# Building and Sustaining Reusable Infrastructure for ePCTs

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Duke Clinical Research Institute Duke University School of Medicine

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

# Panelists

- Julie Fritz, PhD, PT
  - Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics (BeatPain Utah)
- Greg Simon, MD
  - Suicide Prevention Outreach Trial (SPOT)
- Lynn DeBar, MD
  - Collaborative Care for Chronic Pain in Primary Care (PPACT)
  - Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (BackInAction)

# Session Goals

- Describe reusable infrastructure being used to promote ePCTs outside the NIH Collaboratory
- Explore different models for sustaining infrastructure for ePCTs

# Infrastructure Considerations

- The definition can differ depending on the project goals
  - Technical and physical assets
  - Study and non-study personnel
  - Partnerships/goodwill
- Sustainability
  - Understanding the local culture
  - Tailoring approach to specific needs of the setting.
  - Tension between building infrastructure for a trial and what will happen after the trial is over.

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BEATPAIN Utah

# Nonpharmacologic Pain Management in Federally Qualified Health Center Primary Care Clinics

## Building and Sustaining Reusable Infrastructure for ePCTs

**Julie Fritz, PT, PhD**
University of Utah

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

NIH HEAL INITIATIVE

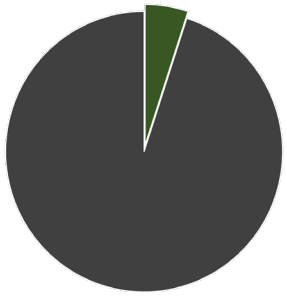
AUCH ASSOCIATION FOR UTAH COMMUNITY HEALTH

UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE

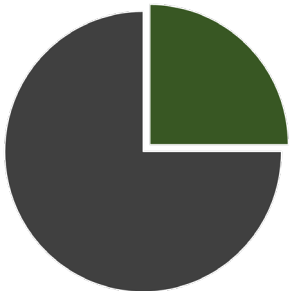
HEALTH UNIVERSITY OF UTAH

AUCH
ASSOCIATION FOR UTAH COMMUNITY HEALTH

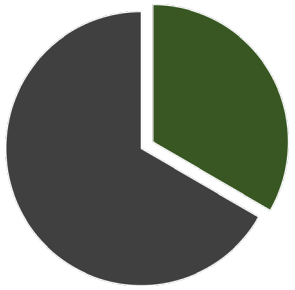
# **14 Utah health centers** operate **60 clinics** and provide care to more than **167,000 people** annually



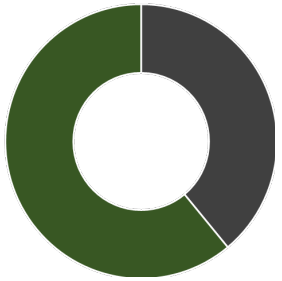
**1** of every **20** Utahns



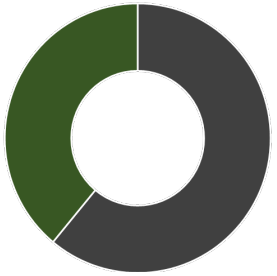
**1** of every **4** uninsured Utahns



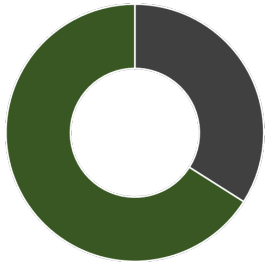
**1** of every **3** Utahns living in poverty



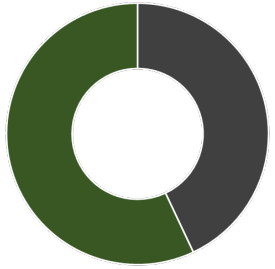
**61%** identity as a racial or ethnic minority



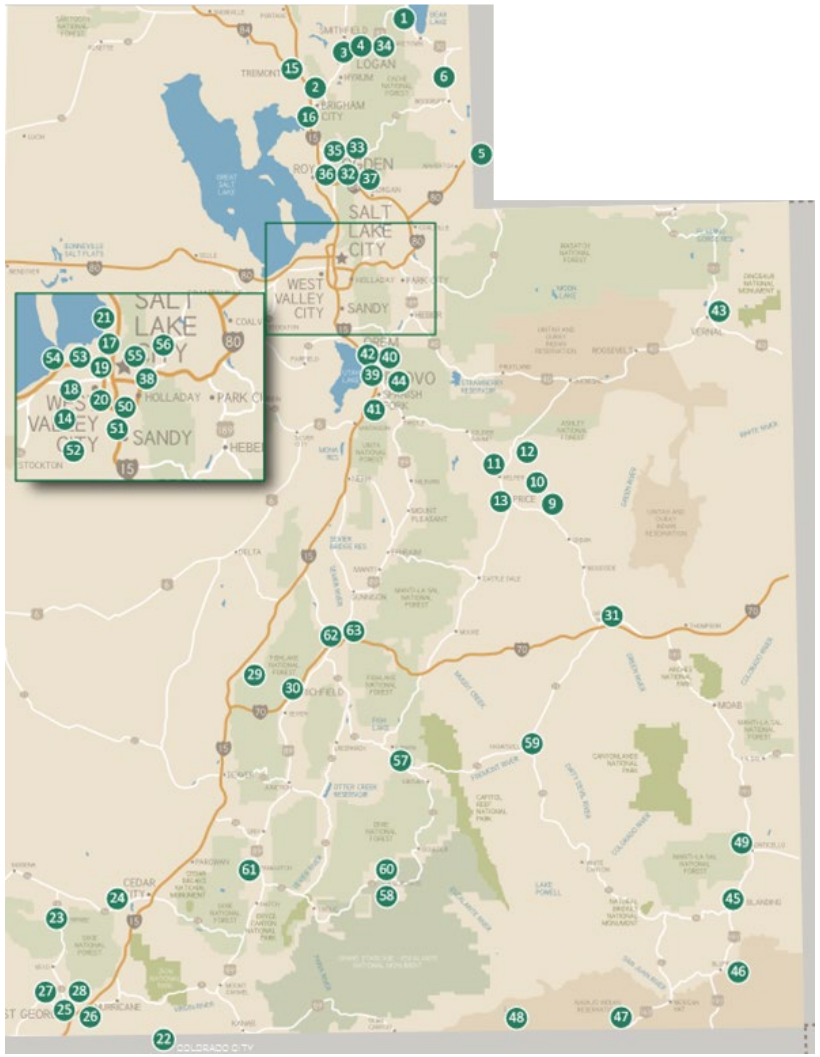
**37%** communicate in a language other than English



