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

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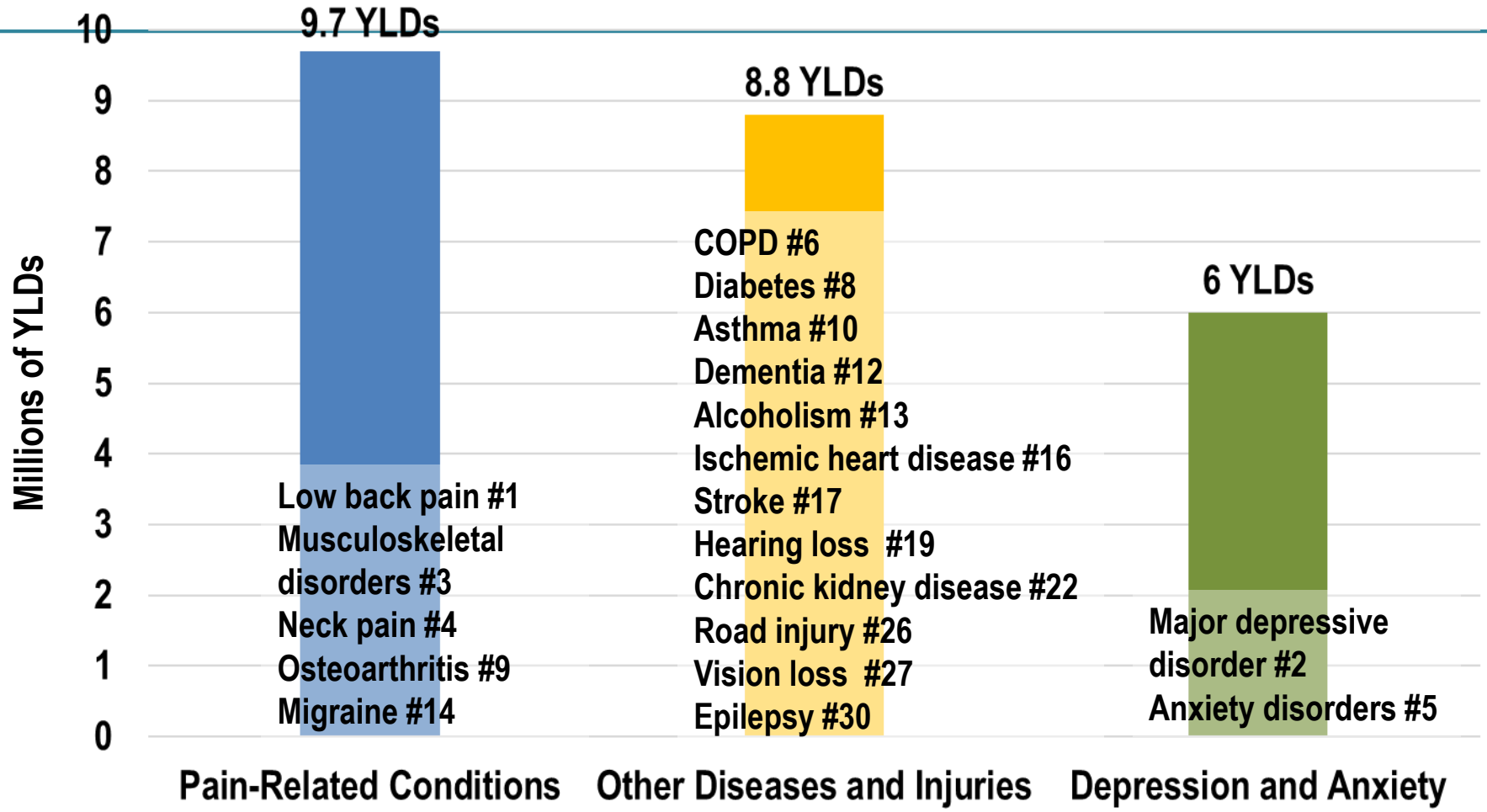
PPACT Study Design & Rationale

Leading Diseases and Injuries Contributing to Years Lived with Disability (YLD) in U.S.



