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

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Portland, Oregon
Agenda

• Background
  • Summary of Study Design
  • Key Contextual Factors (safety concerns, utilization and cost, clinical complexity)
  • The potential underbelly of the timely clinical research question

• Lessons learned:
  1. Innovative Qualitative Methods Driven by PCT Framework
     • Bi-directional learning, understanding your stakeholders, rapid assessment process/use of field notes
  2. Collecting PROs in Pragmatic Trials
     • Pragmatically driven assessment / centrality of the Electronic Health Record
     • Patient Reported Outcomes (PROs) specific considerations
  3. Implementing Behaviorally Intensive Interventions
     • New processes for everyone
     • Complex and urgent clinical focus presents unique challenges and opportunities
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

- Implemented across KPNW, KP-Georgia, and KP-Hawaii regions
- Targeting patients with chronic pain on long-term opioid therapy
- Prioritized recruitment based on operationally identified need:
  - MEQ ≥ 120mg
  - Concurrent opioid and benzodiazepine use
  - High utilization of primary care services
Trial Design

- Cluster-randomized pragmatic clinical trial
- Approximately 500 PCPs will be randomized
- 1,200 + patients

RECRUITMENT
Randomize primary care providers to PPACT Intervention (INT) or Usual Care (UC)

INTERVENTION
Implement in 36 clusters (12 in KP-Georgia, 10 in KP-Hawaii, and 14 in KP-Northwest [INT and UC])

INTERVENTION
Implement in 44 clusters (14 in KP-Georgia, 14 in KP-Hawaii, and 16 in KP-Northwest [INT and UC])

INTERVENTION
Implement in final 40 clusters (14 in KP-Georgia, 16 in KP-Hawaii, and 10 in KP-Northwest [INT and UC])

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

YEAR 2

YEAR 3

YEAR 4

YEAR 5

Refine Implementation guide and disseminate results

Combine Qualitative and Quantitative Analyses Describe factors influencing Reach, Effectiveness, Adoption, Implementation, and Maintenance–REAIM

PPACT Outcome and Cost Analysis
Participant Eligibility Criteria

• Current adult KP member (18 years or older)

• Within the last 180 days either:
  • 90 day supply of short acting opioid spanning at least 120 days
  • 2 or more long acting opioid dispenses

• Pain diagnostic ICD-9 code within the past 180 days
  • Diagnostic categories include but are not limited to:
    Back pain, neck pain, fibromyalgia, arthritis, myofascial pain, neuropathies, migraine, tension headache, tempromandibular joint disorder, carpal tunnel syndrome, nonspecific chronic pain, abdominal pain, pelvic pain
### Pain Characteristics

<table>
<thead>
<tr>
<th>Pain Characteristics</th>
<th>KP Northwest</th>
<th>KP Georgia</th>
<th>KP Hawaii</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total members (18 and older) with chronic non-malignant pain using long term opioid therapy</td>
<td>12,579 (Remaining numbers subset of this N)</td>
<td>1,473 (Remaining numbers subset of this N)</td>
<td>1,560 (Remaining numbers subset of this N)</td>
</tr>
<tr>
<td>Back and neck pain</td>
<td>4,595 (37%)</td>
<td>985 (67%)</td>
<td>866 (56%)</td>
</tr>
<tr>
<td>Joint pain (including osteoarthritis)</td>
<td>2,748 (22%)</td>
<td>439 (30%)</td>
<td>432 (28%)</td>
</tr>
<tr>
<td>Non-specific and other pain</td>
<td>3,910 (31%)</td>
<td>233 (16%)</td>
<td>530 (34%)</td>
</tr>
<tr>
<td>Two or more CNMP diagnoses</td>
<td>2,625 (21%)</td>
<td>359 (24%)</td>
<td>434 (28%)</td>
</tr>
</tbody>
</table>