**66%** at or below the Federal poverty level



**57%** of clinics located in rural/frontier counties



# CENTER FOR HOPE
## HEALTH OUTCOMES & POPULATION EQUITY

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

**Vision:** Equity in cancer and chronic disease incidence, morbidity, and mortality in Utah/Mountain West.

### Key Partners

**Academic Research Center** — HEALTH UNIVERSITY OF UTAH

**Primary Care Association** — AUCH

**Utah Community Health Centers** — 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 Generated by Partners
- Importance of Bridging Capacity
- Leverage Partnership Expertise to Over-come Challenges
- Include Diverse Perspectives to Advance Health Equity
- **Sustainability**

Schlechter CR, Del Fiol G, Lam CY, Fernandez ME, Greene T, Yack M, et al. Application of community - engaged dissemination and implementation science to improve health equity. *Prev Med Rep*. 2021;24:101620.

# Designing for Sustainability

## Consistent Partnership Model

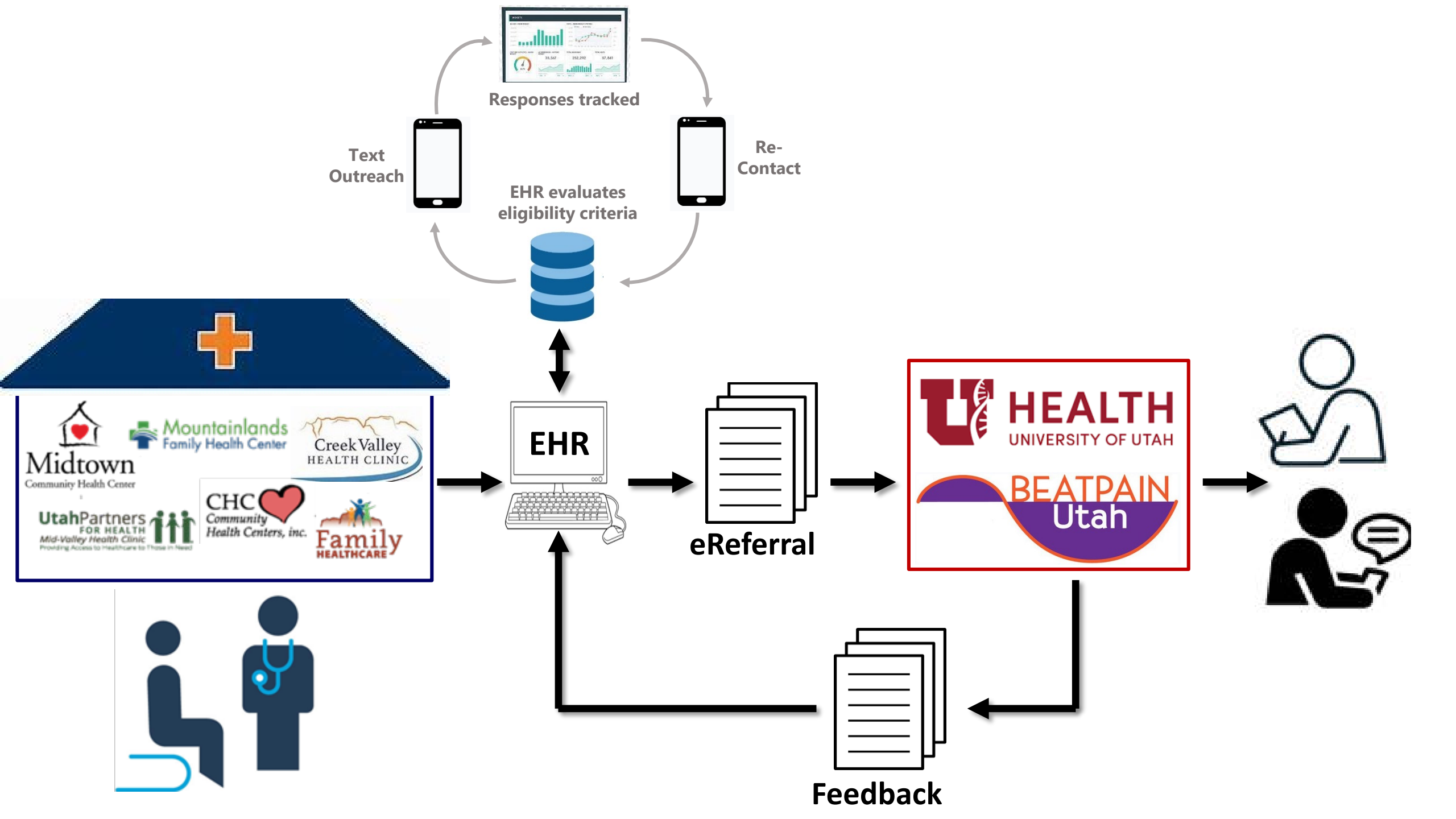
- Research topics reflect priority domains for CHCs
- Bridge capacity

