

Building and Sustaining Reusable Infrastructure for ePCTs

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Panelists

- Julie Fritz, PhD, PT
 - Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics (BeatPain Utah)
- 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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Nonpharmacologic Pain Management in Federally Qualified Health Center Primary Care Clinics

Building and Sustaining Reusable Infrastructure for ePCTs

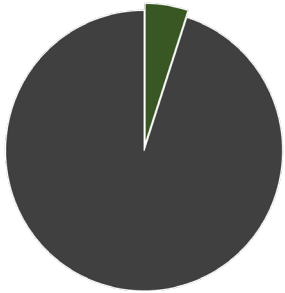
Julie Fritz, PT, PhD
University of Utah

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

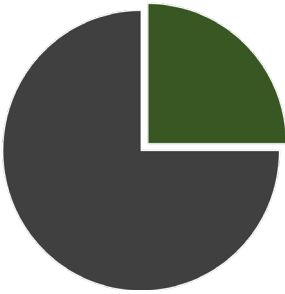
NIH
HEAL
INITIATIVE



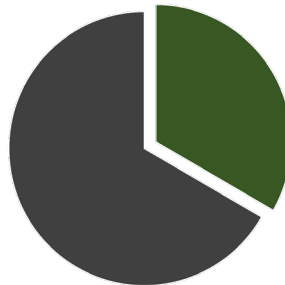
14 Utah health centers operate 60 clinics and provide care to more than 167,000 people annually



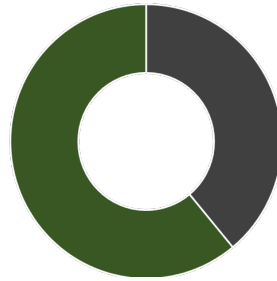
1 of every 20 Utahns



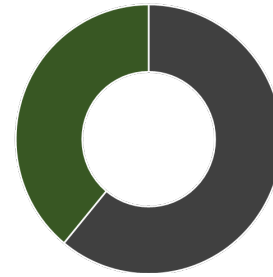
1 of every 4 uninsured Utahns



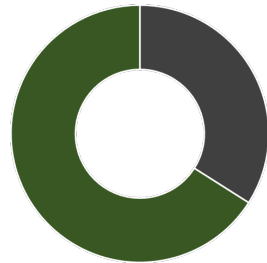
1 of every 3 Utahns living in poverty



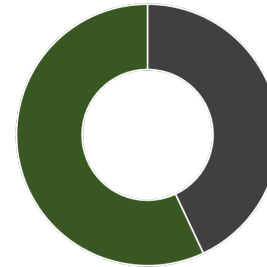
61% identity as a racial or ethnic minority