### Comorbid Medical Conditions

<table>
<thead>
<tr>
<th>Comorbid Medical Conditions</th>
<th>KP Northwest</th>
<th>KP Georgia</th>
<th>KP Hawaii</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>2,444 (19%)</td>
<td>314 (21%)</td>
<td>354 (23%)</td>
</tr>
<tr>
<td>Cardiovascular disorders</td>
<td>4,267 (34%)</td>
<td>852 (58%)</td>
<td>652 (42%)</td>
</tr>
<tr>
<td>Two or more chronic medical conditions (Diabetes, CV, Respiratory)</td>
<td>1,990 (16%)</td>
<td>364 (25%)</td>
<td>302 (19%)</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>3,005 (24%)</td>
<td>550 (37%)</td>
<td>347 (22%)</td>
</tr>
</tbody>
</table>
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
### Outcome Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Analytic Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief Pain Inventory (BPI)</strong>&lt;br&gt;(Severity &amp; Interference)</td>
<td>Primary Outcome</td>
</tr>
<tr>
<td><strong>Opioids Dispensed</strong>&lt;br&gt;(in morphine equivalents)</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Pain related treatment or diagnostic procedures</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of emergency / urgent care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of primary care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of specialty care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Total health service use &amp; cost</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Comorbidities <em>(Depression, anxiety, disability, chronic disease burden, sleep difficulties, kinesiophobia)</em></td>
<td>Covariates</td>
</tr>
<tr>
<td><strong>Patient satisfaction</strong></td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td><strong>Exercise as Vital Sign (EVS)</strong></td>
<td>Secondary Outcome</td>
</tr>
</tbody>
</table>

- All data collected in routine clinical care
- Data pulled from electronic medical record (EMR) and administrative data systems
- KP Virtual Data Warehouse provides common EMR to ensure standardization across 3 regions
- BPI completion for patients using opioids: Recommended at every visit, required quarterly to semi-annually
<table>
<thead>
<tr>
<th>Key Contextual Issues</th>
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</thead>
<tbody>
<tr>
<td><strong>PROBLEMS</strong></td>
</tr>
<tr>
<td>Rising prevalence of chronic pain</td>
</tr>
<tr>
<td>- 1/3 of the US pop. has chronic pain</td>
</tr>
<tr>
<td>- Annual US cost of $560-600 billion in health care costs and lost productivity</td>
</tr>
<tr>
<td>Use of opioids to treat CNMP rising</td>
</tr>
<tr>
<td>- Opioid prescriptions for CNMP doubled since 1980</td>
</tr>
<tr>
<td>- Opioid related morbidity and mortality have increased in past 2 decades</td>
</tr>
<tr>
<td>- Opioids are associated with significant efficacy-limiting side effects</td>
</tr>
<tr>
<td><strong>REALITY</strong></td>
</tr>
<tr>
<td>Primary care plays a central role in managing CNMP</td>
</tr>
<tr>
<td>- Primary care oversees &amp; coordinates care</td>
</tr>
<tr>
<td>- Primary care providers (PCP) are faced with a paucity of systematic resources and support</td>
</tr>
<tr>
<td>- This gap leads to a reliance on opioids as a monotherapy</td>
</tr>
<tr>
<td><strong>SOLUTIONS</strong></td>
</tr>
<tr>
<td>Optimal management relies on patient self-care</td>
</tr>
<tr>
<td>- Chronic illness management necessitates an activated patient</td>
</tr>
<tr>
<td>- Provider-directed treatments not practical nor sustainable</td>
</tr>
<tr>
<td>Multidisciplinary, multimodal treatment shows promise</td>
</tr>
<tr>
<td>- Synthesizes expertise from diverse medical professionals</td>
</tr>
<tr>
<td>- Combines multiple modalities targets multitude of factors that influence pain</td>
</tr>
</tbody>
</table>
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

1999
(range 1 - 50)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State
(per 100,000 population aged 12 and over)

2001
(range 1 – 71)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

2003 (range 2 – 139)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

2005
(range 0 – 214)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

2007
(range 1 – 340)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

2009 (range 1 – 379)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Unintentional overdose deaths involving opioid analgesics parallel per capita sales of opioid analgesics in morphine equivalents by year, US, 1997-2007

Source: National Vital Statistics System, multiple cause of death dataset, and DEA ARCOS

*2007 opioid sales figure is preliminary
# Total Sales & Prescriptions for OxyContin (1996-2002)

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales</th>
<th>Percentage Increase</th>
<th>Number of Prescriptions</th>
<th>Percentage Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>$44,790,000</td>
<td>N/A</td>
<td>316,786</td>
<td>N/A</td>
</tr>
<tr>
<td>1997</td>
<td>125,464,000</td>
<td>180</td>
<td>924,375</td>
<td>192</td>
</tr>
<tr>
<td>1998</td>
<td>286,486,000</td>
<td>128</td>
<td>1,910,944</td>
<td>107</td>
</tr>
<tr>
<td>1999</td>
<td>555,239,000</td>
<td>94</td>
<td>3,504,827</td>
<td>83</td>
</tr>
<tr>
<td>2000</td>
<td>981,643,000</td>
<td>77</td>
<td>5,932,981</td>
<td>69</td>
</tr>
<tr>
<td>2001</td>
<td>1,354,717,000</td>
<td>38</td>
<td>7,183,327</td>
<td>21</td>
</tr>
<tr>
<td>2002</td>
<td>1,536,816,000</td>
<td>13</td>
<td>7,234,204</td>
<td>7</td>
</tr>
</tbody>
</table>