## Health Information Technology as a Foundation

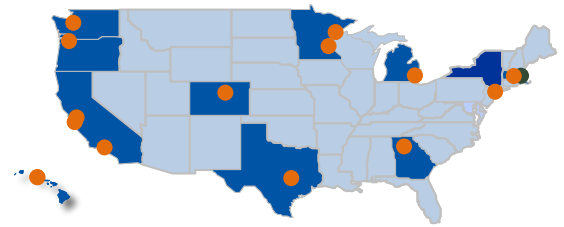
- Work with CHC EHRs and EHR vendors to create solutions that can be immediately disseminated and implemented by other users of those EHRs
- Population Health Management tools to tie CHC systems together to enable identification of patient cohorts and “campaigns” (e.g., texting) to address patient needs

## Utilize Existing Evidence-Based Interventions (EBIs)/Resources

- Linkages for primary prevention utilize existing EBIs (e.g., Tobacco Quitlines, Diabetes Prevention Programs)
- Linkages for screening/testing/vaccination collaborate with state programs (e.g., colorectal, breast and cervical, COVID, HPV)


Responses tracked
Text Outreach
Re-Contact
EHR evaluates eligibility criteria
Midtown Community Health Center
Mountainlands Family Health Center
Creek Valley HEALTH CLINIC
UtahPartners FOR HEALTH Mid-Valley Health Clinic
CHC Community Health Centers, inc.
Family HEALTHCARE
EHR
eReferral
HEALTH UNIVERSITY OF UTAH
BEATPAIN Utah
Feedback

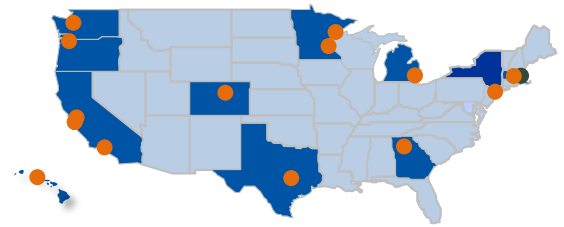
MHRN Mental Health Research Network



# Sustainable Infrastructure for ePCTs: Mental Health Research Network

**Gregory Simon, MD, MPH**
Kaiser Permanente Washington Health Research Institute

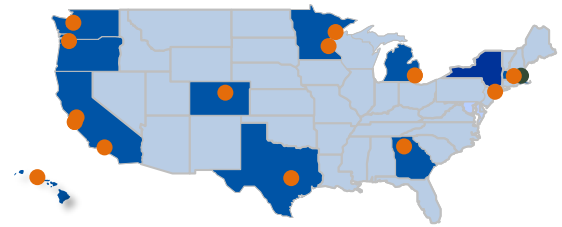
MHRN Mental Health Research Network



# Broad definition of infrastructure

- Physical assets
- Staff to deliver/implement interventions
- Informatics tools and processes
- Regulatory compliance
- Trust and goodwill

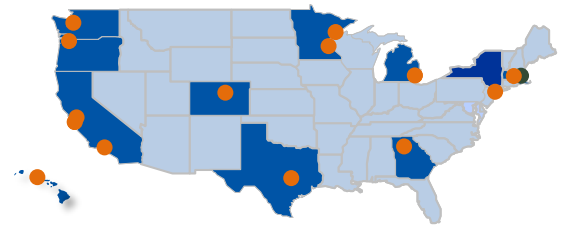
MHRN Mental Health Research Network



# Physical assets

- N/A

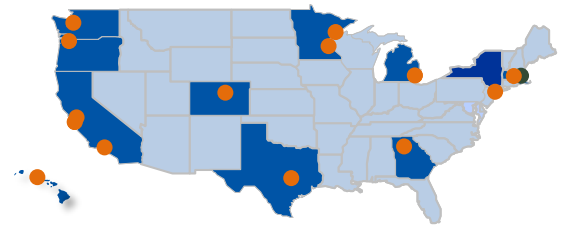
MHRN Mental Health Research Network



# Staff to implement interventions

- Could include:
  - Clinicians providing direct service
  - Practice facilitators supporting implementation
- Sharing across health systems often possible
- Some skills are trial-specific, but many are not
- Variation in requirements for licensing/credentialing

