Primary-care Based Collaborative Care for Chronic Pain: Overcoming Patient, Provider, Data, and System Challenges in Implementing the Pragmatic Trial

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Agenda

• Summary of the Specific Features of PPACT that Invite Implementation Challenges
  • Summary of study design
  • Framework for care

• Specific Barriers and Potential Solutions
  • Engagement of Patients, Clinicians and Health Care Systems
  • Data collection – building robust PRO collection into the HCS
  • Regulatory issues – heterogeneity across “sibling” HC Systems
  • (In)Stability of Usual Care – “may a thousand flowers bloom”

• “If We Knew Then What We Know Now”…Advice for UH2 Projects
Overall Study Aim and Approach

Coordinate and integrate services for helping patients adopt self-management skills for managing chronic pain, limit use of opioid medications, and identify exacerbating factors amenable to treatment that is feasible and sustainable within the primary care setting

- Implementing in three regions of Kaiser Permanente (Northwest, Georgia, and Hawaii)
- Targeting patients with chronic pain from diverse conditions on long-term opioid therapy
- Prioritized recruitment based on operationally identified need:
  - Morphine equivalent dose (MEQ) ≥ 120mg
  - Concurrent opioid and benzodiazepine use
  - High utilization of primary care services (> 12 outpatient contacts / 3 months)
  - Other primary care provider (PCP) nominated patients
About the Intervention

Comprehensive Intake:
- Functional and physical adaptation assessment (Physical Therapist)
- Behavioral assessment of biopsychosocial and contributors (Behavioral Specialist or Nurse)
- Medication review and recommendations (Pharmacist)

Communication with PCP:
- Brief, 1 page summary of intake assessment to PCP
- Dashboard of all assessment info documented in chart (linked from problem list)
- Template to guide PCP communication with patient
- Weekly progress notes from PPACT interaction with patient

Group Session Components:
- Goal setting, barrier identification, problem solving to achieve patient specified goal
- Skills training with in-group practice
- Adapted movement with Yoga of Awareness as foundation
- Relaxation and imagery

Individual Coaching:
- Primarily by phone; in person if needed
- Purpose: Activate patient self care skills and move patient towards goal attainment; coordination of services and resources
**Trial Design**

- **Cluster-randomized pragmatic clinical trial**
- **Between 150-200 PCPs will be randomized (102+ clusters)**
- **1,000 + patients**

**Year 2**
- **Recruitment**
  - Randomize primary care providers to PPACT Intervention (INT) or Usual Care (UC)
- **Intervention**
  - Implement in 20 clusters (8 in KP-Georgia, and 12 in KP-Northwest [INT and UC])

**Year 3**
- **Intervention**
  - Implement in 46 clusters (16 in KP-Georgia, and 30 in KP-Northwest [INT and UC])

**Year 4**
- **Intervention**
  - Implement in final 36 clusters (4 in KP-Georgia, 18 in KP-Hawaii, and 14 in KP-Northwest [INT and UC])

**Year 5**
- **Refine**
  - Implementation guide and disseminate results
- **PPACT Outcome and Cost Analysis**
- **Combine Qualitative and Quantitative Analyses**
  - Describe factors influencing Reach, Effectiveness, Adoption, Implementation, and Maintenance—REAIM
- **Formative and Process Evaluation**
  - Within KP-Hawaii, KP-Georgia, and KP-Northwest

**Collect EHR-based pain data and service use on eligible pain patients from all participating clinics**
### PPACT UH3 Intervention Timeline

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**Intervention Periods**
- Intake visits, Group sessions, Post-program visits
## Barriers Scorecard

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<td>Enrollment and engagement of patients/subjects</td>
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<td>Engagement of clinicians and Health Systems</td>
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<td>Data collection and merging datasets</td>
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<td>Regulatory issues (IRBs and consent)</td>
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<td>Stability of control intervention</td>
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1 = little difficulty  
5 = extreme difficulty

* Expected in advance
Persistent Pain Cycle

- Framework to guide understanding of patient’s condition and care planning
- Informs team’s communication with PCP and patient
- Promotes importance of active coping and self care to interrupt cycle
- Highlights multiple areas to target for improved pain and function

**Green domains:** Reinforce multitude of active strategies

**Brown domain:** Limit patient reliance on provider dependent treatments

**Red domain:** Reframe patient mindset away from focusing on cause towards management
Challenges: Engagement of Patients, Clinicians, and Health Care Systems

- The patients most vexing to the health care system most difficult to engage (all [patients and PCPs alike] have been “fired” more than once)

- Requires different clinical skill set for participating providers (behavioral specialists, nurse case managers, physical therapists, pharmacists, and PCPs) than how they routinely deliver care.