Utilization Associated with Opioid Use

Opiate users are more likely to:
- Use mental health services
- Use specialty pain services
- Be hospitalized
- Have increased outpatient visits

Patients with chronic pain (CP) using long term opiate treatment (LOT) have increased utilization across the system and are associated with a larger treatment burden.
The Potential Underbelly of the Timely Clinical Research Question

• Expect usual care practices to be dynamic if the issue is critical to operational and clinical leaders in your healthcare setting(s)

• What makes this a “timely clinical research question” to healthcare stakeholders portends likely challenges in implementation (i.e., underperformance vs. lack of function)

• Delicate balance between meeting a clinical need with commitment to rigorous evaluation with building sustainability
QUALITATIVE WORK CRITICAL BUT METHODS DRIVEN BY PCT FRAMEWORK
Stakeholder engagement is part of process evaluation

Not passive, one-way evaluation but ongoing evaluation that supports success of trial and becomes part of the implementation guide

Traditional qualitative methods not well-suited; use rapid assessment methods instead

Recruitment
Randomize primary care providers to PPACT Intervention (INT) or Usual Care (UC)

Year 2

Intervention
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Combine Qualitative and Quantitative Analyses
Describe factors influencing reach, effectiveness, adoption, implementation, and maintenance—REAIM

PPACT Outcome and Cost Analysis

• Cluster-randomized pragmatic clinical trial
• Approximately 500 PCPs will be randomized
• 1,200 + patients

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

Adapted Qualitative Methods

• Cluster-randomized pragmatic clinical trial
• Approximately 500 PCPs will be randomized
• 1,200 + patients
Many stakeholders no one size fits all engagement strategy…
Determine what level of engagement you seek

**Inform**
Provide the right information to help people understand what is happening and what the opportunities are

**Consult**
Get targeted feedback on what is working well, what is needed, and what can be done differently

**Involve**
Work directly with staff to ensure their concerns and ideas are understood and considered throughout the process

**Collaborate**
Partner with impacted staff on the actual decision process, including identifying alternatives and solutions

**Empower**
Place final decision-making in the hands of impacted staff
Our Rapid Assessment Process Toolkit:

- Informal stakeholder conversations
- Mapping (organizational relationships, processes)
- Weekly journaling by study staff
- “Postcards” to inform stakeholders and prompt dialogue
- Along with more traditional qualitative techniques: Interviews, naturalistic observation (fieldwork), brief surveys, focus groups
Other Critical Issues for Formative Evaluation of Pragmatic Trials

• Most valuable information is not attainable using traditional interviews and focus groups
  • Need for fast turn around, recognize may learn more “off the record”, observing routine interactions/meetings often more helpful than formal feedback
  • Use of rapid assessment process and field notes helpful approach
• More congruent with PCORI focus on inclusion of patients/clinical stakeholders as partners rather than primarily as study participants
• Regular feedback to stakeholders critical
  • Multiple modalities helpful (advisory groups, postcards, video ethnographies)
  • Emphasize illustrative stories/case histories rather than emphasis on quantitative interim results (easily misinterpreted with small numbers)
COLLECTING PATIENT REPORTED OUTCOMES (PROs) IN PRAGMATIC TRIALS
Clinical Context: KPNW Operational Response to Opioid Use

- Motivating factors for systematic clinical response (safety & efficacy concerns)
  - High dose opioid prescribing
  - Primary care in need of assistance
- Opioid Use Improvement Project (OUI)

Objectives:
- Improve patient safety
- Improve provider and team support
- Improve outcomes with chronic pain management

Opportunity for implementation of pain-related PRO
### Opioid Therapy Plan (OTP) Operational Criteria