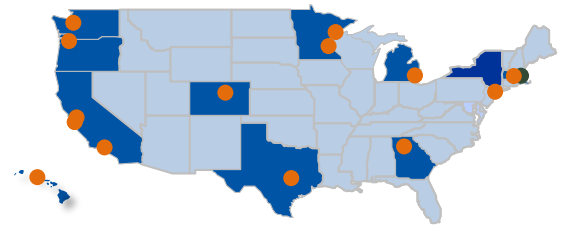
MHRN Mental Health Research Network



# Informatics tools and processes

- Could include:
  - Integrated processes for identifying participants
  - Registry/contact management tools
  - Clinician-facing decision support tools
  - Participant-facing tools for intervention delivery
  - Processes for outcome assessment/ascertainment
- Parts should work together, but still be severable
- Must sometimes design to lowest common denominator
- Be ready to shift from homegrown to EHR-standard tools

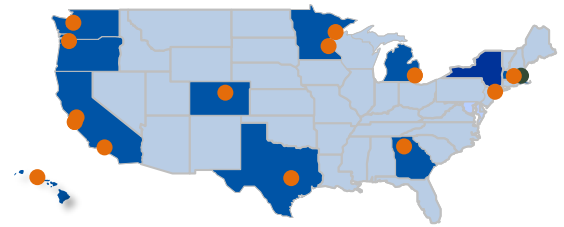
MHRN Mental Health Research Network



# Regulatory compliance

- Established/accepted procedures for:
  - Using records data to identify participants
  - Inviting/enrolling participants
  - Interventions comingled with usual care
  - Safely sharing sensitive data across sites
- Every trial is different, but precedent is powerful
- Be prepared for regulatory changes (e.g. software as medical device guidance)
- More about relationships than rules

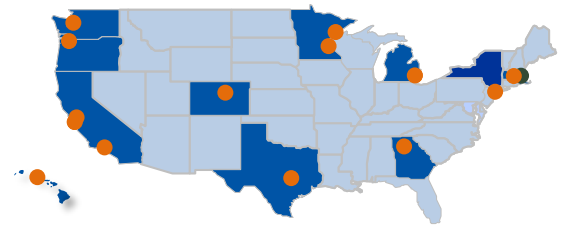
MHRN Mental Health Research Network



# Trust and goodwill

- Involves many stakeholders:
  - Health system leaders
  - Front-line clinical staff
  - Legal and risk management
  - IRBs and privacy offices
- Implementation science constructs are helpful here
- Anecdotes may not be evidence, but they matter a lot!

MHRN Mental Health Research Network



# Use it or lose it?

- Two models for staff delivering interventions:
  - Employed by research center
  - Borrowed from health system roles
- Informatics tools can be patched for a while, but not forever

# Sustainable Infrastructure for ePCTs: PPACT, RESOLVE, and BackInAction

**Lynn DeBar, PhD, MPH**
Kaiser Permanente Center for Health Research

Supported by UH2/UH3NS088731, UG3/UH3AT010739, UG3/UH3AG067493

# Some Select Examples of Sustainable ePCT Infrastructure

- **Informatic Tools**: Building sustainable processes and aligning clinician communication
- Building and sustaining **trust and goodwill** with clinical leaders and frontline clinicians (PPACT)
- **Staff to deliver / implement interventions**: PPACT challenges and RESOLVE course corrections

# Informatic Tools: Building sustainable processes and aligning clinician communication

DeBar et al, Contemporary Clinical Trials, 2018;
DeBar et al, Translational Behavioral Medicine, 2012;
DeBar et al, Annals of Internal Medicine, 2021;
Smith et al, Medical Care, 2022

# PPACT Overview

**AIM:** Integrate interdisciplinary services into primary care to help patients adopt self-management skills to:

- Manage chronic pain (decrease pain severity / improve functioning)
  - Limit use of opioid medication
  - Identify exacerbating factors amenable to treatment

*Focus on feasibility and sustainability*

**DESIGN:** Cluster (PCP)-randomized PCT *(106 clusters, 273 PCPs, 851 patients)*

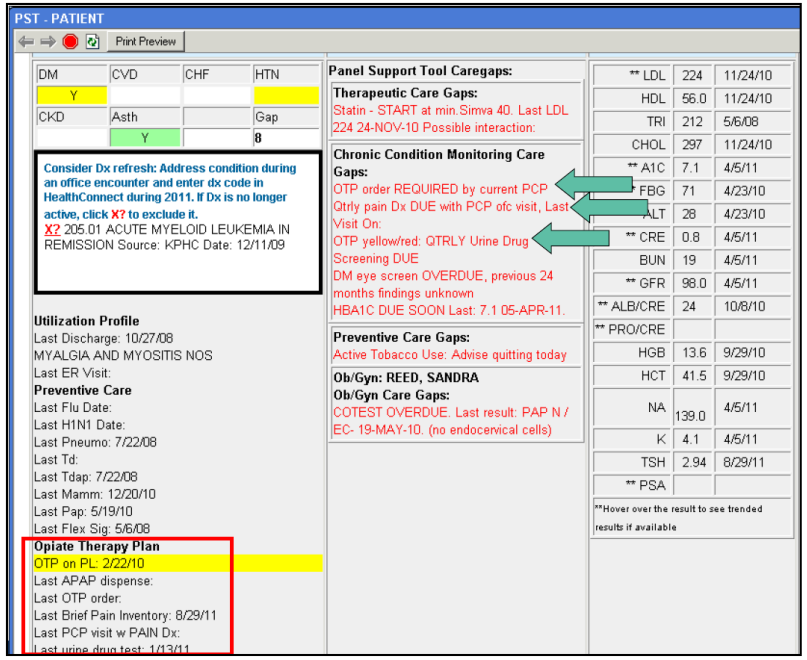
**ELIGIBILITY:** Chronic pain, long-term opioid tx (prioritizing ≥ 120 MED, benzodiazepine co-use, high utilizers [≥ 12 visits in 3 months])

