Lessons Learned about Embedding Complex Pragmatic Trials in Delivery Systems: Collaborative Care for Chronic Pain

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PPACT Study Design & Rationale
Leading Diseases and Injuries Contributing to Years Lived with Disability (YLD) in U.S.

- **9.7 YLDs**: Low back pain #1, Musculoskeletal disorders #3, Neck pain #4, Osteoarthritis #9, Migraine #14
- **8.8 YLDs**: COPD #6, Diabetes #8, Asthma #10, Dementia #12, Alcoholism #13, Ischemic heart disease #16, Stroke #17
- **6 YLDs**: Hearing loss #19, Chronic kidney disease #22, Road injury #26, Vision loss #27, Epilepsy #30, Major depressive disorder #2, Anxiety disorders #5

What motivated the PPACT study: an “ask” from clinical and health plan leadership...

How do we keep our primary care providers from burning out and leaving the health care system?

What do we do with the patients with complex pain who “belong to everyone and no one?”
Pain Management in Usual Care

Interdisciplinary Pain Management Embedded in Primary Care

- Behavioral Health Coach: Goal setting & Lifestyle Changes
- Nurse: Care Coordination
- Pharmacist: Medication Review
- Physical Therapist: Improved Movement

Primary Care

- Addiction Medicine
- Social Work
- PT / OT
- Case Management
- Sleep Clinic
- Psychiatry
- Pharmacy
- Neurology / Neurosurgery
- Chiropractic Services
- Acupuncture
- Primary Care
- Pain Clinic
- Hospital
- Membership Services
- Rheumatology
- Occupational Medicine
- Emergency Department

Patient
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

DeBar et al, Contemporary Clinical Trials, 2018; DeBar et al, Translational Behavioral Medicine, 2012
1st Lesson Learned: Pragmatic for some kinds of trials may not mean a “fully inflated tire” for PRECIS-2 (and other design learnings)
Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory

Karin E. Johnson, Gila Neta, Laura M. Dember, Gloria D. Coronado, Jerry Suls, David A. Chambers, Sean Rundell, David H. Smith, Bermei Liu, Stephen Taplin, Catherine M. Stoney, Margaret M. Farrell and Russell E. Glasgow

**ABATE Infection**

- Eligibility
- Recruitment
- Setting
- Organization
- Adherence
- Delivery

**PPACT**

- Eligibility
- Recruitment
- Setting
- Organization
- Adherence
- Delivery

**LIRE**

- Eligibility
- Recruitment
- Setting
- Organization
- Adherence
- Delivery

**STOP CRC**

- Eligibility
- Recruitment
- Setting
- Organization
- Adherence
- Delivery

**TiME**

- Eligibility
- Recruitment
- Setting
- Organization
- Adherence
- Delivery

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**Fig. 1** PRECIS wheels as assessed by raters for each of the five trials at two time points. Ratings on a 1–5 scale are more pragmatic ratings. The dashed line indicates the planning phase. The solid line indicates the implementation phase.

**Figure 3.** PPACT PRECIS-2 Scoring

- **5.0** Primary Analysis
- **4.0** Eligibility
- **3.4** Follow-Up
- **3.0** Flexibility (Adherence)
- **2.9** Recruitment
- **4.7** Setting
- **3.4** Organization
- **3.6** Flexibility (Delivery)
Utilize Telehealth Variants of Behavioral Interventions

National Institute of Aging HEAL funded Project involving >2,000 patients targeting medically underserved and rural communities
Increasing Scalability and Sustainability

1. Centralization & Automation: \(\uparrow\) clinics/site coverage by fewer well-trained providers; delegate more workload to “machines”

2. Diversification: \(\uparrow\) the number of conditions covered by a care / intervention program (avoid “single condition” programs / care managers)

3. Strategic Care Delivery: Lowest [provider] rung that works, stay at home as much as possible, stratification; tailored and treat to target

Adapted from Kurt Kroenke
2\textsuperscript{nd} Lesson Learned: For chronic pain, mind body split still deeply embedded in “behavior” of health care systems
• Low uptake of behaviorally focused interventions
• Substantial patient and provider (chronic pain-related) stigma
• Compelling patient values not addressed / role models not visible
• Weak inoculations of nondrug/device treatment common
Connecting Patients with Behavioral Skills Training on the Front End

**First Line Recommendations / Active Approaches**

**Develop & Improve Pain Management Skills**
- Understanding pain
- Activity/rest cycling (building activity tolerance)
- Relaxation skills (progressive muscle relaxation, body scan, guided imagery, & biofeedback)
- Pleasant activity scheduling
- Attentional awareness & distraction techniques
- Challenging distorted thinking & calming self-statements
- Managing your moods
- Pain Psychology Therapies: Cognitive Behavioral Therapy, Mindfulness Based Stress Reduction, & Acceptance and Commitment Therapy

**Movement & Body Awareness Strategies**
- Physical therapy
- Regular physical activity (e.g., walking, water exercise, gardening, etc.)
- Mind/body practices (e.g., yoga, tai chi, etc.)
  - Ergonomics/body movement awareness (i.e., biodynamics)
  - Assistive devices and environmental accommodations

**Restricted Activity & Avoidance**

**Pain Amplifiers**
- Sleep problems
- Stress, anxiety, depression
- Unhealthy eating and weight
- Drug, alcohol, and tobacco use

**Integrative Health Practices**
- Massage
- Acupuncture
- Chiropractic and Osteopathic care (spinal manipulation)

**Pain Causes**
- Disease
- Accident or injury
- Nervous system sensitivity

**Second Line Treatment / Passive Approaches**

**Common Conventional Medical Treatment Options**
- Pain medications & topical products*
- Injections*
- Surgery*
- TENS Unit
- Heat & ice

* Limited effect on long term functioning use judiciously. Higher risk, limited benefit, less evidence it helps patients long term.

**Beyond Pain**

Reversing the Persistent Pain Cycle

Let's Get Started
[FACT CONGRUENT]

STORIES

REDUCING STIGMA AND INCREASING HOPE:
live or virtual contact with others with lived experience
(patients and providers)
3rd Lesson Learned:
The one predictable constant is change
(the ugly underbelly of the timely clinical question)
If we knew then what we know now… the one predictable constant is change

• A sense of clinical urgency can lead to quick and sometimes unstable program shifts to which you may need to adapt

• Difference between “good” and “bad” contextual features can be a matter of timing (e.g., PCMH, behavioral health integration)

• Stakeholder engagement is a continuous and intensive activity, requires two-way communication, and needs to be both top down and bottom up
Advice?... know what you are stepping into

- Local champions / surveillance invaluable

- Challenging the status quo requires persistent and vertical health care system partnership

- Rethink your process evaluation toolkit
Consider health care organizations as complex adapted systems?

- **Interconnected** – entangled components and systems that differ in “responsivity” to change

- **Nonlinear** – complex chain of cause and effect loops → output not proportional to input

- **Dynamic** – always adjusting to internal or external perturbations (and system history can’t be ignored)

  Difficult to reliably predict “behavior” of the system...BUT Unique change opportunities: look for leverage points, turn small changes into big effects and don’t assume large efforts lead to major impacts
Unique Benefits of the Collaboratory

• Very supportive group of investigators, CoC, and NIH personnel candid about challenges

• Great sounding board for helping one to construct most rigorous and interpretable trial possible

• Unique learnings from building partnerships with those in very different science domains