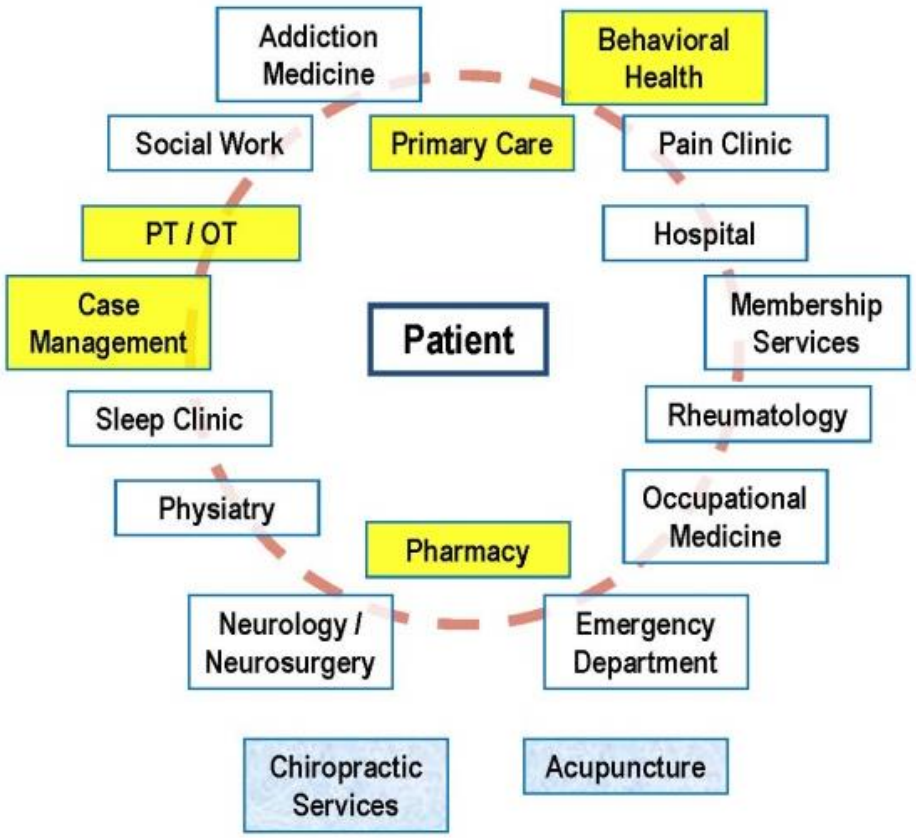
Source: U.S. Burden of Disease Collaborators. The state of US health, 1990-2010: burden of diseases, injuries, and risk factors. *JAMA.* 2013 Aug 14;310(6):591-608.