**INTERVENTION:** Behavioral specialist, nurse case manager, PT, and pharmacist team; 12 week core CBT + adapted movement groups

**OUTCOMES: Pain (3-item PEG),** opioid MED, pain-related health services, and cost

# PPACT: What does it take to collect PRO data in routine clinical care?

- Opioid therapy plans required for all patients on long-term opioids and included “regular” BPI administration
- 12-item BPI resisted by clinicians (too long, focused on pain intensity)
- Shifted national KP EHR-embedded standard to PEG(S) (Pain, Enjoyment of Life, General Activity, Sleep)



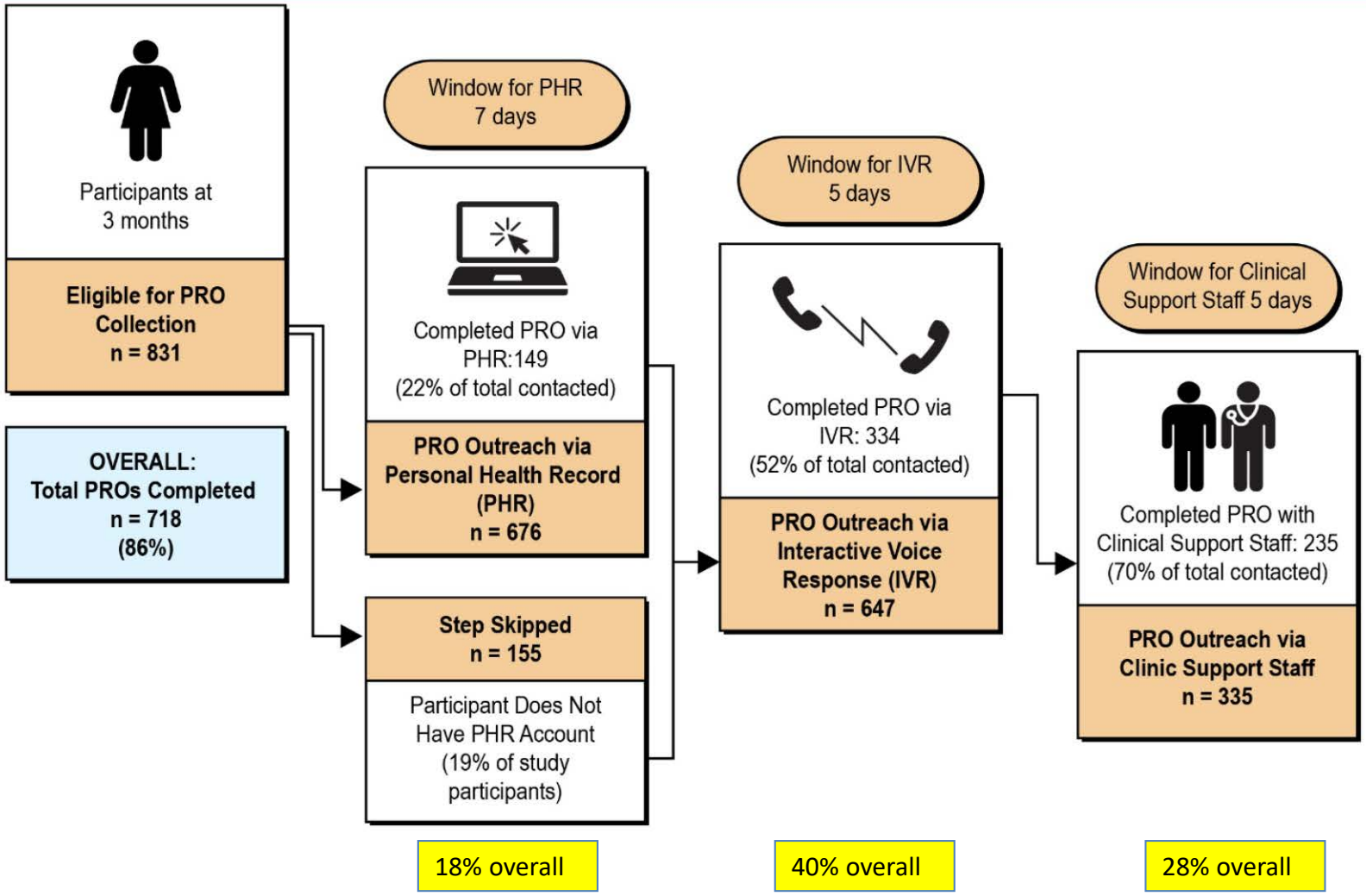

Opioid Therapy Plan (OTP) Operational Criteria

| PATIENT CRITERIA | BASIC GREEN | COMPLEX YELLOW | COMPLEX RED |
|---|---|---|---|
| Follows plan reliably | X | | |
| No history of opioid abuse | X | | |
| No history of other substance abuse within past 2 years | X | | |
| No current behaviors indicating drug misuse | X | | |
| Current behaviors raise questions about the ability to follow the OTP | | X | |
| History of opioid abuse | | X | |
| History of other substance abuse within past 2 years | | X | |
| Calculated overall opioid dosing level at 180mg morphine equivalent or higher | | X | |
| Have demonstrated repeated problems following the OTP (e.g. unexpected UDS) | | | X |
| Active substance abuse | | | X |
| Have current behaviors which raise concerns about possibility of diversion | | | X |