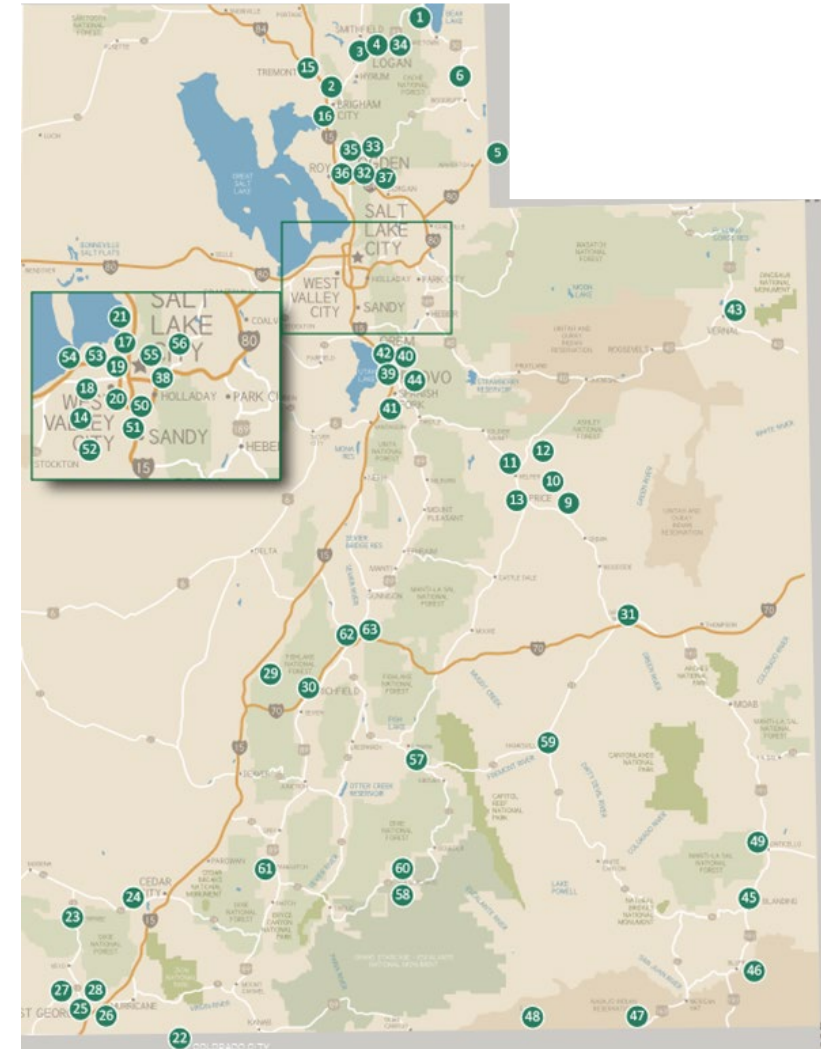
37% communicate in a language other than English



66% at or below the Federal poverty level



57% of clinics located in rural/frontier counties

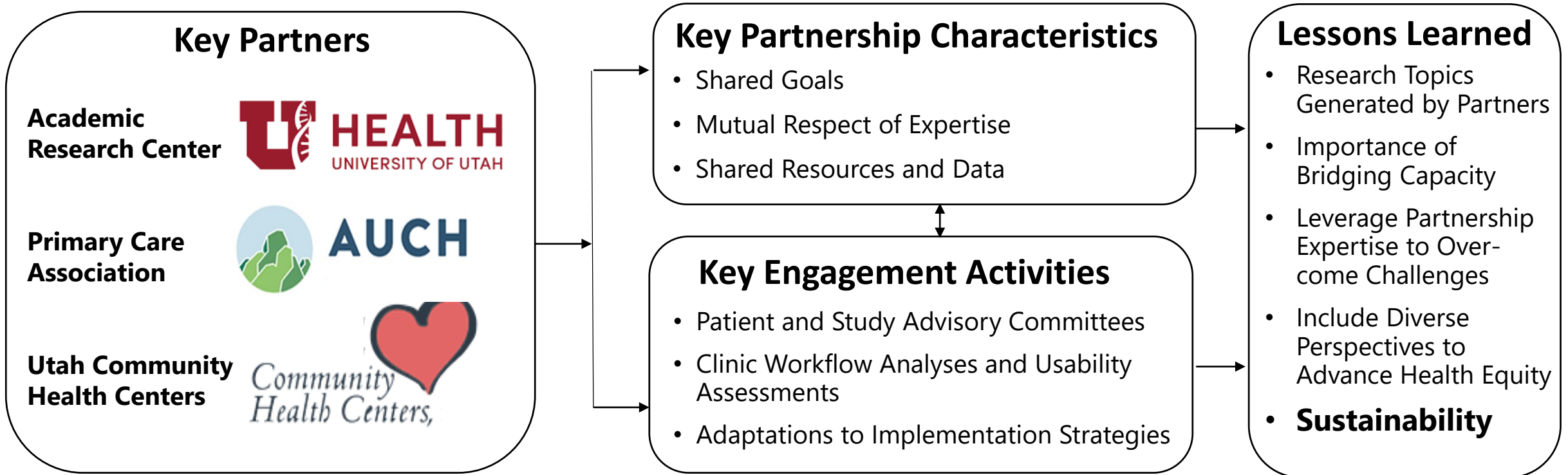


CENTER FOR HOPE

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.