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

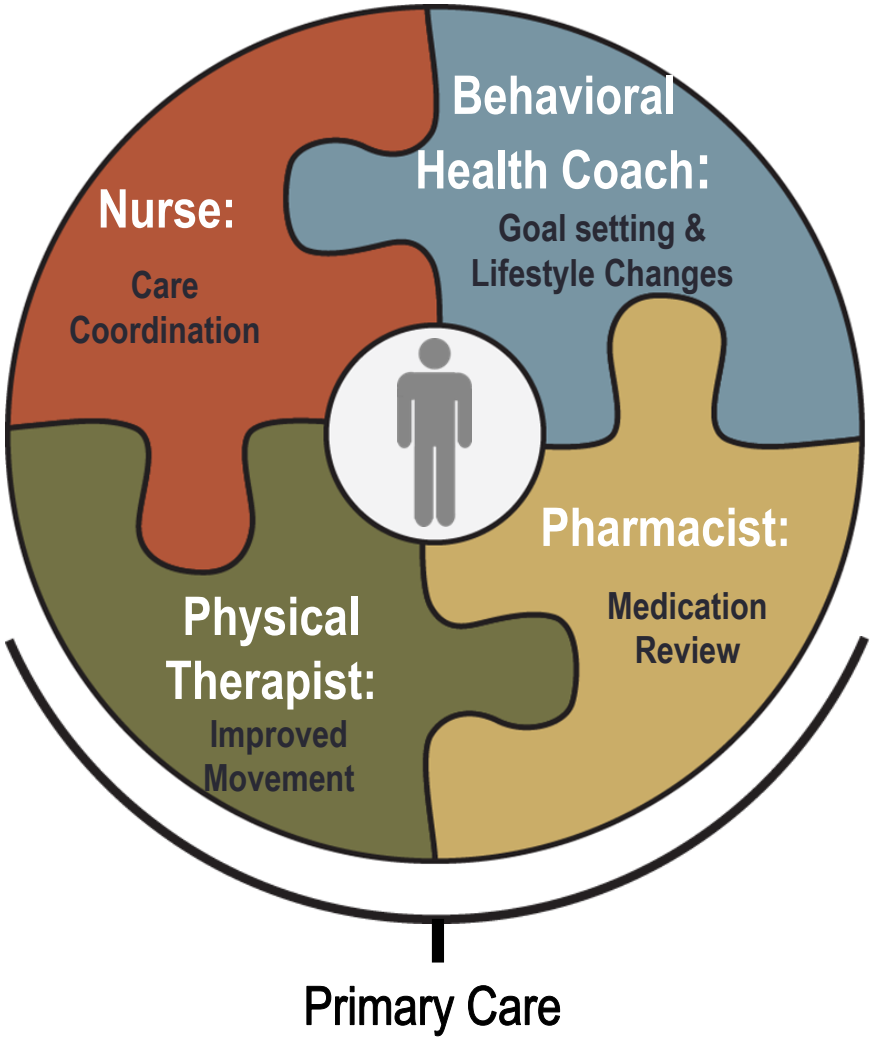
How do we keep our primary care providers from burning out and leaving the health care system?

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



DeBar et al, Contemporary Clinical Trials, 2018;
DeBar et al, Translational Behavioral Medicine, 2012

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

1st Lesson Learned: Pragmatic for some kinds of trials may not mean a “fully inflated tire” for PRECIS-2

(and other design learnings)

RESEARCH Open Access

Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory

Trials

Karin E. Johnson[1†], Gila Neta[2*†], Laura M. Dember[3], Gloria D. Coronado[4], Jerry Suls[2], David A. Chambers[2], Sean Rundell[5], David H. Smith[4], Benmei Liu[2], Stephen Taplin[2], Catherine M. Stoney[6], Margaret M. Farrell[2] and Russell E. Glasgow[7]