| PCP REQUIREMENTS | BASIC GREEN | COMPLEX YELLOW | COMPLEX RED |
|---|---|---|---|
| Office visit frequency (minimum) | Semi-annually (1 may be TAV) | Quarterly (2 may be TAVs) | Quarterly (no TAVs) |
| Office visit required for any dosing changes | No | Yes | Yes |
| Brief Pain Inventory (BPI) completed (minimum) *[Recommended to be administered at every office visit]* | Semi-annually | Quarterly | Quarterly |
| Refresh pain diagnosis on problem list | Yearly | Yearly | Yearly |
| Verify current dosing level is reflected on OTP on the problem list | Yes | Yes | Yes |
| Discuss with the patient their use of opioid, non-opioid and non-pharmacological modalities to control pain | Each visit | Each visit | Each visit |
| UDS ordered and resulted (minimum) | Yearly | Quarterly | Quarterly |
| Confirm random pill counts completed | PRN | 2x/Year & PRN | 2x/Year & PRN |
| Create AVS or send letter with patient’s dosing and instructions after dosing change | Yes | Yes – AVS only | Yes – AVS only |
| Create separate monthly opioid prescriptions, no refills and no mail order | No | Yes* | Yes |
| Early refills for travel | Yes | Yes | Up to 2/year |
| May refill prescriptions early for lost or stolen reasons (Police report needed before receiving refill of stolen medications) | Yes | Limited supply only | No |
| New OTP required when prescriber changes or OTP color changes | Yes | Yes | Yes |

Panel Support Tool – it takes more than EPIC to prompt administration

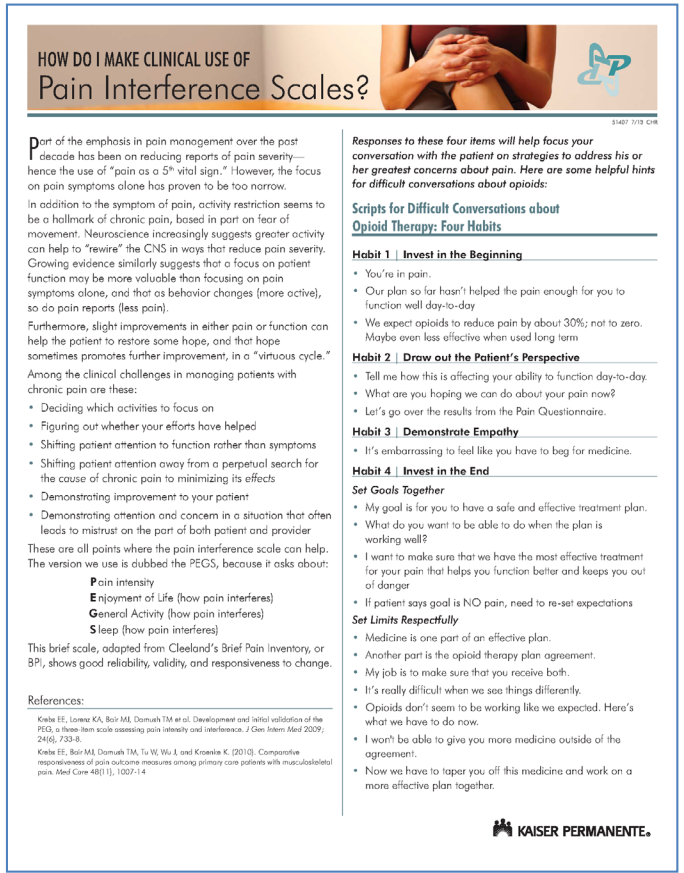
# PPACT: What it might <u>really</u> takes to collect PRO data in routine clinical care




Owen-Smith et al, Journal of General Internal Medicine, 2018

# PPACT & BIA: EHR Embedded PROs/Tx Forms as Clinician Communication Alignment Tool

- PPACT: Moving the focus from pain intensity to functioning
- BackInAction: Opening communication between PCPs and acupuncturists



HOW DO I MAKE CLINICAL USE OF
## Pain Interference Scales?

Part of the emphasis in pain management over the past decade has been on reducing reports of pain severity—hence the use of "pain as a 5th vital sign." However, the focus on pain symptoms alone has proven to be too narrow.

In addition to the symptom of pain, activity restriction seems to be a hallmark of chronic pain, based in part on fear of movement. Neuroscience increasingly suggests greater activity can help to "rewire" the CNS in ways that reduce pain severity. Growing evidence similarly suggests that a focus on patient function may be more valuable than focusing on pain symptoms alone, and that as behavior changes (more active), so do pain reports (less pain).

Furthermore, slight improvements in either pain or function can help the patient to restore some hope, and that hope sometimes promotes further improvement, in a "virtuous cycle."