- Primary or specialty care services – are our health care systems really prepared to bridge the divide?

- Inherent tension between process needed for rigorous evaluation and building towards sustainability of the intervention
Challenges: Building Robust PRO Collection into the Health Care System

• Timing and amount of data variable
  - Heterogeneity across health care providers
  - More frequent PRO collection among patients with higher rates of health care use
  - Less routine collection among patients showing improvement

• Need to support “enhanced” PRO collection for evaluation and improved clinical utility
  - Low burden modes of collection critical to encourage more frequent PRO collection (e.g., Personal Health Record / e-mail, IVR)
  - Piloting suggested that shorter (4- vs 12-item BPI) and more targeted scale (emphasis on functioning) improved work flow and clinical utility

• Resource and staffing needs intensive for integrating PROs using our 3-tiered system (online, IVR, medical assistant calls)
Process for “Automated” Enhanced Quarterly PRO (BPI-SF) Collection
Challenges: Regulatory issues (heterogeneity across “sibling” HC systems)

• Kaiser Permanente regional IRBs unwilling to agree to centralized IRB process
  • Despite agreeing intervention low risk (reorganization of existing clinical services)
  • Despite broader encouragement by KP overall to streamline IRB processes and to work in closer partnership across regions
  • Sensitivity/concern about vulnerability of target patient population and controversies surrounding opioid treatment
  • Discomfort with “newness” of PCT model/design?
• Resulting heterogeneity in regional IRB requirements affecting elements of the study
  • KP-Georgia insistence on “research” language in patient materials may impact recruited sample / perception of embedded nature of the intervention
  • KP-Hawaii unwillingness to collect data from PCPs limits ability to evaluate intervention impact; unwillingness to share PHI requires additional data QA resources
Challenges: (In)stability of usual care (“may a thousand flowers bloom”)

- Ongoing initiatives to launch patient-centered care / primary care medical home initiatives
  - KP-Northwest (aborted PCMH; complex conditions clinic; team-based care)
  - KP-Georgia (partial implementation of PCMH model)
  - KP-Hawaii (integrating behavioral health into primary care; “experiments” in nursing support)

- The continued dilemma of “feasible” alternatives to opioid pharmacotherapy for chronic non-malignant pain
  - KP-Northwest (partially overlapping initiatives: STORM, Global spine initiative, Opioid use initiative)
  - KP-Georgia (continued willingness to implement PPACT despite massive recent re-organization of delivery care system and leadership shifts)
  - KP-Hawaii (Maui consult pain pilot; PPACT at center of regional alternatives to opioid monotherapy)
  - KP-National Interregional Medication Adherence, Reconciliation and Safety (IMARS) group initiatives
“If We Knew Then What We Know Now”… Advice for UH2 Projects

• NOTHING is static / everything is new in “hybrid” system
  • Requires resilience and “can do” mind set of research and clinical staff alike for good fit
  • PPACT as counter-evidence for the “bigger, faster, cheaper” model for PCTs

• Adopt change processes “native” to health care delivery systems whenever possible
  • Language/procedures for internal quality improvement initiatives
  • Consider hiring HCS QI project managers as key partners in the process

• Optimize study infrastructures to enhance critical and ongoing communication across all “sectors” of the project
  • Everyone working at the top of their game and out at the end of a limb → adjustments have repercussions but intensive work makes frequent meetings/communication challenging

• What makes this a “timely clinical research question” to health care stakeholders portends likely challenges in implementation
  • Underperformance vs. lack of pre-existing services
We're going to do something easier next time

...but still the right thing to be doing!