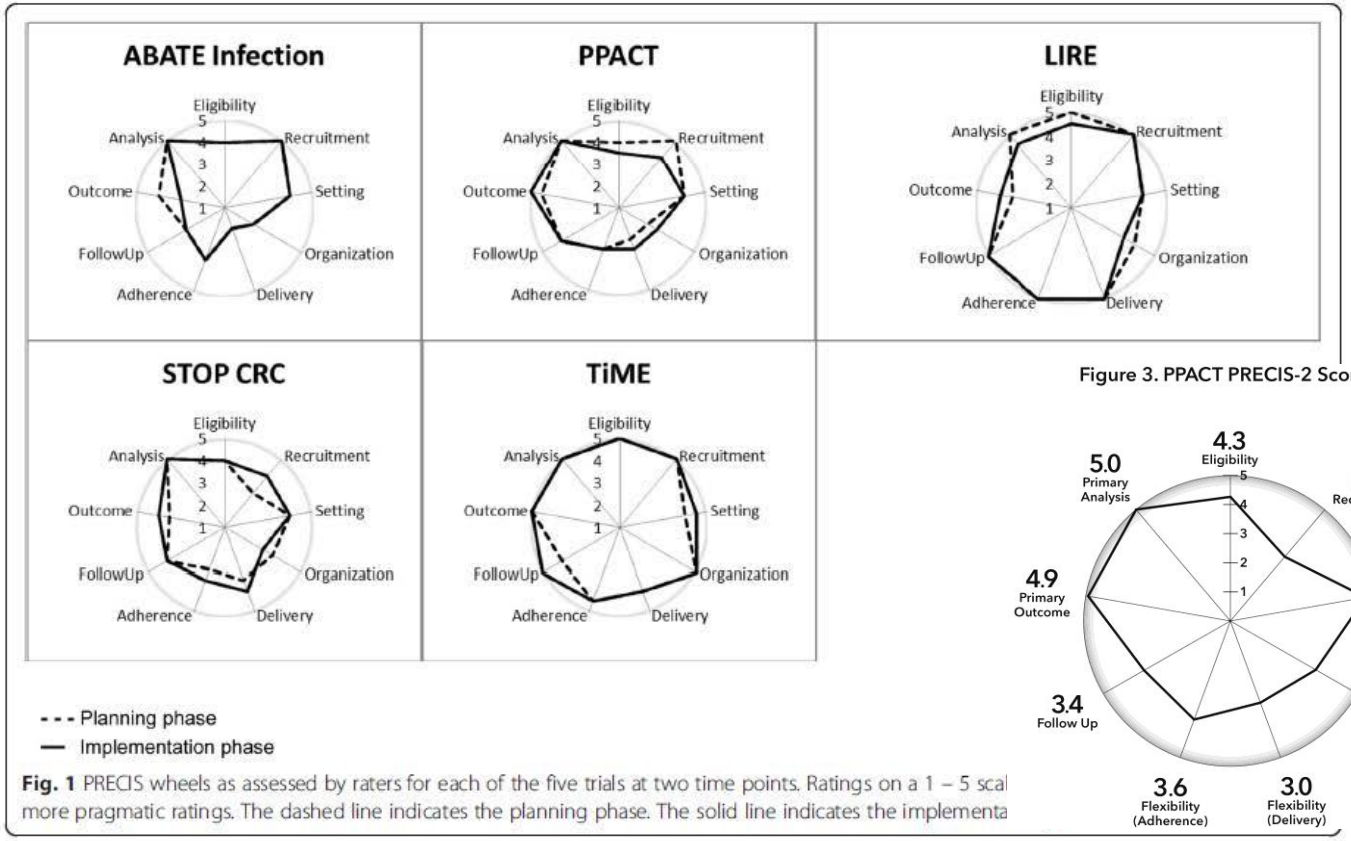