Among the clinical challenges in managing patients with chronic pain are these:

- Deciding which activities to focus on
- Figuring out whether your efforts have helped
- Shifting patient attention to function rather than symptoms
- Shifting patient attention away from a perpetual search for the cause of chronic pain to minimizing its effects
- Demonstrating improvement to your patient
- Demonstrating attention and concern in a situation that often leads to mistrust on the part of both patient and provider

These are all points where the pain interference scale can help. The version we use is dubbed the PEGS, because it asks about:

**P**ain intensity
**E**njoyment of Life (how pain interferes)
**G**eneral Activity (how pain interferes)
**S**leep (how pain interferes)

This brief scale, adapted from Cleeland's Brief Pain Inventory, or BPI, shows good reliability, validity, and responsiveness to change.

References:


Krebs EE, Lorenz KA, Bair MJ, Damush TM et al. Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. *J Gen Intern Med* 2009; 24(6), 733-8.

Krebs EE, Bair MJ, Damush TM, Tu W, Wu J, and Kroenke K. (2010). Comparative responsiveness of pain outcome measures among primary care patients with musculoskeletal pain. *Med Care* 48(11), 1007-14


*Responses to these four items will help focus your conversation with the patient on strategies to address his or her greatest concerns about pain. Here are some helpful hints for difficult conversations about opioids:*

### Scripts for Difficult Conversations about Opioid Therapy: Four Habits

**Habit 1 | Invest in the Beginning**

- You're in pain.
- Our plan so far hasn't helped the pain enough for you to function well day-to-day
- We expect opioids to reduce pain by about 30%; not to zero. Maybe even less effective when used long term

**Habit 2 | Draw out the Patient's Perspective**

- Tell me how this is affecting your ability to function day-to-day.
- What are you hoping we can do about your pain now?
- Let's go over the results from the Pain Questionnaire.

**Habit 3 | Demonstrate Empathy**

- It's embarrassing to feel like you have to beg for medicine.

**Habit 4 | Invest in the End**

*Set Goals Together*

- My goal is for you to have a safe and effective treatment plan.
- What do you want to be able to do when the plan is working well?
- I want to make sure that we have the most effective treatment for your pain that helps you function better and keeps you out of danger
- If patient says goal is NO pain, need to re-set expectations

*Set Limits Respectfully*

- Medicine is one part of an effective plan.
- Another part is the opioid therapy plan agreement.
- My job is to make sure that you receive both.
- It's really difficult when we see things differently.
- Opioids don't seem to be working like we expected. Here's what we have to do now.
- I won't be able to give you more medicine outside of the agreement.
- Now we have to taper you off this medicine and work on a more effective plan together.

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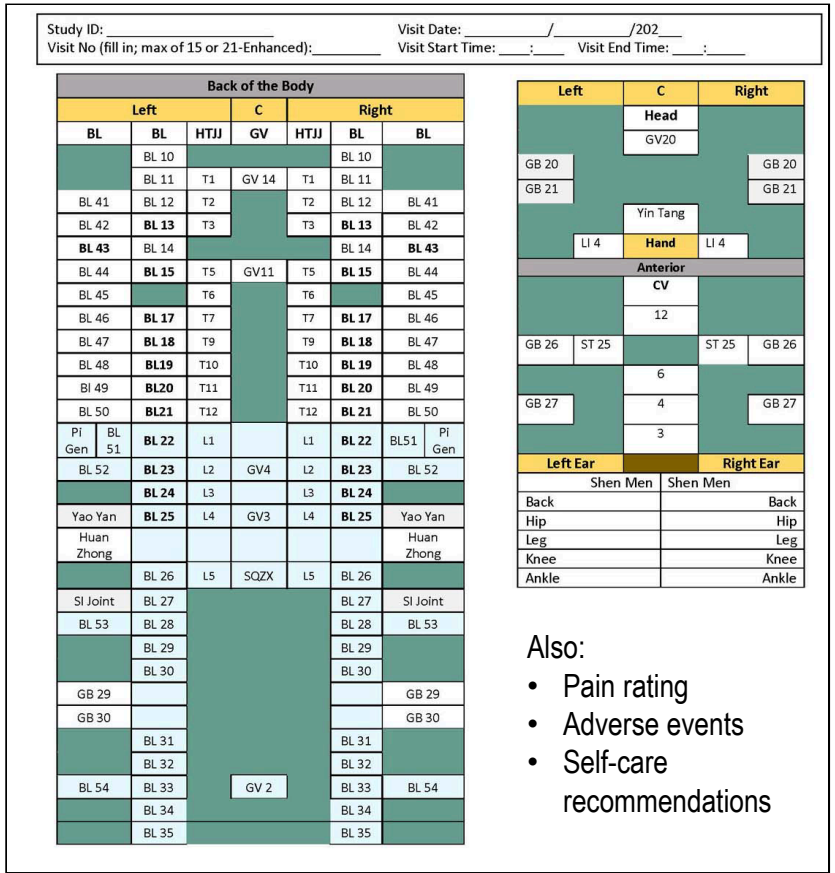

Study ID: _____ Visit Date: _____/_____/202___
Visit No (fill in; max of 15 or 21-Enhanced):_____ Visit Start Time: ____:____ Visit End Time: ____:____

