (PRaCTICE)
- University of Wisconsin – Madison (WREN)
- West Virginia University (WVR3)
- University of Alabama – Birmingham (HEART-NET)
- University of Oklahoma Health Sciences Center (PRIME-OK)
- University of New Mexico Health Sciences Center (PC BRIDGE)
- ★ Stars indicate location of Hub institution



Primary Care Rural and Frontier Clinical Trials Innovation Center (PRaCTICE)

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

With support from our Institutional Clinical and Translational Science Award (CTSA) Programs



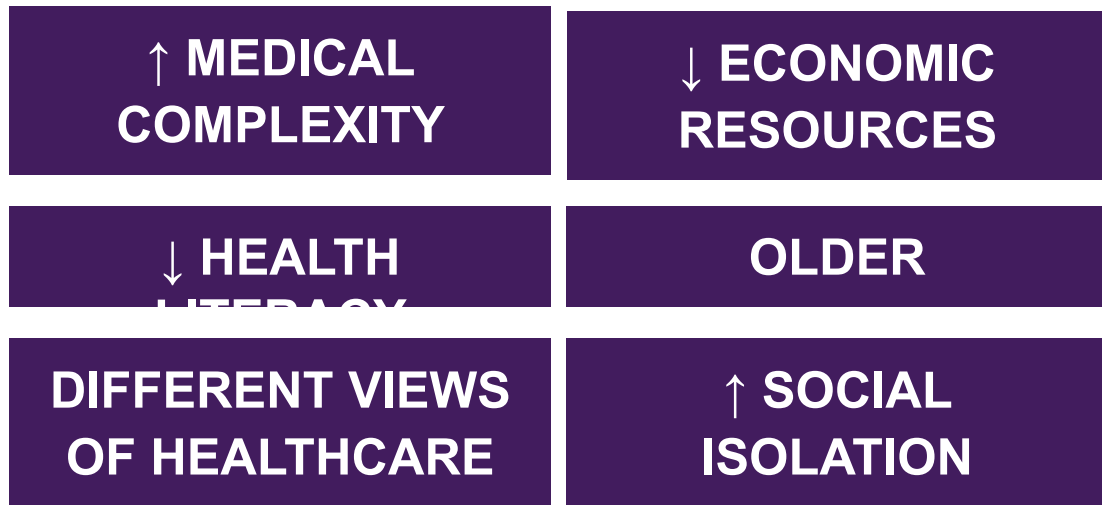


CHALLENGES

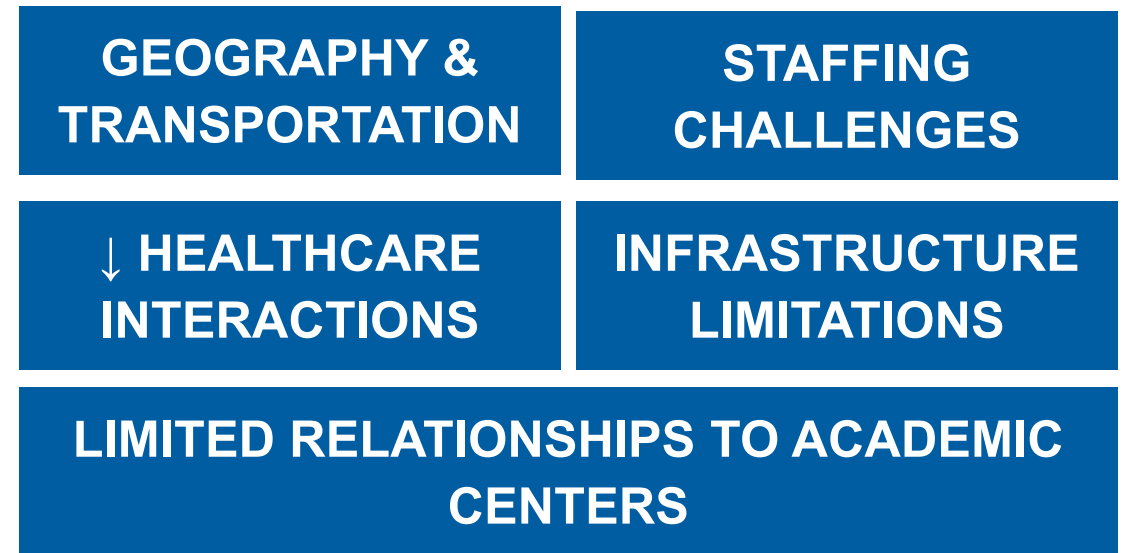
- Rapid trust building, branding of the trial
- Implementing decentralized methods – provider licensing, EHR integration
- Regulatory oversight – perspectives on who is involved in research differed by IRBs.

Reasons for Under-Representation of Rural Residents

Person-Level



Structural



Maher L. Increasing Participation in Clinical Trials by Those in Rural Areas. *Increasing Participation in Clinical Trials by Those in Rural Areas - PCNA*

Baker MB, et al, Overcoming Barriers: A Comprehensive Review of Chronic Pain Management and Accessibility Challenges in Rural America. *Healthcare*. 2024;12::1765.

<https://nihcm.org/publications/rural-health-in-america-how-shifting-populations-leave-people-behind>



Nonpharmacologic Pain Management in Federally Qualified Health Center Primary Care Clinics

All Persons Referred (1,269)
Age (mean) = 51.7
Female = 63.7%
Hispanic/Latino = 51.9%
Medicaid Beneficiary = 23.3%
Uninsured = 38.9%
Rural Resident = 32.9%

All Persons Enrolled (506)
Age (mean) = 50.4
Female = 67.4%
Hispanic/Latino = 53.3%
Medicaid Beneficiary = 24.9%
Uninsured = 39.2%
Rural Resident = 30.6%

Benefits of Community Partnerships

- ✓ Requires practical problem-solving
- ✓ Teamwork and mutual respect for expertise are keys to overcoming challenges
- ✓ Important lessons about the impact of contextual factors
- ✓ Working with amazing people



Xavi Martinez-Ziegenfuss and Roni Hyde table at One Community Health-Hood River waiting room on April 2nd

Thank You

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