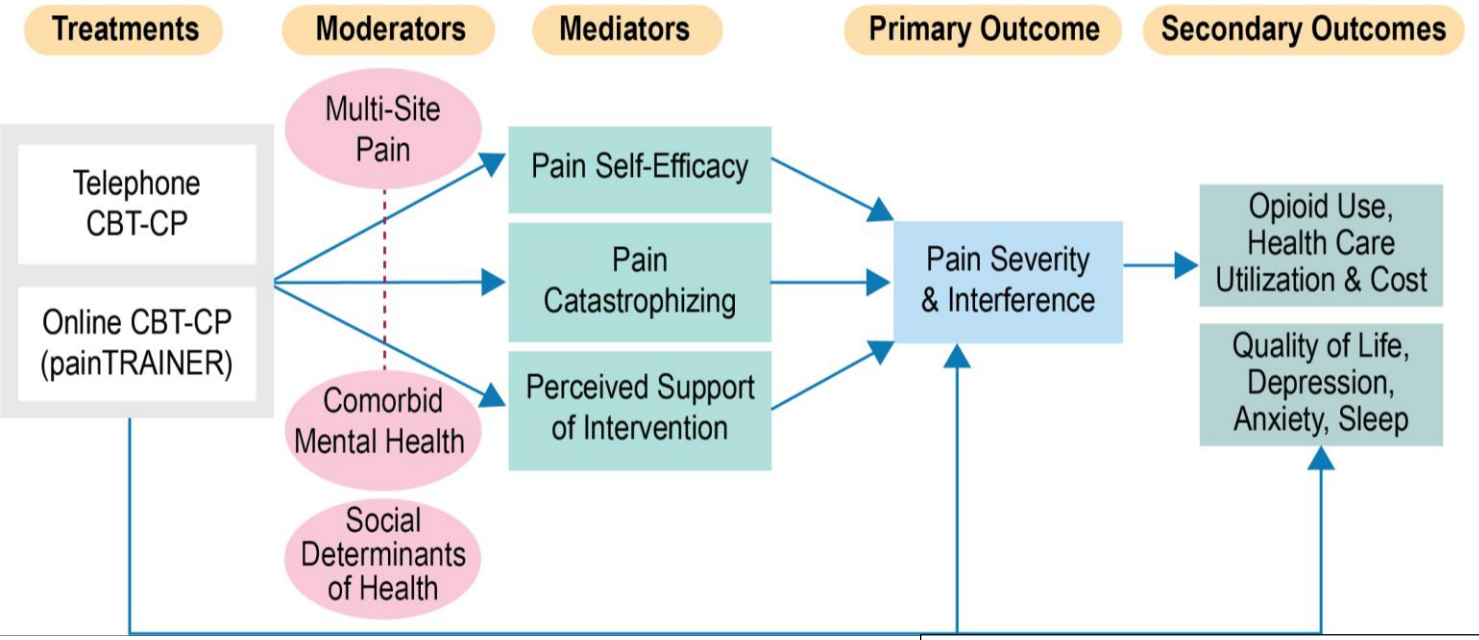