Designing for Sustainability

Consistent Partnership Model

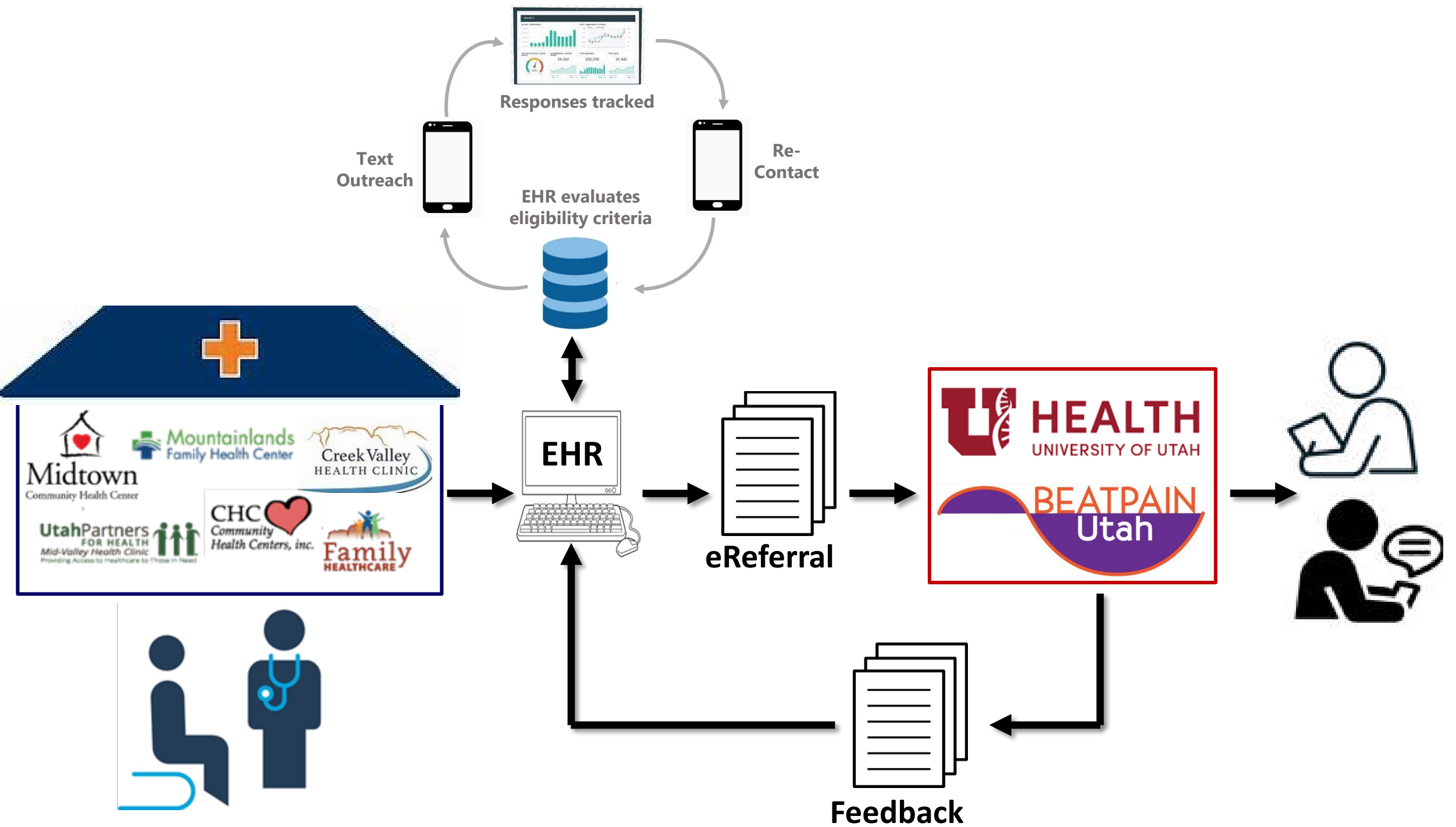
- Research topics reflect priority domains for CHCs
- Bridge capacity