<table>
<thead>
<tr>
<th>Patient Criteria</th>
<th>Basic Green</th>
<th>Complex Yellow</th>
<th>Complex Red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follows plan reliably</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No history of opioid abuse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No history of other substance abuse within past 2 years</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No current behaviors indicating drug misuse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current behaviors raise questions about the ability to follow the OTP</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>History of opioid abuse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of other substance abuse within past 2 years</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculated overall opioid dosing level at 180mg morphine equivalent or higher</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have demonstrated repeated problems following the OTP (e.g., unexpected UDS)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active substance abuse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have current behaviors which raise concerns about possibility of diversion</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PCP Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Basic Green</th>
<th>Complex Yellow</th>
<th>Complex Red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office visit frequency (minimum)</td>
<td>Semi-annually</td>
<td>Quarterly (2 may be TAVs)</td>
<td>Quarterly (no TAVs)</td>
</tr>
<tr>
<td>Office visit required for any dosing changes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Brief Pain Inventory (BPI) completed (minimum)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>[Recommended to be administered at every office visit]</strong></td>
<td>Semi-annually</td>
<td>Quarterly</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Refresh pain diagnosis on problem list</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Verify current dosing level is reflected on OTP on the problem list</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Discuss with the patient their use of opioid, non-opioid and non-pharmacological modalities to control pain</td>
<td>Yes</td>
<td>Yes – AVS only</td>
<td>Yes – AVS only</td>
</tr>
<tr>
<td>UDS ordered and resulted (minimum)</td>
<td>Each visit</td>
<td>Each visit</td>
<td>Each visit</td>
</tr>
<tr>
<td>Confirm random pill counts completed</td>
<td>PRN</td>
<td>2x/Year &amp; PRN</td>
<td>2x/Year &amp; PRN</td>
</tr>
<tr>
<td>Create AVS or send letter with patient’s dosing and instructions after dosing change</td>
<td>Yes</td>
<td>Yes – AVS only</td>
<td>Yes – AVS only</td>
</tr>
<tr>
<td>Create separate monthly opioid prescriptions, no refills and no mail order</td>
<td>No</td>
<td>Yes*</td>
<td>Yes</td>
</tr>
<tr>
<td>Early refills for travel</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>May refill prescriptions early for lost or stolen reasons (Police report needed before receiving refill of stolen medications)</td>
<td>Yes</td>
<td>Limited supply only</td>
<td>No</td>
</tr>
<tr>
<td>New OTP required when prescriber changes or OTP color changes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Kaiser Permanente’s Panel Support Tool

- Web-based software extracts information from KP HealthConnect EMR (Epic) to help physicians improve and manage patient care.

- Highlights “gaps” between delivered care and guidelines for chronic disease management and preventive care.

- Includes “gaps” associated with OTP (regular administration of Brief Pain Inventory).

- Specifies actions a primary care team must take to resolve these gaps both for individual patients and across PCP panel.
Opiate Therapy Plan

- OTP on PL: 2/22/10
- Last APAP dispense:
- Last OTP order:
- Last Brief Pain Inventory: 8/29/11
- Last PCP visit w PAIN Dx:
- Last urine drug test: 1/13/11

Therapeutic Care Gaps:
- Statin - START at min Simva 40. Last LDL 224 24-NOV-10 Possible interaction:

Chronic Condition Monitoring Care Gaps:
- OTP yellow/red: QTRLY Urine Drug Screening DUE
- DM eye screen OVERDUE, previous 24 months findings unknown HBA1C DUE SOON Last: 7.1 05-APR-11.

Preventive Care Gaps:
- Active Tobacco Use: Advise quitting today

Ob/Gyn: REED, SANDRA
Ob/Gyn Care Gaps:
- COTEST OVERDUE. Last result: PAP N / EC- 19-MAY-10. (no endocervical cells)
Establishing Routine BPI Administration in Clinical Workflow

**Planning and Obtaining Approvals**
- Identify stakeholders
  - Medical Group: Associate Medical Directors, Department Chiefs
  - Health Plan: Operations, Information Technology
- Consult with stakeholders
  - BPI length: 4- vs. 12-item?
  - New EMR build for BPI-SF vs. edit 12-item?
  - BPI-4 implementation: how to prompt completion?
  - Decision: Use 4-item (short-form) version
  - Decision: Build new EMR questionnaire
  - Decision: Create new care gap
- Obtain regional approvals
  - Clinical Decision Support Workgroup
  - Care Delivery System Advisory Group
  - Workflow Advisory Group

