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

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PPACT Study Design & Rationale
The “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?”
Policies/guidelines

- NCQA, State Medical Boards, DEA opioid prescription mandates
- Changes in expectations
- Shifting marijuana laws & policies

Brief visits

- Complicated patients
- Gaps in coordination with specialty care
- Measurement and alert fatigue
- Limited pain treatment options

adapted with permission from Rollin Gallagher
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

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**Patient**

- 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

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**Primary Care**
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
### Table 1. PPACT Outcome Variables

<table>
<thead>
<tr>
<th>Measure</th>
<th>Source</th>
<th>Schedule of Assessment</th>
<th>Study Month</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Up to 12 months preceding patient enrollment</td>
<td>0</td>
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<tr>
<td><strong>Patient-Reported Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PEG</td>
<td>Primary outcome</td>
<td>Study survey</td>
<td>✓</td>
</tr>
<tr>
<td>Roland Morris Disability Questionnaire</td>
<td>Secondary outcome</td>
<td>Study survey</td>
<td>✓</td>
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<tr>
<td>Patient Satisfaction Survey</td>
<td>Secondary outcome</td>
<td>Study survey</td>
<td>✓</td>
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<tr>
<td><strong>Medication-Related Outcomes</strong></td>
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<tr>
<td>Opioids dispensed</td>
<td>Secondary outcome</td>
<td>EHR</td>
<td></td>
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<tr>
<td>% of patients with morphine equivalents ≥ 90 and morphine equivalents ≥ 50</td>
<td>Secondary outcome</td>
<td>EHR</td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines dispensed</td>
<td>Secondary outcome</td>
<td>EHR</td>
<td></td>
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<tr>
<td><strong>Health Service Utilization</strong></td>
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<tr>
<td>Primary care utilization (outpatient visits, emails, telephone contacts and total)</td>
<td>Secondary outcome</td>
<td>EHR</td>
<td></td>
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<tr>
<td>Emergency and urgent care services</td>
<td>Secondary outcome</td>
<td>EHR</td>
<td></td>
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<tr>
<td>Use of specialty pain services (physiatry, pain clinic, physical and occupational therapy)</td>
<td>Secondary outcome</td>
<td>EHR</td>
<td></td>
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<tr>
<td>Overall outpatient service utilization</td>
<td>Secondary outcome</td>
<td>EHR</td>
<td></td>
</tr>
<tr>
<td>Inpatient services related to pain condition</td>
<td>Secondary outcome</td>
<td>EHR</td>
<td></td>
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</tbody>
</table>
Unique Features of Complex Behavioral PCTs?
PRECIS footprint / cluster randomization downside
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

Figure 3. PPACT PRECIS-2 Scoring

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.
The plan, the reality, & consequences of our PCP cluster randomized approach
Collect and Sharing Patient Reported Outcomes (PROs) in Pragmatic Trials
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)

Panel Support Tool – it takes more than EPIC to prompt administration
What it might **really** takes to collect PRO data in routine clinical care

**OVERALL:** Total PROs Completed

- **Participants at 3 months**
  - Eligible for PRO Collection: n = 831
  - OVERALL: Total PROs Completed: n = 718 (86%)

**PRO Outreach via Personal Health Record (PHR)**
- Completed PRO via PHR: 149 (22% of total contacted)
  - Participants:
    - PHR 7 days
    - Window for PHR 7 days
  - n = 676

**PRO Outreach via Interactive Voice Response (IVR)**
- Completed PRO via IVR: 334 (52% of total contacted)
  - Participants:
    - IVR 5 days
    - Window for IVR 5 days
  - n = 647

**Step Skipped**
- n = 155
  - Participant Does Not Have PHR Account (19% of study participants)

**Completed PRO with Clinical Support Staff**
- n = 235 (70% of total contacted)

**PRO Outreach via Clinic Support Staff**
- n = 335

**Overall Completion Rates**
- 18% overall
- 40% overall
- 28% overall

Owen-Smith et al, Journal of General Internal Medicine, 2018
There is no obvious best way to communicate with PCPs about individual patients within the EMR

- EMR-based PPACT pre/post summaries not as effective as hoped
- PCP workload/workflow attentional constraints
- Emailing/messaging providers about specific actionable concerns works well, but does not provide the “big picture” required for co-management

“Unless we were specifically alerted to look in this place... there’s way too much noise in the chart”
- PCP, about reviewing a PPACT report
Enhancing PRO use in routine clinical care: Lessons learned

- “Pulling” PROs from EHR (data availability / quality)
  - Most PRO adoption “stick” rather than “carrot” driven
  - EMR IT enhancements critical for routine PRO collection
  - Frequency and amount of PRO data often confounded with patient’s clinical severity

- “Pushing” PROs into EHR (enhancing clinical utility)
  - Multimodality support for enhanced collection may be needed
  - PRO EHR display may limit clinical utility (esp for complex conditions)
  - HCS technology often lags, untethered systems may be most feasible