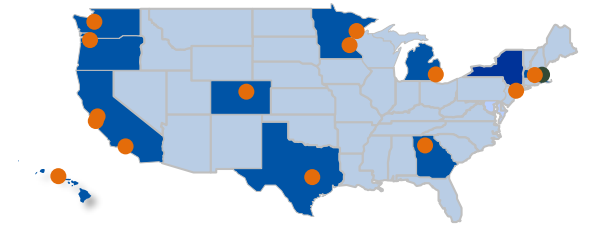
Health Information Technology as a Foundation

- 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)

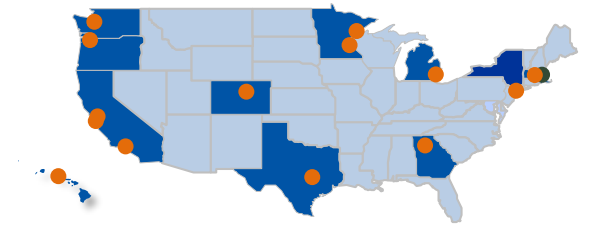




Sustainable Infrastructure for ePCTs: Mental Health Research Network

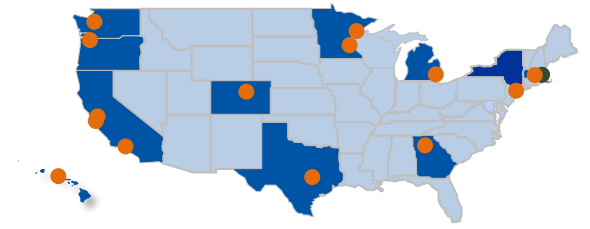
Gregory Simon, MD, MPH

Kaiser Permanente Washington Health Research Institute



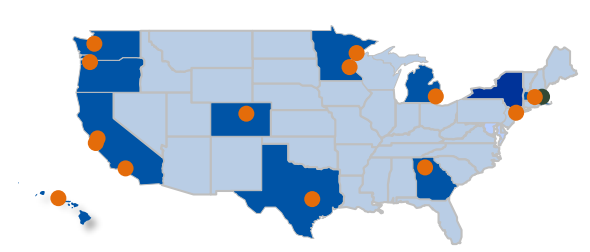
Broad definition of infrastructure

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



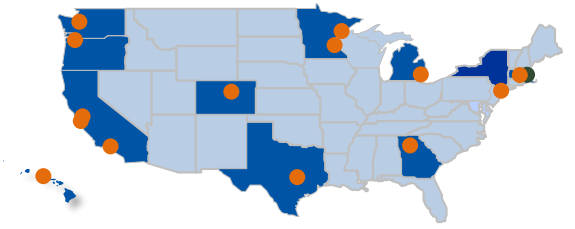
Physical assets

- N/A