**Back of the Body**

| Left | | | C | Right | | |
|---|---|---|---|---|---|---|
| **BL** | **BL** | **HTJJ** | **GV** | **HTJJ** | **BL** | **BL** |
| | BL 10 | | | | BL 10 | |
| | BL 11 | T1 | GV 14 | T1 | BL 11 | |
| BL 41 | BL 12 | T2 | | T2 | BL 12 | BL 41 |
| BL 42 | **BL 13** | T3 | | T3 | **BL 13** | BL 42 |
| **BL 43** | BL 14 | | | | BL 14 | **BL 43** |
| BL 44 | **BL 15** | T5 | GV11 | T5 | **BL 15** | BL 44 |
| BL 45 | | T6 | | T6 | | BL 45 |
| BL 46 | **BL 17** | T7 | | T7 | **BL 17** | BL 46 |
| BL 47 | **BL 18** | T9 | | T9 | **BL 18** | BL 47 |
| BL 48 | **BL19** | T10 | | T10 | **BL 19** | BL 48 |
| Bl 49 | **BL20** | T11 | | T11 | **BL 20** | BL 49 |
| BL 50 | **BL21** | T12 | | T12 | **BL 21** | BL 50 |
| Pi Gen / BL 51 | **BL 22** | L1 | | L1 | **BL 22** | BL51 / Pi Gen |
| BL 52 | **BL 23** | L2 | GV4 | L2 | **BL 23** | BL 52 |
| | **BL 24** | L3 | | L3 | **BL 24** | |
| Yao Yan | **BL 25** | L4 | GV3 | L4 | **BL 25** | Yao Yan |
| Huan Zhong | | | | | | Huan Zhong |
| | BL 26 | L5 | SQZX | L5 | BL 26 | |
| SI Joint | BL 27 | | | | BL 27 | SI Joint |
| BL 53 | BL 28 | | | | BL 28 | BL 53 |
| | BL 29 | | | | BL 29 | |
| | BL 30 | | | | BL 30 | |
| GB 29 | | | | | | GB 29 |
| GB 30 | | | | | | GB 30 |
| | BL 31 | | | | BL 31 | |
| | BL 32 | | | | BL 32 | |
| BL 54 | BL 33 | | GV 2 | | BL 33 | BL 54 |
| | BL 34 | | | | BL 34 | |
| | BL 35 | | | | BL 35 | |

| Left | C | Right |
|---|---|---|
| | Head | |
| | GV20 | |
| GB 20 | | GB 20 |
| GB 21 | | GB 21 |
| | Yin Tang | |
| LI 4 | Hand | LI 4 |
| | Anterior | |
| | CV | |
| | 12 | |
| GB 26 / ST 25 | | ST 25 / GB 26 |
| | 6 | |
| GB 27 | 4 | GB 27 |
| | 3 | |
| Left Ear | | Right Ear |

| Shen Men | Shen Men |
|---|---|
| Back | Back |
| Hip | Hip |
| Leg | Leg |
| Knee | Knee |
| Ankle | Ankle |

Also:

- Pain rating
- Adverse events
- Self-care recommendations

# Building and Sustaining Trust and Goodwill with Clinical Leaders / Frontline Clinicians

# Rethink your process evaluation toolkit & communicate often

**Dealing with the "underbelly" of the timely research question and dynamic leadership**

- Mapping (organizational relationships, processes) – done repeatedly
- Weekly journaling by intervention staff to inform needed refinements/communication
- "Postcards" to inform clinical partners and prompt dialogue
- Using "FACT CONGRUENT STORIES"
- Rapid Assessment approach
- Along with more traditional qualitative techniques (and well integrated key clinical representative engagement efforts)

# Staff to deliver / implement interventions: PPACT challenges and RESOLVE course correction

# PPACT's Embedded Intervention Staffing: The trials and tribulations….

**PPACT INTERVENTIONISTS:** Behavioral specialist, nurse case manager, PT, and pharmacist team staffed primarily from frontline clinicians in participating healthcare systems (per HCS request)

Challenges:

- Identifying qualified staff with available FTE in designated PC clinics / PT practice scope limits
- Re-assignment of designated staff time (trained PPACT skills valued!)

## Post PPACT Sustained Programming:

**KPNW (and WA) – Uptake of shorter variant**

- 4 sessions delivered by primary care-integrated behavioral health providers
- Challenge: Adequate therapist training / support

**KP Hawaii – Malama Ola adaptation**

- 6-week variant with whole health / wellness focus housed in Integrated Physical Rehabilitation Dept. (nurse led)

**KP Georgia – No direct uptake**

- Regional focus on restructuring at study conclusion


*Broad psychoeducation approaches with brief / limited contacts are common*

# Benefits of pivoting to a centralized intervention staffing "contracted service" consistent model

RESOLVE

HEAL NIA-funded PCT comparing 2 telehealth CBT interventions among 2,333 (50% rural) with high impact chronic pain

*Staff centralization, for whom does live touch matter?*

- What it solves for:
  - Reducing patient participation barriers
  - Identifying and retaining qualified interventionists
  - Discouraging intervention drift / obtaining better fidelity to treatment

- Other realized benefits:
  - Unanticipated outsized benefits for staff morale and mutual support for rigorous delivery of pain intervention
  - Less patient/participant focus on pain-related medical care (e.g., medication, interventions) and more engagement with behavioral skills training

**Sustainable in theory BUT not current pathway to do so among participating HCSs**

# Questions