**Development and Implementation**
- Develop Care Gap
  - Identify care gap criteria
  - Provide needed data (questionnaire IDs, relevant NDC and ICD-9 codes)
- Develop Health Connect documentation
  - Develop appropriate and comprehensive search criteria
  - Develop "smart phrases" to allow for efficient documentation
- Test Care Gap
  - Identify positive and negative test cases
  - Complete BPI-SF on KPGA staff, evaluate data quality

**Communication and Evaluation**
- Develop communication and training plan
  - Presentations to primary care department and operations team meetings
  - Staff messages via HealthConnect
  - Additional how-to resources available online
- Develop and implement ongoing evaluation plan
  - BPI care gap added to regional workflow efficiency report
  - BPI care gap added to panel support tool weekly reporting
  - KPGA analysts pull BPI data from EMR
Using the Personal Health Record to Collect PROs

Available EHR questionnaires include:
- BPI
- PHQ-9
- GAD
- Total Health Assessment

Personal Digital Devices

EPIC Terminal

www.KP.org

© 2013 Epic Systems Corporation. Used with permission.
Scoring or compilation of relevant assessments

Online or paper collection

EMR Provider Summary Report

Kaiser Permanente

Outside (untethered) Vendor
Health Care Delivery System PROs: Lessons Learned

- Timing and amount of data likely to be 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
- May need to support “enhanced” PRO collection for evaluation needs and improved clinical utility
  - Low burden modes of collection critical to encourage more frequent PRO collection (e.g., Personal Health Record / e-mail, IVR)
  - Shorter (4- vs 12-item BPI) and more targeted scale improves work flow and clinical utility
- IT/medical informatics partnerships are critical for successful PRO assessment as part of regular clinical care workflow
ADDITIONAL ISSUES IN IMPLEMENTING INTEGRATED AND BEHAVIORALLY INTENSIVE PRIMARY CARE BASED INTERVENTIONS
Intervention – Lessons Learned

• Anticipate roadblocks and organizational change needs if the intervention is not culturally consistent with current system. (In our case, behavioral change may not be optimally/consistently supported)

• Scope of practice and financial compliance/billing issues may restrict elements of optimal intervention (e.g., physical therapy)

• Intervention (structure, training, and supervision/consultation) should be structured so that staffing can be realistically sustained in everyday clinical care

• Expect that there will be some evolution of the intervention structure across the course of the trial (accommodating fit with clinical work flow and clinical/operational stakeholder input)
Broader Study Challenges: What is New

• Everyone* doing things/creating partnerships never done before:
  • Redeploying/hiring clinical staff for intervention roles not well aligned with existing health plan structure or traditional scope of practice
  • Expanding use of EHR (real time pulling-out / pushing-in data utilizing clinically actionable formats)
  • Creating scalable staff training model with attention to fidelity and cost/resources
  • Sharing costs (building infrastructure processes) – NIH/health plan, patient/CMS
  • IRBs unfamiliar with pragmatic trials and uneasy relinquishing tight research constraints (low risk intervention but among patients and focused on clinical care issue contentious and fraught with risk)

* Operational/clinical leaders; health plans’ finance, billing and compliance departments; HR; IT; front line clinical staff; IRBs; study investigators and broader research staff
Broader Study Challenges: What is Complex

- Complex and urgent clinical focus presents unique challenges and opportunities
  - Politics tricky – many stakeholders who see challenges/needs differently
  - Usual care practices dynamic – researchers need to understand usual care and get a seat at the table in discussions regarding overlapping initiatives, changes in practice
  - Tension between availability of care for high needs patients and rigorous design/evaluation

(All of the above requires regular and systematic feedback to stakeholders)

- Simple constrained interventions have been unsuccessful
  - Patients have “failed” multiple treatments and PCPs/specialists have “failed” the patients making the behavioral intervention particularly challenging and adequate dose and intervention quality important
  - Enhanced training of / communications to PCPs critical to support patients in culture not optimally/consistently supporting behavior change
Closing Thoughts on Conducting Multifaceted Behavioral Pragmatic Trials…

- Rewarding but more complicated and potentially expensive (at least now) than traditional randomized clinical trials

- Organizational change framework of change, communication and stakeholder engagement strategies as well as data collection tools and reporting should be native to health care system

- Know that perception of “research” to clinical and operational stakeholders (e.g., untested) can impact buy-in and stakeholder actions during trial roll-out

- More to “carry” (patients, context of care) with behavioral change intervention than in traditional/non-embedded trials

- Many of the challenges in this type of trial (e.g., PCP level paneling, continued health plan leadership support, integration into primary care clinics) never substantively “settle down” as would be expected for most RCTs