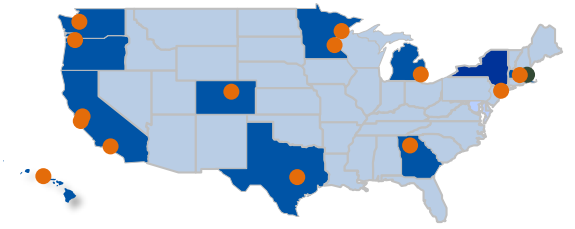
Staff to implement interventions

- 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



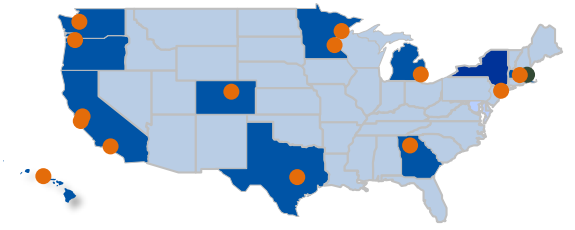
Informatics tools and processes

- 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



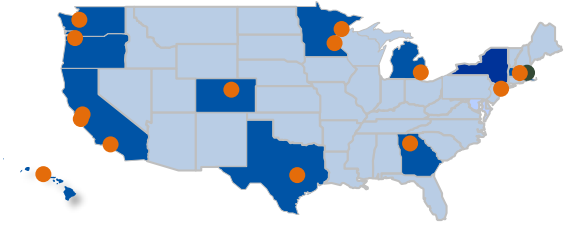
Regulatory compliance

- 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



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!



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

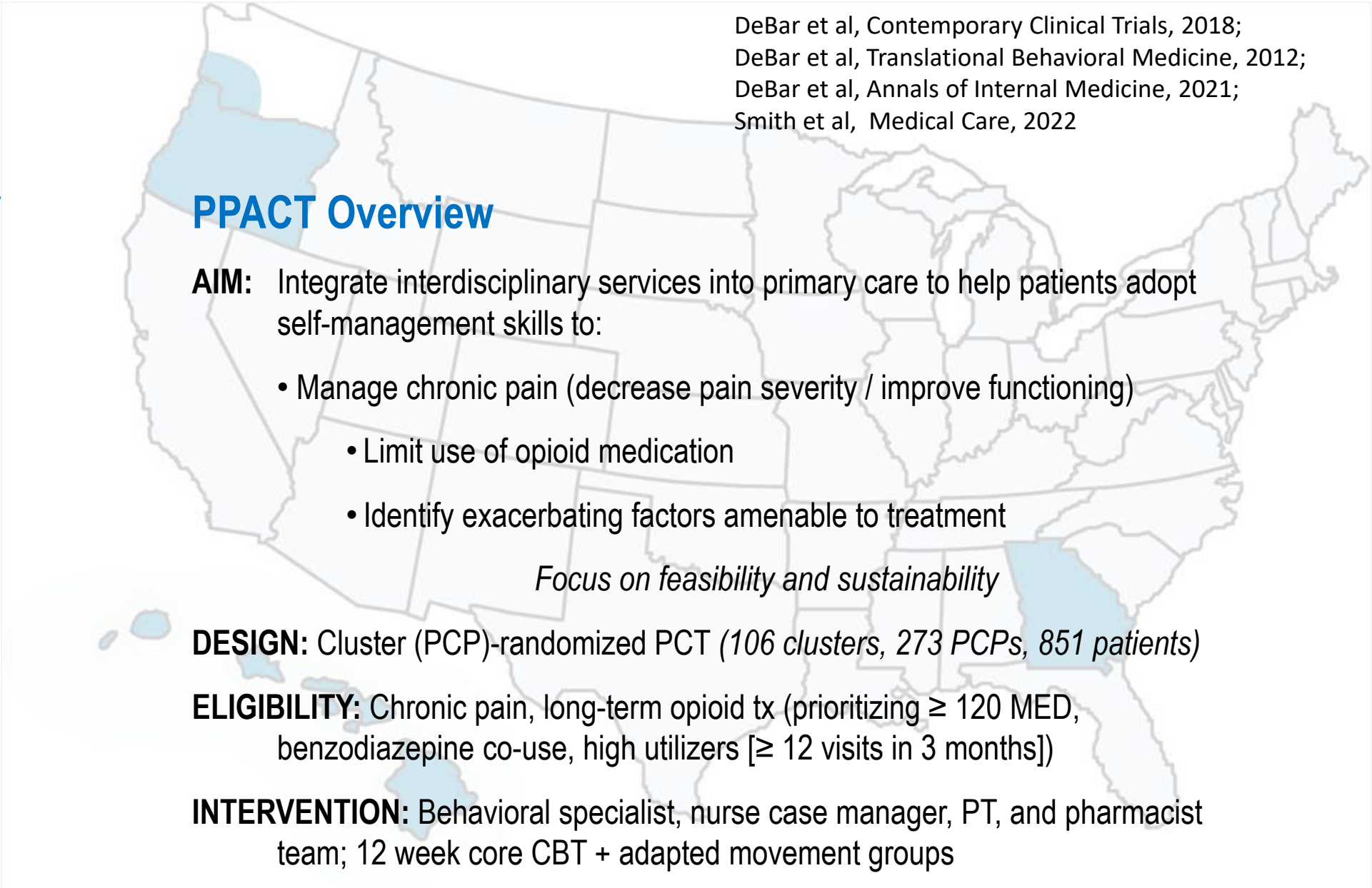
Kaiser Permanente Center for Health Research