Fig. 1 PRECIS wheels as assessed by raters for each of the five trials at two time points. Ratings on a 1 – 5 scal more pragmatic ratings. The dashed line indicates the planning phase. The solid line indicates the implementa

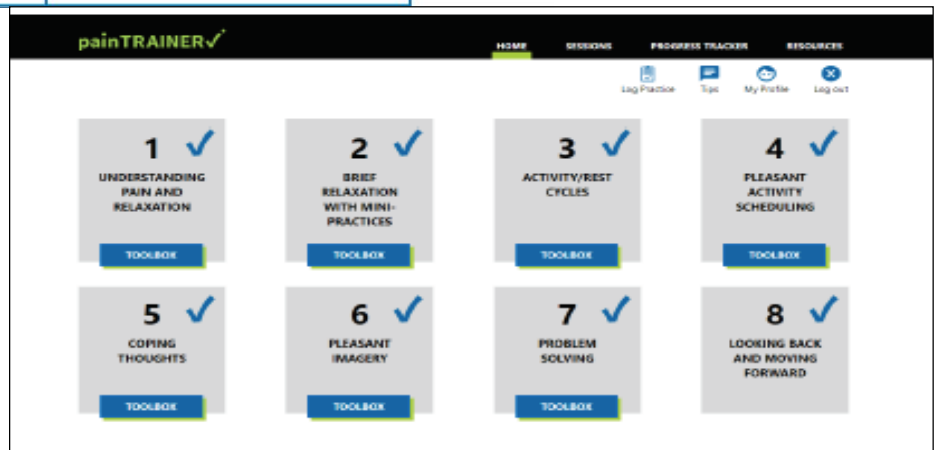
Figure 3. PPACT PRECIS-2 Scoring

Johnson *et al. Trials* (2016) 17:32
DOI 10.1186/s13063-016-1158-y

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

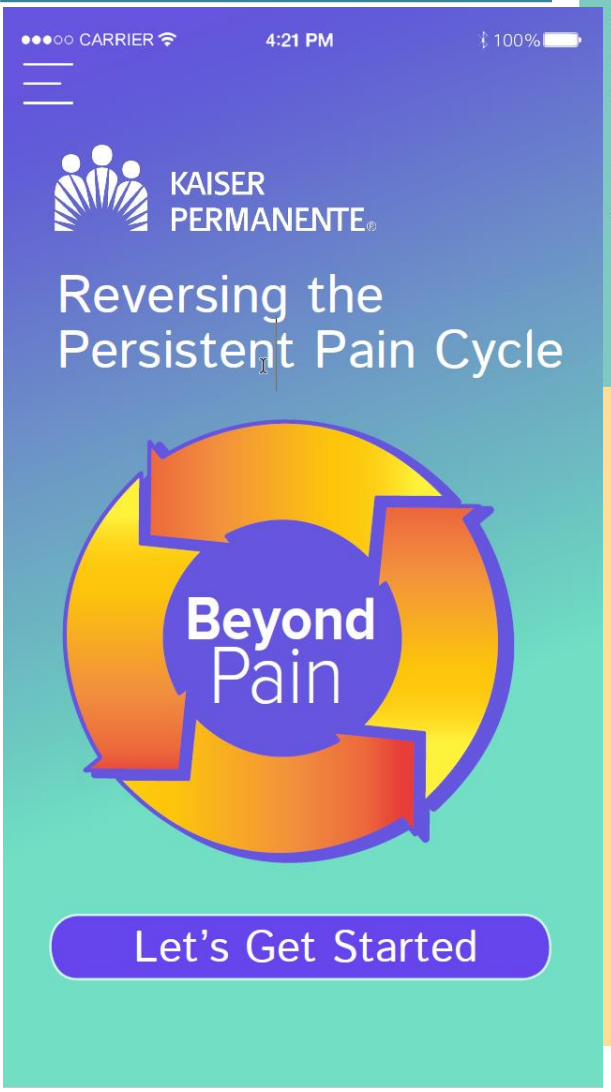
1. Centralization & Automation: ⬆clinics/site coverage by fewer well-trained providers; delegate more workload to “machines”
2. Diversification: ⬆the number of conditions covered by a care / intervention program (avoid “single condition” programs / care managers)
3. Strategic Care Delivery: Lowest [provider] rung that works, stay at home as much as possible, stratification; tailored and treat to target

Adapted from Kurt Kroenke

2nd 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



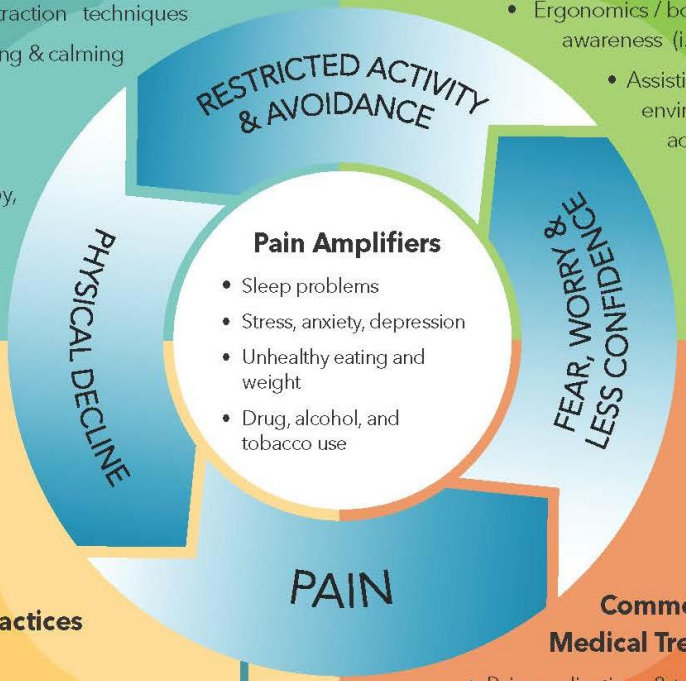
First Line Recommendations / Active Approaches

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



Integrative Health Practices

- Massage
- Acupuncture
- Chiropractic and Osteopathic care (spinal manipulation)

Pain Causes

- Disease
- Accident or injury
- Nervous system sensitivity

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.

Second Line Treatment / Passive Approaches

[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

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

Journal entry:

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