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

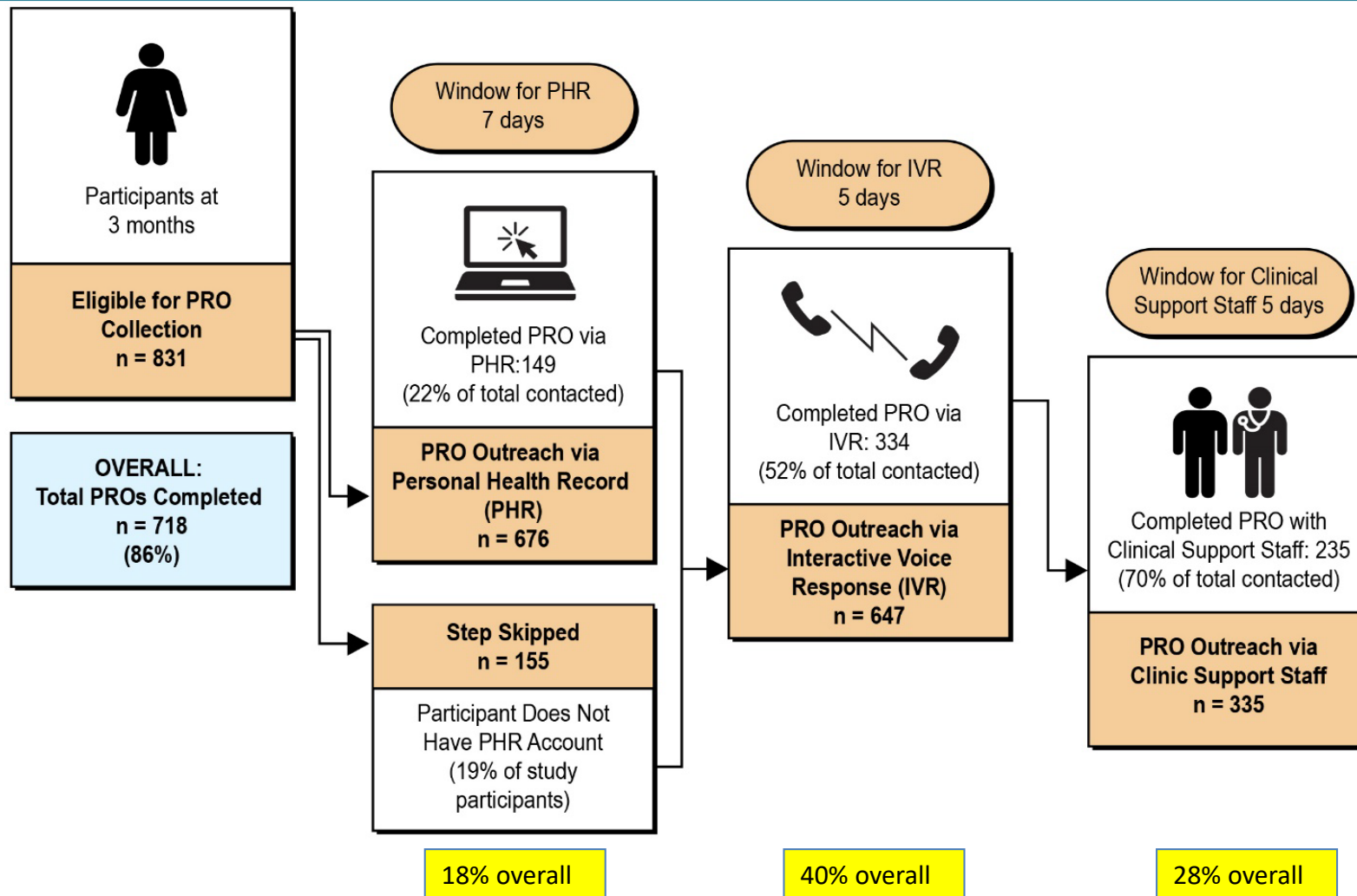
PPACT: What does it take to collect PRO data in routine clinical care?

- 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	BASIC GREEN	COMPLEX YELLOW	COMPLEX RED
PATIENT CRITERIA			
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			
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) <i>[Recommended to be administered at every office visit]</i>	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 really takes to collect PRO data in routine clinical care



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, Lamer KA, Bair MJ, Damush TM et al. Development and initial validation of the PEGS, 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. (2013). Comparative responsiveness of pain outcome measures among primary care patients with musculoskeletal pain. *Med Care* 48(11): 1027-14

KAISER PERMANENTE.

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	GV	BL	BL	BL	BL	HTJJ	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	BL 19	T10		T10		BL 19	BL 48				
BL 49	BL 20	T11		T11		BL 20	BL 49				
BL 50	BL 21	T12		T12		BL 21	BL 50				
Pi Gen	BL 22	L1		L1		BL 22	BL 51	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										
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
	6	
GB 27		GB 27
	4	
	3	
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)

PPACT STUDY – Weekly Implementation Journal

Date: _____ Name: _____

Please include anything you think might help us understand barriers and facilitators to PPACT implementation.

Reminders:

- Goal is to reveal the stories and ongoing processes of implementation.
- Please be specific and include details (how, who, what & when) whenever possible.
- Note the feedback source (i.e. nurse, clinic administrator, clinician, etc).
- Use square brackets when sharing your insights and interpretations
- Use quotation marks for verbatim quotes.

Potential topics for your feedback log:

- ✓ Implementation (day-to-day logistics)
- ✓ Stakeholder engagement
- ✓ Communication (formal and informal)
- ✓ Tools (BPI, Intervention materials, scheduling tools)

Journal entry:

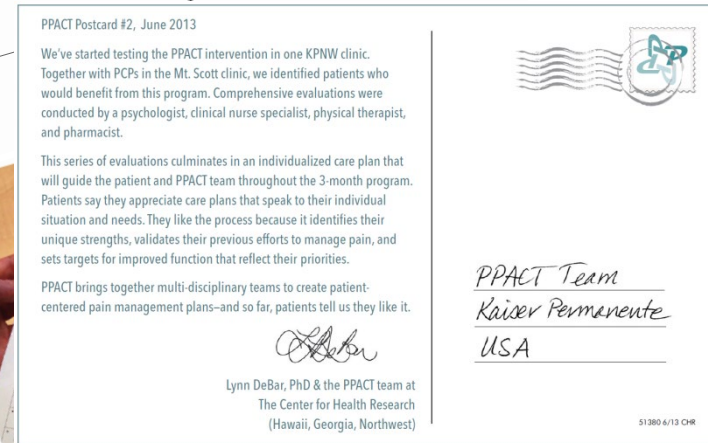
- ✓ Surprises, challenges, solutions
- ✓ Unresolved or ongoing issues
- ✓ Other feedback that you think is relevant



We listen
to patients' perspectives on pain.



Together, we plan
for 3 months of active coping & training.



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